

GROUP MANAGEMENT REPORT 2016

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GROUP MANAGEMENT REPORT 2016

INFORMATION ABOUT THE GROUP

The Group's business model

Boehringer Ingelheim is a family-owned company which was established in 1885 and is based in Ingelheim, Germany. The focus of the company is on the research and development, production and sale of innovative pharmaceuticals improving health and quality of life and contributing great therapeutic benefit to both human medicine and animal health. With 143 affiliated companies and more than 45,600 employees worldwide, the Group achieved net sales of EUR 15.9 billion in 2016, making it one of the world's top 20 pharmaceutical companies. In the 2016 financial year, Boehringer Ingelheim's business activities covered prescription medicines, consumer health care, animal health, biopharmaceuticals and industrial customers. At the start of 2017, the exchange of Boehringer Ingelheim's consumer health care business (CHC) for Sanofi's animal health business (Merial) took place as scheduled and is thus not included in the figures for the financial year 2016. This step marks the successful conclusion of this strategic transaction, which was started through exclusive negotiations in December 2015.

Prescription medicines form the core of Boehringer Ingelheim's activities. Medicines from Boehringer Ingelheim have long been standard treatments for cardiovascular diseases, respiratory disorders, oncology, diseases of the central nervous system and immunology. In 2016, the company's biggest revenue contributor was once again SPIRIVA®, which is used to treat chronic obstructive pulmonary disease (COPD) and asthma. Moreover, PRADAXA®, which is used to prevent strokes in patients with atrial fibrillation, as well as for the prevention and treatment of thromboembolic disorders, and TRAJENTA® and JARDIANCE®, which remain on an impressive trajectory and are used to

treat type 2 diabetes, also made significant contributions to Boehringer Ingelheim's success. OFEV®, which was newly introduced in 2015 and which offers people with the rare, fatal respiratory disease idiopathic pulmonary fibrosis (IPF) a new treatment option, also achieved strong growth.

The business aim of Boehringer Ingelheim is to continue to drive forward with the innovative development of its existing product portfolio through organic growth,

Net sales by business (in EUR million)

Prescription Medicines



Consumer Health Care



Animal Health



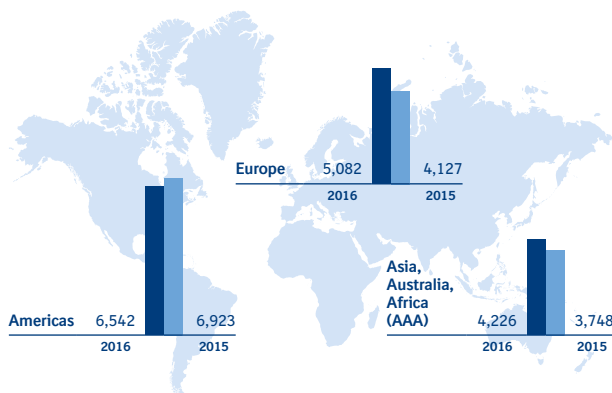
Biopharmaceuticals



Industrial Customers and other sales



Net sales by region (in EUR million)



in cooperation with its external partners. To do this, Boehringer Ingelheim operates a global research network with major facilities in Biberach, Hanover and Ingelheim (Germany), Ridgefield and St. Joseph (USA) and in Vienna (Austria), supported by two smaller facilities in Kobe (Japan) and Milan (Italy).

Within consumer health care, DULCOLAX®, BUSCOPAN®, PHARMATON® and MUCOSOLVAN® were among the company’s best selling medicines in the past financial year.

Animal health is another major pillar of Boehringer Ingelheim’s business. The swine vaccine INGELVAC circoFLEX®, used to treat porcine circovirus type 2, is the most significant product in animal health in terms of sales. To boost its competitiveness in this area over the long term, Boehringer Ingelheim acquired the animal health business (Meril) of the French company Sanofi in January 2017.

The biopharmaceuticals business is another important growth area for Boehringer Ingelheim. Boehringer Ingelheim’s biopharmaceutical activities comprise the manufacture of own-brand marketable products (such as ACTILYSE®, METALYSE® and PRAXBIND®), the process development of new biological entities (NBEs) and biosimilars, and – as one of the world’s leading companies – process development and contract manufacturing in commercial production for third-party industrial customers.

Once again, Boehringer Ingelheim achieved the majority of its sales in 2016 in the Americas (41%) and Europe (32%) regions. However, revenue from the region of Asia / Australia / Africa (AAA) is also gaining significance, making up 27% of the Group’s total net sales in 2016. The three biggest markets, the USA, Japan and Germany accounted for around 53% of sales last year.

Research and development (R&D)

In line with its mission statement, Boehringer Ingelheim’s primary goal is to research and develop innovative medicines and therapies for the treatment of diseases for which there are as yet no satisfactory treatments available. Our aim at all times is to make a major contribution in areas where the need for treatment is high and to occupy a leading position in major indication areas.

To achieve this aim, Boehringer Ingelheim can, besides its own R&D activities, draw on a global network comprising academic groups, public research institutions and biotech companies. In addition, we are expanding our product portfolio with partnership agreements and the systematic incensing of technologies and products. In the year under review, for example, Boehringer Ingelheim agreed a long-term partnership for the development of a next-generation oncolytic virus platform with the Austrian company ViraTherapeutics, with a purchase option agreement entitling Boehringer Ingelheim to acquire ViraTherapeutics upon completion of phase I of clinical development.

Boehringer Ingelheim’s R&D activities are the basis for the company’s success. Together with our innovative prowess, it has been the primary driver behind the Group’s positive growth in recent years. In-house research and development – supplemented by external cooperation and partnerships – will also continue to be a top priority in the future.

In the 2016 financial year, we employed an average of 8,055 people at our R&D sites. A total of more than EUR 3.1 billion was invested in the research and development of new medicines, corresponding to 19.6% of the Group’s net sales and thus, as forecast, to the same level as the previous year.

Research and development	2016	2015	2014	2013	2012
Expenditure in EUR million	3,112	3,004	2,654	2,743	2,795
– as % of net sales	19.6	20.3	19.9	19.5	19.0
Prescription Medicines expenditure in EUR million	2,870	2,780	2,333	2,444	2,563
– as % of Prescription Medicines net sales	23.8	24.8	23.1	22.4	22.5
Average number of employees	8,055	7,895	8,104	7,741	7,492
Investments in tangible assets (without investments in infrastructure) in EUR million	92	77	78	114	139

Human pharmaceuticals

Boehringer Ingelheim carried out research and development in 2016 for its prescription medicines businesses at facilities in the USA, Germany, Austria, Italy and Japan.

The key focus of our research work in 2016 was on the following indication areas:

- Immunology and respiratory disorders
- Cardiometabolic diseases (cardiovascular and metabolic diseases)
- Oncology and immuno-oncology
- Diseases of the central nervous system

Expenditure for R&D in prescription medicines accounted for 23.8% of net sales generated in this business.

In 2016, Boehringer Ingelheim continued to pursue intensive research into chronic respiratory disorders such as asthma, COPD and IPF, to be able to offer affected patients the best possible treatment.

A key goal of COPD therapy is to enable patients to remain physically active for longer. In September 2016, the findings of the phase III study PHYSACTO® were presented at the congress of the European Respiratory Society (ERS). They show that the combination of SPIOLTO® RESPIMAT®, physical training and a change of behaviour significantly improved the functional capacity of COPD patients. The PHYSACTO® study forms part of the TOviTO® trial programme, which examines the efficacy and safety of SPIOLTO® RESPIMAT® in treating COPD.

A further key treatment goal in this therapeutic area is to reduce the risk of exacerbations. Two post-hoc analyses of the WISDOM study published in 2016 suggested that the gradual reduction in the dosage of inhaled corticosteroids (ICS) did not result in an increased risk of exacerbation in most patients if they continued to receive SPIRIVA® (tiotropium) and an LABA (salmeterol). This only appeared to harm a small group of patients with severe or very severe COPD, an increased eosinophil blood count and frequent exacerbations.

The new large-scale DYNAGITO® study is also examining the effect of SPIOLTO® RESPIMAT® by comparison to SPIRIVA® RESPIMAT® in the case of COPD exacerbations. The first results are expected in 2017.

The TOviTO® trial programme and the WISDOM study are part of the current study evidence which has served as the basis for the updated position paper of the GOLD committee (Global Initiative for Chronic Obstructive Lung Disease) on the treatment of COPD. The GOLD update 2017 recommends therapy with a long-acting anticholinergic (LAMA) and a long-acting beta2-agonist (LABA), the combination as included in SPIOLTO® RESPIMAT®, for a broad range of COPD patients in GOLD stages B to D.

The clinical UniTinA-Asthma® trial programme, which examined SPIRIVA® (tiotropium) RESPIMAT® in asthma, was completed in 2016. The new data supplement the existing evidence and confirm that SPIRIVA® RESPIMAT® is well-tolerated and effective for many asthma patients with continuing symptoms, despite a basic therapy of

inhaled corticosteroids (ICS) and/or long-acting beta-agonists (LABA).

The phase II and large-scale UniTinA-Asthma® trial programme included 18 clinical studies worldwide at more than 150 study centres with over 6,000 patients, including 1,800 children and young people aged between 1 and 17.

New post-hoc analyses were presented at the annual meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI). They demonstrated that SPIRIVA® RESPIMAT® is effective as an add-on therapy in addition to other basic therapies, irrespective of the individual subtype of an allergic asthma.

These data were supported by the publication of a new analysis of the PrimoTinA-Asthma® studies, which showed that SPIRIVA® RESPIMAT® is effective independently of a broad range of baseline characteristics, if used as an add-on therapy in patients who continue to display symptoms despite ICS/LABA.

A further pooled data analysis of seven studies (phase II and phase III) found that the safety and tolerability profile of SPIRIVA® RESPIMAT®, as an add-on therapy for at least ICS, was comparable with that of a placebo.

At the annual meetings of the American Thoracic Society (ATS) and the European Respiratory Society (ERS), data from the paediatric studies of the UniTinA-Asthma® programme showed that SPIRIVA® RESPIMAT® is also effective, in addition to a basic therapy for children and young people with symptomatic asthma between the ages of 6 and 17, and for children with symptomatic asthma, is already well-tolerated from the age of one.

These new data form part of applications in the EU and the USA with the goal of extending the indications for SPIRIVA® RESPIMAT® in the case of asthma.

In the EU, SPIRIVA® RESPIMAT® is approved for the treatment of adults who continue to display asthma symptoms, despite ICS/LABA therapy. In the USA, SPIRIVA® RESPIMAT®

is approved for use with children 12 years of age and older and was included in the “Global Strategy for Asthma Management and Prevention” of the Global Initiative for Asthma (GINA) in 2016.

Since its market approval in 2014, more than 20,000 patients worldwide suffering from IPF have been treated with OFEV® (nintedanib).

In 2016, new analyses of the pivotal phase III INPULSIS® studies and the INPULSIS-ON® follow-up study, as well as data from everyday practice provided further evidence of the efficacy of OFEV® for a broad range of patients. These analyses showed that OFEV® consistently slowed the course of the disease, with a considerable reduction in the rate of FVC decline, while also significantly reducing the risk of acute IPF exacerbations. The INPULSIS®-ON follow-up study also confirmed the side-effects profile of INPULSIS® in the case of a maximum exposure time of more than four years. No new safety concerns were identified here.

Moreover, in June 2016 the first of 350 IPF patients were enrolled in a new study. This international phase IV study (INMARK™) is investigating the effect of OFEV® on the change in certain biomarkers in the blood and examines whether biomarkers can predict the individual clinical course of IPF.

With SENCIS™ (Safety and Efficacy of Nintedanib in Systemic Sclerosis), the largest-ever study of sufferers of systemic sclerosis (SSc) who have developed interstitial lung disease (ILD) in connection with this, Boehringer Ingelheim is continuing to pursue its commitment to examine the potential that OFEV® offers for other forms of progressive fibrotic interstitial lung diseases. In September 2016, the European Commission (EC) and the U.S. Food and Drug Administration (FDA) both granted nintedanib orphan drug status for the treatment of SSc-ILD.

In July 2016, Boehringer Ingelheim pooled its cardiovascular and metabolic diseases therapeutic areas to create the new, combined therapeutic area cardiometabolic diseases.

A key milestone in the past year was the inclusion of the EMPA-REG OUTCOME® study data in the product characteristics information for JARDIANCE® (empagliflozin) in countries around the world, including in the USA and Canada. In January 2017, the European Commission decided to include these data in the European product characteristics information. Further subanalyses of the EMPA-REG OUTCOME® study were presented at major international congresses over the course of the year. An analysis which examined the effect of JARDIANCE® on new or deteriorating kidney disease was presented at the American Diabetes Association (ADA) 76th Scientific Sessions and published in the *New England Journal of Medicine* at the same time. In order to pursue further research into the potential of JARDIANCE® in the field of cardiovascular disease, Boehringer Ingelheim and Eli Lilly announced that they would initiate two new clinical studies in 2017. These two sister studies are intended to examine empagliflozin for the treatment of chronic cardiac insufficiency in patients with and without diabetes. The other studies underway in the company's diabetes portfolio are progressing to schedule. They include the two cardiovascular outcome trials for TRAJENTA® (linagliptin) CARMELINA® and CAROLINA®. Both JARDIANCE® and TRAJENTA® are jointly marketed by Boehringer Ingelheim and Eli Lilly.

In the field of anticoagulation, further data from clinical practice have been published for PRADAXA® (dabigatran etexilat). This includes an independent analysis of data from clinical practice provided by authors who work for the U.S. Food and Drug Administration. The initial findings of phase II of the GLORIA-AFTM register study were presented at various congresses over the course of the year. Two randomised clinical studies for PRADAXA®, RE-DUAL PCI® and RE-CIRCUIT® completed their recruitment of patients in 2016. The results will be presented at medical congresses in 2017 and will provide further insights into the efficacy and safety profile of PRADAXA®. These studies examined patients undergoing percutaneous coronary intervention (PCI) with a stent implantation (RE-DUAL PCI®) and patients with atrial fibrillation ablation (RE-CIRCUIT®). For PRAXBIND® (idarucizumab), the specific drug for the reversal of the

anticoagulant effect of PRADAXA®, updated data from the RE-VERSE AD® study and from subanalyses were presented at various congresses. PRAXBIND® is now approved in more than 50 countries worldwide.

In the indication area oncology Boehringer Ingelheim has successfully advanced research and development of its pipeline compounds and marketed treatments, with the aim of providing new treatment options that may offer patients added therapeutic value and contribute to quality of life improvements.

In 2016, we made huge progress in the highly competitive lung cancer market while also continuing our activities in the area of research and development for other cancers where the need for treatment is high. Afatinib (GIOTRIF®/GILOTRIF®), a second-generation medicine for the treatment of a specific type of non-small cell lung cancer (NSCLC), has been available to patients since 2013. This product became a market leader in many markets in 2016. The results of two major studies from the LUX-Lung trial programme and the commitment of Boehringer Ingelheim's teams worldwide played a key role here. In the LUX-Lung 8 study, afatinib was compared with erlotinib (Tarceva®) for patients with squamous cell carcinoma of the lung. An improved overall survival rate with afatinib therapy was demonstrated, with a safety profile comparable with that of previous studies. These data resulted in the approval of afatinib in this new indication. Moreover, data from the further advanced LUX-Lung 7 study were presented in 2016 which confirmed an improved profile for patients by comparison with gefitinib (Iressa®).

In the second half of 2016, Boehringer Ingelheim decided to return the rights for the joint development and marketing of olmutinib, a third-generation active substance for the treatment of NSCLC, to Hanmi Pharmaceuticals. This decision was made following a reassessment of all the clinical data for olmutinib and while considering the current progress in the area of lung cancer with a positive EGFR mutation.

Boehringer Ingelheim's second product on the market for the treatment of advanced NSCLC, nintedanib (VARGATEF®), was approved in further markets worldwide in 2016. To examine the effect of nintedanib on other types of cancer, the pivotal LUME-Meso phase III study for malignant pleural mesothelioma, a rare type of cancer triggered by contact with asbestos over a period of many years, began in 2016.

In addition to the products already approved, significant progress was made in the oncological development pipeline in 2016. The company has established a series of important partnerships and strategic agreements on both sides of the Atlantic, with the goal of further strengthening its oncology portfolio. This has already delivered important results in clinical development.

In the therapeutic area of the central nervous system, Boehringer Ingelheim focuses in its research on identifying the functions in the brain that are responsible for key symptoms of the main psychiatric illnesses. These include schizophrenia, Alzheimer's disease and depression.

We continue to operate in a complex research field in which a number of other companies have recently suffered setbacks. However, we are confident that our symptom-based approach will help to develop effective therapies that may be useful for a whole range of diseases. Therefore, we are focussing on initially achieving a better understanding of the biology of the brain as well as of its relevant circuitry.

Our research portfolio includes substances which influence the disruption of the glutamatergic signalling pathway which occurs in the case of cognitive impairments. In connection with this, we are examining substances, such as phosphodiesterase inhibitors, which influence the transmission of signals in the brain through cAMP and/or cGMP.

Boehringer Ingelheim has been active in the area of immunology research and development for many years and is set to invest in this important therapeutic area and to expand its capacities.

In order to drive forward the two substances in its portfolio that have made the most progress, Boehringer Ingelheim signed a global cooperation agreement with AbbVie in March 2016. The substances risankizumab and BI 655064 are being examined for various immunological diseases (e.g. psoriasis and Crohn's disease). This development and marketing partnership offers the best means of ensuring that these two medicines reach the largest possible number of the right patients and thereby achieve their full potential.

Several other active substances are in the early clinical development stage and are already showing signs of offering strong therapeutic potential for patients with various immunological diseases, such as inflammatory bowel disease or lupus nephritis.

Animal health

In its research and development work in the field of animal health, Boehringer Ingelheim concentrates on innovative vaccines for the protection of livestock and pets, as well as on pharmaceutical products focusing on the treatment of pets' chronic diseases.

At our facilities in the USA, Germany, China, Mexico, Japan, Denmark and India, we focus on research into new drugs and the development of future therapeutic solutions. Since many vaccines are based on local pathogens and pathogen variants, it is imperative that we are present in key market regions with local R&D and production facilities.

In the past year, we again invested in the expansion of existing facilities, as well as the construction of a centre for clinical research in China. In Ames (Iowa, USA) – an established site for animal health research – the company has moved into a new research building, which offers space for around 100 employees, in the immediate vicinity of Iowa State University. These investments demonstrate the company's commitment and its intention to sustainably strengthen its position in animal health.

A large number of extensive pivotal clinical studies were launched in 2016 and, in some cases, have already been

successfully completed. This serves as the cornerstone for further regulatory submissions in 2017. In addition to our internal research and development, external projects and products are also assessed and in some cases integrated into our portfolio. Activities for the preservation of existing products and for the expansion of their geographical distribution are another important aspect of our R&D work.

Globally, Boehringer Ingelheim's animal health business received 70 new product authorisations in 2016.

Biopharmaceuticals

Boehringer Ingelheim is committed to its strategic decision of actively entering into the biosimilars business and thereby increasing the access to high-quality biologics for patients around the world. Biosimilars will increase the range of treatment options for doctors and their patients in the health sector while providing a vital contribution to the efficiency of health care systems throughout the world to patients' benefit. We are currently concentrating, in particular, on our first biosimilar monoclonal antibodies in immunology and oncology. Here, two biosimilar candidates are at the late clinical development stage: BI 695501, a biosimilar candidate for Humira® (adalimumab) and BI 695502, a biosimilar candidate for Avastin® (bevacizumab).

In November 2016, we published the first results of our pivotal phase III study for BI 695501. In this study, BI 695501 demonstrated a similar level of efficacy and safety in comparison to Humira® (adalimumab) for patients with rheumatoid arthritis. BI 695501 has now been accepted for review by the relevant regulatory authorities in the USA and Europe (the FDA and the EMA). In 2016, we also published data from a phase I study for the biosimilar candidate BI 695502. They demonstrate bio-equivalence between BI 695502 and the reference product Avastin® (bevacizumab). The ongoing pivotal phase III study is examining the safety and efficacy of BI 695502 in comparison to Avastin® for patients with advanced, non-small cell lung cancer.

Production

Human pharmaceuticals

The overarching aims in the production of human pharmaceuticals are the reliable market launch of our products and the routine care of our patients using high-quality pharmaceuticals at competitive prices. Therefore, Boehringer Ingelheim optimised its supply strategy in 2015. In early 2016, the company began to implement this strategy throughout its value chain and at all of its facilities.

With the motto "From Volume to Value", our supply network is set to be rigorously focused and made more flexible in the next few years to reflect the requirements of our businesses. At our own production facilities, we manufacture the products of particular relevance to our Group or whose manufacturing technology requires unique expertise. We operated 19 own production facilities in nine countries in the year under review. These can be divided into eleven pharmaceutical, three chemical and four biopharmaceutical facilities, as well as one production facility for medical products.

Our own production capacities are supplemented by external contract manufacturers, which primarily focus on the manufacture of products that are in an advanced stage of their life cycle. This ensures a reliable and competitive supply of prescription medicines and consumer health care products. The close cooperation with external partners secures Boehringer Ingelheim access to technologies that are not currently available in our internal production portfolio and enables us to focus our investments on those products that are particularly relevant for us.

Boehringer Ingelheim therefore primarily invested in additional production capacity for the respiratory disease products SPIRIVA® HANDIHALER® and the RESPIMAT® platform in 2016. To cover the increasing demand for our anti-diabetic portfolio, Boehringer Ingelheim invested a further EUR 30 million in the production facilities in Mexico City and Koropi (Greece).

Animal health

In the field of animal health, Boehringer Ingelheim is primarily active with a production network comprising four facilities for manufacturing vaccines and one facility for nutraceuticals. This is supplemented by contract manufacturers, primarily in North and Central America as well as Europe. With the construction of a new Chinese facility in Taizhou continuing apace in 2016, an Asian location will soon join our production network. As a major component of our animal health growth strategy, this facility will focus on the manufacture of vaccines against porcine diseases for the Chinese market.

Biopharmaceuticals

The biopharmaceutical activities of Boehringer Ingelheim in Germany (Biberach), Austria (Vienna), the USA (Fremont) and China (Shanghai) comprise the manufacture of own-brand marketable products (such as ACTILYSE®, METALYSE® and PRAXBIND®), the process development of NBEs and biosimilars, and – as one of the world's leading companies – process development and contract manufacturing in commercial production for third-party industrial customers. Thereby, Boehringer Ingelheim covers the entire biopharmaceutical value chain from genetic development of the cell, followed by manufacturing of the active substance and of the finished pharmaceutical product down to the product launch and global market supply.

In 2016, use of capacity at production facilities was again at a very high level. Boehringer Ingelheim met increasing demand for ACTILYSE®. Our active substance PRAXBIND® was launched on further markets in the past financial year, following its successful market introduction in the USA and Europe in 2015.

Moreover, our industrial-scale cell culture facility in Biberach was approved for the manufacture of a further customer market product. The expansion project (a new industrial-scale biopharmaceutical production facility) at our site in Vienna reached further milestones, such as the award of its first official permits, enabling the ground breaking ceremony in 2017. Our commercial facility in Shanghai (China) for various biopharmaceutical

development services for Chinese and international customers will go into operation as planned in the first quarter of 2017.

Occupational safety and environmental protection

The protection of the employees, the facilities and the environment, as well as the sustainable use of natural resources and the promotion of environmental awareness are major components of our company's mission statement and are of prime importance to Boehringer Ingelheim. Compliance with social and environmental aspects has been anchored in our corporate philosophy for many years now. The company strives to maintain natural resources and advocates environmental awareness both within and outside the company. Observing social and ecological concerns is the only way to ensure that we can achieve sustainable economic success for future generations.

Group-wide, our company has developed binding standards in terms of environmental protection, health and safety at work. These internal guidelines reflect the respective country-specific requirements. In many cases, they go far beyond the standards prescribed by law.

Within Boehringer Ingelheim, Corporate Department Environment, Health, Safety & Sustainability (EHS&S) is responsible for our conceptual focus. For Boehringer Ingelheim, 2016 was characterised by the negotiations with Sanofi on the exchange of Boehringer Ingelheim's consumer health care business for Sanofi's animal health division, Merial. From the very start, Corporate EHS&S monitored the negotiations in order to ensure compliance with the company's EHS&S duty of care. In addition, a comprehensive environmental due diligence process was implemented for the facilities. Regular EHS&S audits, both at Boehringer Ingelheim's internal facilities and at the premises of suppliers and contract manufacturers, likewise ensure compliance with our own as well as with international standards (Pharmaceutical Supply Chain Initiative, PSCI). This programme is supplemented by the code of conduct for all relevant suppliers. The status of environmental protection and occupational safety is con-

tinuously reviewed and potential for improvement is identified on this basis.

As part of our sustainability efforts, we took part in an independent assessment of our performance by EcoVadis in 2016, for which we were awarded a silver medal. A further example of our continuous improvements in the field of environmental protection is our extensive work to analyse and decontaminate the soil at our Ingelheim site in Germany.

As our contribution towards reducing global CO₂ emissions, we have set ourselves the goal of reducing our entire CO₂ emissions by 20% by 2020 as compared with 2010 values. As part of our Group-wide BE GREEN initiative, we have achieved a reduction of 15% (per m² of floor space) to date through energy savings and reductions in emissions.

The health and safety of our employees is a high priority at Boehringer Ingelheim. This is reflected in our international safety standards and in the safety culture that we practise. The Group-wide BE SAFE initiative, which aims to further reduce the number of workplace accidents, has been rolled out in a second wave since 2016, with a focus on safety in our global sales organisation. In 2016, our global accident frequency rate (AFR) amounted to 1.8 accidents per million hours worked. This represents a further reduction of 0.1 points.

Employee reporting

In 2016, Boehringer Ingelheim employed 45,692 people worldwide. This represents a decrease of - 3.8% on the previous year. From a regional perspective, the number of staff in America was reduced, mainly due to the sale of our US generics business, while the number of employees in Europe increased and remained stable in the AAA region.

Average number of employees by region	2016	2015
Americas	11,469	13,623
Europe	24,164	23,817
Asia/Australia/Africa (AAA)	10,059	10,061
	45,692	47,501

A major success factor for the positive growth of the Group is its innovative and motivated staff. Accordingly, we are very committed to actively developing and supporting our employees. In order to be best prepared for the challenges ahead and as part of a comprehensive training system, we do not only set great store by the acquisition of technical expertise but also by promoting social skills.

With the integration of various experiences, cultural backgrounds and personalities, Boehringer Ingelheim creates an openness to different approaches and opinions, living up to its vision “Value through Innovation”. As a global company, it is important to Boehringer Ingelheim that the diversity of the markets is reflected in its workforce. Creating a working environment that embraces diversity and differences is one of the pillars of the corporate culture of Boehringer Ingelheim and is a contributing factor to the company’s success.

In addition to competitive salaries, Boehringer Ingelheim offers further state-of-the-art benefits to its employees. These benefits include company pension plans, flexible and home-based work options and numerous health-related benefits. As a significant component of our corporate strategy, it is part of our talent management to ensure the employability of our staff, promote a wide range of opportunities for innovation at work, and motivate our employees to develop as individuals.

Vocational training has always been of major importance to Boehringer Ingelheim. As part of its understanding of social responsibility, the company offers career opportunities to a great number of young people. At the same time, we secure a talented and well-qualified workforce of young professionals against a backdrop of demographic change. In 2016, 224 young professionals started their careers with

Boehringer Ingelheim in Germany in over 27 different scientific, technical and commercial fields. More than 700 young people are currently enrolled on our training programme in Germany.

One of the company's aims is to strengthen the appeal of Boehringer Ingelheim as a top employer for our current and future employees. Boehringer Ingelheim was the recipient of various awards for its efforts in this area in 2016. We received top marks from the auditors of the international, independent Top Employers' Institute in major HR categories, such as "talent strategy and executive development", "staff planning" and "performance management and onboarding". This is evidence of the strong appeal and development opportunities at our company – both for employees and for potential recruits.

Social responsibility

Taking social responsibility beyond our business activities is also an important aspect of our corporate culture. Our commitment to the well-being of our patients, employees and their families is the focus of a range of projects. In addition, we support people in need through various initiatives, particularly in countries and regions where we are active as a company. All of our company's activities also focus on protecting and maintaining the environment. In 2016, the German chemical industry association presented Boehringer Ingelheim with its Responsible Care Award for the company's own power station at its Ingelheim facility and the associated long-term improvement in its carbon footprint.

A major pillar of our social commitment is our MMH initiative. For over six years, Boehringer Ingelheim has been in partnership with Ashoka, a global nonprofit organisation. The aim of this partnership is to integrate health as a major factor in people's lives around the world, including their families and their social environment. It aims to identify and support promising ideas for improving health. In order to achieve this, Making More Health currently promotes more than 80 selected social entrepreneurs around the world, who are attempting to come up with effective solutions in the healthcare sector.

Social commitment within the company is also encouraged at Boehringer Ingelheim. Our employees in more than 30 countries work on the MMH initiative. In the MMH Youth Venture project, entrepreneurial skills are developed by working together on designing social entrepreneurship projects, actively supported by mentors from our workforce. The initiative is supported by the Executive in Residence (EiR) and MMH Insight India staff development programmes. As part of a network of partnerships with nonprofit organisations and social entrepreneurs in the healthcare sector, this programme gives young managers the opportunity to support the participants at their project facilities for a specific period of time and to jointly develop and implement projects. The goal is to develop and promote a socially aware and innovative approach to business and to integrate new perspectives and approaches in everyday business.

As a manufacturer with tradition and high expertise in the field of stroke therapy and prevention, Boehringer Ingelheim is promoting broader public awareness and improved care. Together with patient organisations and politics, Boehringer Ingelheim has been providing information on the causes and consequences of strokes, options for their prevention and how to act in case of an emergency for more than 13 years. Last year, Boehringer Ingelheim was once again involved in the "Herzessache Schlaganfall" (taking stroke to heart) awareness-raising initiative and organised various projects and awareness-raising events. The initiative, which was launched by Boehringer Ingelheim in 2010, promotes projects that raise awareness of atrial fibrillation and the associated risk of stroke, as well as improving public perception. With its "Herzessache Lebenszeit" (taking life to heart) awareness-raising campaign throughout Germany, Boehringer Ingelheim, together with various foundations and associations in the stroke and diabetes fields, is providing information on the risks associated with these two widespread diseases and the possibilities for their prevention, through events in more than 120 towns and cities. The goal is to reduce the number of new cases.

To improve the European system for handling strokes, Boehringer Ingelheim in 2016 set up the "Angels Initiative"

together with the European Stroke Organisation (ESO), with the goal of developing a European network of clinics equipped to handle strokes.

Boehringer Ingelheim has always actively supported research, science and culture. It continuously affirms this strategy through its partnerships with academic institutions. In addition to supporting scientific activities, scientists are also awarded the annual Boehringer Ingelheim FENS Research Award for neuroscience, or the Heinrich Wieland Prize for research into biologically active substances and systems.

REPORT ON ECONOMIC POSITION

Macroeconomic environment

In 2016, the global economy grew by 2.5% on the previous year, and thereby fell slightly short of the previous year's increase as well as the expected trend.

The major industrialised countries' economic recovery continued in 2016. While the unexpected Brexit vote did temporarily increase uncertainty on the financial markets, the effects on the real economy have been limited to date. In the eurozone and Japan especially, economic output rose faster than production potential. The expansionary monetary policy of the European Central Bank and the Bank of Japan, as well as their decision to implement a negative interest-rate policy and to expand their bond-buying programmes, acted as a stimulus. The economic situation for the emerging economies also largely stabilised in 2016. China and India, in particular, strengthened their economic output. Due to the stabilisation of commodity prices, the end of recession was in sight in Russia and Latin America.

For 2017, the global economy is expected to maintain a moderate growth rate of 2.8%. The United States as well as Japan and the eurozone are expected to maintain their stable levels of growth. For the emerging economies, too, the ongoing process of stabilisation is expected to continue.

Positive economic development continued in 2016 in Germany, with economic output rising by 1.9%. The upturn was supported, in particular, by significantly greater private and public consumer spending as well as housing investments. Moreover, the increase in consumer spending also improved the situation on the labour market, meaning that the number of people in employment increased. With a growth rate of 3.3%, the rise in exports fell short of the previous year's level and thereby reflects the still quite subdued economic recovery processes of the country's key trading partners.

With a view to 2017, we can assume that the positive economic growth in Germany will continue, with forecast growth of around 1.4%. The slowdown in growth by comparison with the previous year is mainly attributable to the decrease in the number of working days in 2017. Only a weak growth in global trade will prevent further economic expansion in Germany.

With an average rate of inflation of 0.5% in 2016, prices in Germany decreased compared with the previous year, as measured by the consumer price index. The rate of inflation for the whole eurozone was 1.1% and, thus, higher than the previous year.

In addition to the euro, the major currencies for the Boehringer Ingelheim Group are the US dollar (USD) and the Japanese yen (JPY). At the end of the year, the euro devalued sharply against the US dollar but, as in the previous year, fluctuated between USD/EUR 1.04 (December) and USD/EUR 1.16 (May) overall.

The euro fluctuated relatively strongly against the Japanese yen in the past financial year. After reaching an annual high in January (JPY/EUR 132), the euro devalued significantly against the yen over the course of the year (low: JPY/EUR 111 in July), followed by an upward revaluation in the fourth quarter.

The global pharmaceuticals market registered growth of around 6% in the 2016 financial year. This trend was driven by rising demand in the industrialised countries

for cancer medicines, products for the treatment of auto-immune diseases and anti-diabetic medicines. Due to the ageing population in the industrialised countries and the increasing level of prosperity in the emerging economies, the industry’s growth remained stable, albeit slightly weaker than in previous years.

Course of business

Long-term and sustainably successful development forms the basis for securing the company’s independence over the long term. Combined with stable earnings and sound financing, this is at the core of Boehringer Ingelheim’s strategic focus. As in previous years, we based our approach on these principles.

The year 2016 was characterised by significant changes for Boehringer Ingelheim; these were changes that also represented important steps for the company’s future. The completion of the exchange of our consumer health care business (CHC) for Sanofi’s animal health business (Merial) at the turn of the year was the biggest change within our business portfolio of the past few years. This transaction will significantly improve our future market position in the field of animal health and establish us in future as one of the largest global players in this segment.

In addition, ownership of our US generics business was transferred to Hikma Pharmaceuticals PLC in the first quarter of 2016. A corresponding sales agreement had been signed in July 2015.

Together with the company AbbVie Boehringer Ingelheim agreed on a long-term global collaboration for the development of two compounds in the therapeutic area immunology.

Boehringer Ingelheim recorded net sales of EUR 15,850 million in the 2016 financial year, which corresponds to an increase of 7.1% compared with the previous year’s figure of EUR 14,798 million. The exchange rate developments on the foreign exchange markets and the associated exchange rate effects had only a slight impact. Currency adjusted, Boehringer Ingelheim’s growth rate stood at 7.3%.

With sales of EUR 6,542 million, the Americas region represents around 41% of our total sales and remains the biggest market for Boehringer Ingelheim. The decline of 5.5% in sales compared with the previous year is mainly due to the sale of our US generics business. Strong growth was recorded once more in the Asia/Australia/Africa (AAA) region with 12.8%. Boehringer Ingelheim achieved revenues of EUR 4,226 million in this region, corresponding to a stable share of around 27% of the Group’s total revenues. The Europe region showed high sales growth (+23.1%) to EUR 5,082 million. This also reflects the payment received for development and marketing rights within the scope of the company’s cooperation with AbbVie in the field of immune diseases. The Group made 32% of its sales in Europe.

Net sales by region (in EUR million)	2016	2015	Change	currency adjusted
Americas	6,542	6,923	-5.5%	-1.6%
Europe	5,082	4,127	+23.1%	+19.0%
Asia/Australia/Africa (AAA)	4,226	3,748	+12.8%	+9.7%

In general, sales growth conformed to expectations. Supported by good results from clinical trials, we have been able to place promising new products on the market and successfully push ahead with well-established products. On the other hand, we are experiencing an increasingly difficult market situation with constantly challenging market access and growing price pressure in our key markets of the USA, Japan and Europe. Overall, the company has asserted itself well despite the difficult conditions and has laid the foundations for future growth.

Boehringer Ingelheim recorded an operating income of EUR 2,872 million, corresponding to a return on sales of 18.1%, which is 2.8 percentage points above the previous year’s return on sales. The operating income includes significant positive and negative extraordinary effects compared with the previous year and was increased in absolute terms by EUR 603 million.

Key figures (in EUR million)	2016	2015	Change
Net sales	15,850	14,798	+ 7.1%
Operating income	2,872	2,269	+ 26.6%
Return on net sales	18.1%	15.3%	

Results from operations

In the past financial year, Boehringer Ingelheim's business activities were divided into prescription medicines, consumer health care, animal health, biopharmaceuticals and industrial customers.

Net sales by businesses (in EUR million)	2016	2015	Change	currency adjusted
Prescription Medicines	12,036	11,201	+ 7.5%	+ 7.4%
Consumer Health Care	1,578	1,513	+ 4.3%	+ 5.5%
Animal Health	1,460	1,363	+ 7.1%	+ 8.5%
Biopharmaceuticals	613	576	+ 6.4%	+ 6.4%
Industrial Customers and other sales	163	145	+ 12.4%	+ 12.8%

Prescription medicines

With around 76% of total revenue, prescription medicines is the main pillar of Boehringer Ingelheim's business activities. In 2016, revenues from prescription medicines amounted to EUR 12,036 million. This is equivalent to a change of around + 7.5% (+ 7.4% currency adjusted) compared with the previous year. As well as the successful placement of innovative products and the good market position of established medicines, the positive sales growth is due to the receipt of a payment agreed within the scope of the company's cooperation with AbbVie in the field of immune diseases. We are continuing to experience increasing price pressure, however, particularly for established medicines, in a number of major markets. Overall, Boehringer Ingelheim was again able to assert itself well in this difficult environment in 2016 and has laid the foundations for further growth.

As in previous years, SPIRIVA®, which is used to treat chronic obstructive pulmonary disease (COPD), was once again the biggest contributor to sales in 2016. It achieved revenues of EUR 2,995 million within the reporting period, but thus fell short of the level of the previous year (EUR 3,553 million). On the company's biggest sales market,

the USA, in particular, sales of SPIRIVA® fell significantly due to price pressure.

The second biggest sales contributor for Boehringer Ingelheim, the anticoagulant PRADAXA®, recorded sales of EUR 1,385 million, which corresponds to an increase over the 2015 level (+ 7.6%).

At EUR 1,128 million, the medicine TRAJENTA®, which is used for the treatment of type 2 diabetes, achieved sales in excess of one billion euros for the first time in 2016 (+ 24.1%).

OFEV®, which offers people with the rare, fatal respiratory disease idiopathic pulmonary fibrosis (IPF) a new treatment option and achieved product authorisation in 2015, generated sales of EUR 613 million (+ 70.9%).

Net sales (in EUR million)	2016	2015	Change
SPIRIVA®	2,995	3,553	- 15.7%
PRADAXA®	1,385	1,287	+ 7.6%
TRAJENTA® / JENTADUETO®	1,128	909	+ 24.1%
MICARDIS®	959	956	+ 0.3%

With regard to the regional distribution of sales, the Americas, with a share of around 45%, were once more by far the largest market. In this region, Boehringer Ingelheim generated net sales of EUR 5,362 million, which corresponds to a change of - 4.5% compared with the previous year (- 3.3% currency adjusted) and was impacted by the sale of our US generics business.

The second-biggest market, Europe, accounted for 28%, with revenues of EUR 3,383 million. Sales thus increased compared with 2015 (EUR 2,729 million) and were not subject to any significant exchange rate effects.

Net sales by region (in EUR million)	2016	2015	Change
Americas	5,362	5,613	- 4.5%
Europe	3,383	2,729	+ 24.0%
Asia/Australia/Africa (AAA)	3,291	2,838	+ 16.0%

The Asia /Australia /Africa (AAA) region achieved sales of EUR 3,291 million, which is equivalent to about 27% of total sales of prescription medicines. This region showed an increase of + 16.0% as compared with last year (+ 10.7% currency adjusted).

Consumer health care

In consumer health care, sales increased by + 4.3% compared with the previous year (+ 5.5% currency adjusted). In this business, Boehringer Ingelheim generated revenues amounting to EUR 1,578 million.

In 2016, the biggest sales contributors in the consumer health care segment were DULCOLAX®, BUSCOPAN®, PHARMATON® and MUCOSOLVAN®. All products generated revenue of significantly more than EUR 100 million each. As in the previous year, DULCOLAX® was the biggest seller, with sales of EUR 237 million (+ 5.3%). BUSCOPAN® also showed an increase (+ 5.8%) in the past financial year and generated sales of EUR 236 million. Positive results were also achieved with PHARMATON®, with sales increasing by 3.6% to EUR 145 million.

Net sales (in EUR million)	2016	2015	Change
DULCOLAX®	237	225	+ 5.3%
BUSCOPAN®	236	223	+ 5.8%
PHARMATON®	145	140	+ 3.6%
MUCOSOLVAN®	136	168	- 19.0%

Of all the regions, Europe generated the highest sales of EUR 582 million. This corresponds to a 37% share of global sales in the consumer health care business. As such, sales here were up by 1.0% on last year.

The AAA region ended the 2016 financial year with sales amounting to EUR 548 million and an increase of 8.3% compared with the previous year (+ 4.2% currency adjusted). This market therefore accounted for just under 35% of Boehringer Ingelheim’s consumer health care business.

The Americas region, the third largest sales market in the consumer health care business, ended the financial year with a raise in revenues of + 3.9% (+ 11.4% currency

adjusted) compared with the previous year, achieving total sales of EUR 448 million.

Animal health

Revenues from products in the animal health business increased to EUR 1,460 million in 2016, corresponding to a + 7.1% increase on the previous year (+ 8.5% currency adjusted). Sales of products for livestock accounted for the largest share of this, EUR 1,028 million, corresponding to around 70% of the entire animal health segment. In the pet segment, revenues amounted to EUR 432 million.

Net sales (in EUR million)	2016	2015	Change
INGELVAC CIRCOFLEX®	283	281	+ 0.7%
INGELVAC® PRRS	114	99	+ 15.2%
METACAM®	106	101	+ 5.0%
DURAMUNE®	100	88	+ 13.6%

The growth of the animal health segment was most significant in the Americas region. Accounting for about 50% of total sales, the biggest sales market for Boehringer Ingelheim in this business grew by 4.4% (+ 5.9% currency adjusted) to EUR 729 million. In the US market, the most important country for Boehringer Ingelheim, sales increased by 5.9% to EUR 612 million.

Boehringer Ingelheim also saw revenues grow in Europe in 2016, increasing to EUR 394 million, or a rise of 7.7% (+ 10.1% currency adjusted), and accounting for 27% of total revenues of the animal health business. Sales increased in every country, particularly in Germany.

With an increase of 13.1% (+ 12.8% currency adjusted), the AAA region also reported positive growth compared with the previous year, recording sales of EUR 337 million, which corresponds to around 23% of Boehringer Ingelheim’s total animal health sales. China in particular was able to achieve a growth of + 9.1%, with net sales amounting to EUR 108 million.

Biopharmaceuticals

Sales for 2016 in biopharmaceutical contract manufacturing amounted to EUR 613 million, which represents growth of +6.4% compared with the previous year.

Industrial customers and other sales

The industrial customer business consists of our third-party businesses in the field of pharmaceutical and chemical production and sales of pharma chemicals. Sales of EUR 163 million were achieved in 2016, corresponding to an increase in revenue of 12.4% compared with the previous year.

Presentation of expenditure and income

Operating expenses at Boehringer Ingelheim increased to EUR 15,492 million in the 2016 financial year, representing a rise of 10.7% compared with the previous year. Cost of materials were 7.2% higher than the previous year (EUR 2,466 million), coming in at EUR 2,643 million. The corresponding cost of materials ratio makes up 16.7%. Personnel expenses amounted to EUR 4,570 million (+1.2%), corresponding to a personnel cost ratio of 28.8%, which was -1.7 percentage points lower than the previous year.

Depreciation and amortization recorded an increase of EUR 34 million (+5.8%) to EUR 620 million. Other operating expenses rose by 19.2% compared with the previous year, coming in at EUR 7,659 million. Among other items, this cost category includes commission and licence payments that are dependent on sales.

The operating income amounted to EUR 2,872 million, which was 26.6% up on the previous year (EUR 2,269 million). It was influenced by significant positive and negative extraordinary and one-time effects (sale of US generic business; license payments AbbVie; expenses for legal risks) and was, adjusted by these effects, on previous year's level. Thus, the operating income met our expectations.

In the reporting period, the financial result amounted to EUR -76 million, which is EUR 527 million above the previous year. This was largely due to the effect

from changes in interest rates related to the conversion of the average interest rate for discounting pension plan obligations.

Income before taxes developed in line with the operating and financial result, increasing to EUR 2,792 million. Tax expenses amounted to EUR 943 million. The increase in comparison to 2015 (EUR 273 million) particularly results from higher results of the US companies and provision for tax risks. It must be noted in this regard that under the provisions of German commercial law, shareholders' personal taxes arising from Group business activities may not be recognised as tax expenses. Instead, these taxes are presented as part of withdrawals from Group equity. Taking this extraordinary effect into account, the actual tax ratio is markedly higher than the figure shown in the profit and loss statement.

In the 2016 financial year, the group profit of Boehringer Ingelheim totalled EUR 1,853 million, corresponding to an increase of 17.5% on the previous year's level of EUR 1,577 million.

Financial position

Boehringer Ingelheim's financial management instruments and methods are aimed at securing liquidity, minimising financial and economic risks and optimising the cost of capital with an appropriate capital structure. Our financial activities are therefore geared towards supporting the business strategy.

As a global company, exchange rate volatility has a significant impact on Boehringer Ingelheim's financial performance. The importance of our US business and the associated supply relationships mean that the exchange rate development of the US dollar constitutes the greatest individual risk. Within the framework of Group-wide financial reporting, foreign exchange risk is calculated and hedged through derivative financial instruments. The nature and scope of these measures are set out in our Group guidelines and are regularly discussed and approved by the relevant committee in a standardised process.

Investments are of great importance to Boehringer Ingelheim from a strategic point of view. Continuous investment is a requirement for long-term success and the development of the company and forms the basis for the profitable growth of our business divisions.

A total of EUR 697 million was invested in tangible and intangible assets in the year under review.

In the 2016 financial year, Boehringer Ingelheim invested further EUR 40 million in the expansion of production capacity for the RESPIMAT® Soft Mist™ inhaler at its Dortmund and Ingelheim facilities in Germany. Boehringer Ingelheim microParts GmbH in Dortmund manufactures the RESPIMAT® Soft Mist™ inhalation system, which is then filled with the relevant active substances from the pharmaceutical production facility in Ingelheim, ready for global sales.

Boehringer Ingelheim once again invested in the significant growth market of China. The Group continued its investment programme for the expansion of its biopharmaceutical and animal health manufacturing facilities in Shanghai and Taizhou.

The investments made in the research facilities in Germany, Austria and the USA during 2016 reflect the top priority of research and development in the fields of human and animal medicines for Boehringer Ingelheim.

Cash flow amounted to EUR 2,484 million in 2016. This represents a decline of 4.6% on 2015. Cash flow from operating activities increased by EUR 656 million to EUR 2,888 million, which was mainly due to the receipt of a payment agreed within the scope of the company's cooperation with AbbVie in the field of immune diseases. As in previous years, this meant that investments could be financed entirely through funds generated by the company itself. A total of EUR 645 million was invested in tangible assets and EUR 52 million in intangible assets. In terms of cash flow from financing activities, we recorded an outflow of funds amounting to EUR 1,027 million. This was mainly due to loan repayments. Overall, the changes in

cash flow led to an increase in liquidity of EUR 1,789 million to EUR 11,989 million (+ 17.5%).

Net assets

In the 2016 financial year, Boehringer Ingelheim's total assets amounted to EUR 26,139 million, an increase of EUR 2,854 million (+ 12.3%) compared with the previous year. Tangible and intangible assets totalled EUR 3,595 million.

As at the end of the year, financial investments amounted to EUR 6,092 million, which corresponds to an increase of EUR 159 million on the previous year's value. Inventories showed growth of 5.1% to EUR 2,610 million. Trade receivables declined by EUR 162 million to EUR 3,055 million in 2016. Liquid funds, including securities within current assets, stood at EUR 7,005 million (previous year: EUR 4,536 million).

Due to the aforementioned changes in cash and cash equivalents, Group equity amounted to EUR 11,327 million and therefore more than fully covers tangible and intangible assets. In addition to equity, the pension provisions and long-term liabilities are also available to the Group in the long term. The total of these three items amounted to EUR 15,762 million in 2016, representing a share of 60.3% of the total assets. Consequently, long-term disposable capital covers all intangible and tangible assets, inventories and trade receivables.

While other provisions were 30.6% higher than last year at EUR 6,450 million, liabilities were reduced by 20.5% to EUR 1,984 million during the previous year.

The status already shown in the financial position remains resoundingly positive on both the balance sheet and in the respective balance sheet ratios. To sum up, Boehringer Ingelheim's net assets, financial and earnings position confirm its credentials as a soundly financed and profitable company.

RISK REPORT

Risk and opportunity management

The aim of the risk management system implemented at Boehringer Ingelheim is to identify business-specific risks and, in particular, risks that jeopardise the continued existence of the company as early as possible, to assess them and to reduce them to a reasonable level by means of suitable measures.

When assessing the risks in the context of holistic risk management, we also endeavour to take into account the resulting opportunities. Opportunity management is based on the strategies and objectives of the company, individual businesses and operating business units and is an integral part of the Group-wide planning and management systems. Those responsible for the businesses and functions bear direct responsibility for the early and systematic identification, analysis and use of opportunities. For Boehringer Ingelheim as a research-driven and innovative, pharmaceutical company, the current research and development activities are naturally considered a relevant opportunity. Relevant projects have already been illustrated in the research and development chapter.

The persons responsible for the key businesses and functions are included in the process of calculating and assessing risks. The Group-wide risk and information system ensures that all identified risks are analysed and assessed carefully. Following an appropriate classification into various categories, adequate countermeasures are initiated and their implementation is consistently monitored.

In the year under review, internal auditing performed targeted routine audits as well as extraordinary audits around the world. In addition to adherence to legal requirements and internal Group guidelines, the main focal points were the functionality of systems, the effectiveness of internal controls for the prevention of loss of assets and the efficiency of structures and processes. Corresponding adjustments or optimisations were initiated as necessary.

Individual risks

The most important risks to which Boehringer Ingelheim is exposed are broken down into the following specific categories: financial risks, legal risks, production and environmental risks, personnel risks and sector-specific risks.

Risks are identified below as being “concrete” when they appear to be controllable by means of specific management procedures. The term “abstract” is used in the case of risks that cannot be completely controlled, even by means of targeted management procedures, regardless of the probability of their occurrence.

Financial risks

Relevant financial risks are themselves broken down as follows: currency risks, credit and country-specific risks, as well as the management of financial investment risks.

Currency risks

The global orientation of our business activities results in currency risks due to exchange rate volatility, particularly with regard to the US dollar and Japanese yen. The Group monitors and quantifies these risks at regular intervals, making them predictable for future business by means of relevant hedging strategies and appropriate financial instruments, such as forward exchange contracts. The resultant risks are subsequently designated as being concrete and therefore controllable.

Credit and country-specific risks

Boehringer Ingelheim is exposed to various credit and country-specific risks as a result of its international business activities. From the portfolio of trade accounts receivable and trade accounts payable, we have not identified any extraordinary risks for the Group beyond the usual level in the sector. The same applies to possible default risks for receivables, which are largely hedged against economic risks. We will continue to carefully track credit and country-specific risks to be in a position to respond to negative changes in a timely manner. These risks are therefore regarded as concrete.

Management of financial investment risks

The Group pursues a defensive investment strategy in the management of its financial assets. This is reflected in the orientation of its portfolio, which is focused on European Economic and Monetary Union (EMU) government bonds with top credit ratings and short-term investments at selected banks, so that this results in a concrete and thus controllable risk.

Legal risks

The business activities of the Group are exposed to legal risks. A distinction is made between regulatory, liability and patent protection risks.

Regulatory risks

Boehringer Ingelheim is exposed to risks arising from legal disputes and proceedings as well as official investigations. As the legal or administrative decisions in ongoing or future proceedings cannot be predicted, we regard the resultant risks as being abstract.

Liability risks

The marketing and sale of pharmaceuticals are exposed to a potential product liability risk. Boehringer Ingelheim currently has product liability insurance for the Company's risk profile. There is absolutely no guarantee, however, that this insurance coverage can be maintained at reasonable cost and acceptable conditions, or that it is sufficient to protect Boehringer Ingelheim against a claim or loss, or against all potential claims or losses.

Furthermore, product liability claims could tie up substantial financial resources and management capacity and be detrimental to the company's image in the event that the market considers the product to be unsafe or ineffective as a result of unexpected side effects. We regard this risk as abstract.

Patent protection risks

Protection of innovations through trademark, brand and patent rights is of particular importance to Boehringer Ingelheim as a research company. These commercial protective rights are increasingly the target of attacks and

breaches. We have taken the necessary precautions to allow us to detect threats at an early stage and, by commencing appropriate countermeasures, defend our legal position using all legal means available to us so that these risks are regarded as concrete.

Production and environmental risks

Our quality management system and compliance processes are continuously optimised in close cooperation with the relevant authorities in order to ensure compliance with cGMP standards (current good manufacturing practices) in future. Risks in this area continue to be of high significance to the Group and are classified as abstract.

In order to guarantee the supply of our products to the market, we have implemented measures that guarantee reliable and high-quality supplies for internal and external customers. In addition to supplier management on the procurement side, this also involves building up internal standby capacities. As a result, we see the risk as concrete.

Risks in the areas of environment, health, safety and sustainability (EHS&S) are pre-emptively minimised by ensuring global adherence to our high safety standards. Appropriate emergency plans have been drawn up for possible incidents of any kind and are practised and subjected to comprehensive quality testing at regular intervals. As a result of these measures, these risks are classed as concrete.

Personnel risks

Boehringer Ingelheim, as other companies, is exposed to demographic change and the resultant risk of being affected by a lack of appropriately qualified personnel. This risk can have a substantial impact on the company's business activities. This potential risk has therefore been included in the long-term planning process for many years and has acquired strategic significance as a result. Boehringer Ingelheim counters the risk by means of a comprehensive personnel concept. Regardless of their ethnic background, gender or religion, we offer all company employees development opportunities based on their vocational skills, social

expertise, personal aptitudes and willingness to take on responsibility in accordance with the needs of the company. In view of the countermeasures described above, the risk is regarded as concrete.

Sector-specific risks

Boehringer Ingelheim is exposed to business risks specific to the pharmaceutical industry. Some of these risks materialised in the past financial year (changes to the health-care system in the USA) and are increasing in significance as a result of their impact on Boehringer Ingelheim. They will continue to be classed as abstract.

In addition to the loss of exclusivity of products established on the market and risks associated with the development and registration of new products, these risks increasingly include changing and restrictive requirements relating to pricing and reimbursement on many sales markets. Frequently, the prices of pharmaceutical products are subject not only to state monitoring and regulation, but also to price pressure from cheaper generic drugs caused by the state reimbursement systems. Boehringer Ingelheim is therefore keeping a close eye on the various changes in its sales markets and has already responded to current developments with respective cost-saving and efficiency-improving measures.

Overall statement on the risk situation

From a current perspective, we are not aware of any risks that alone or in conjunction with other risks could lead to an impairment of the company's assets, financial position or earnings which could jeopardise the continued existence of Boehringer Ingelheim.

REPORT ON EXPECTED DEVELOPMENTS

The year under review was an intense and challenging time for Boehringer Ingelheim, during which we laid the foundations for the sustainable development and long-term growth of our company with several major decisions.

The consistent focus of our business on innovation-oriented fields is attested by the strategic exchange of Sanofi's animal health business (Merial) and Boehringer Ingelheim's consumer health care business (CHC). The contract for this exchange was signed in June 2016 and the transaction was successfully closed on 1 January 2017. This transaction will improve the competitiveness of our animal health business in the industry's important growth markets. We will establish ourselves as one of the largest global players in this business, and we will be able to offer our customers worldwide even more innovation and added value at a very high level by pooling the complementary product portfolios of Merial and Boehringer Ingelheim, the existing technology platforms for vaccines and anti-parasitics, as well as pharmaceutical speciality products.

Besides increasing political unreliability and volatility, the difficult market environment and increased unpredictability of doing business posed major challenges for the entire pharmaceutical industry and will continue to require significant attention from Boehringer Ingelheim in 2017, too. With regard to competitiveness, it is all the more important, therefore, that we retain our scope for growth and innovation so that we can continue to be successful on the market in the future.

With regard to the many changes in healthcare systems and the increasing price pressure, particularly for well-established medicines in many major markets, and with regard to increasing challenges to market access for new products, we only expect to see low growth impetus for the pharmaceutical industry in the coming year. Boehringer Ingelheim has asserted itself despite the difficult condi-

tions and has laid the foundations for further growth. Through the integration of Merial's business, we assume that sales in our animal health division will more than double in 2017 compared with the previous year, which will more than make up for the countervailing effect of the sale of the company's consumer health care business to Sanofi. This will make a significant contribution to the considerable year-on-year increase in revenues that we expect to see in overall terms in the current financial year, after adjustment for currency effects.

Research and development costs remained high in 2016, in keeping with our strategy to drive growth and promote new products in the future primarily with products from our own research and development facilities. We invest in this area with care after close investigation of the therapeutic benefit and the associated prospects for success. Our comprehensive portfolio of prospective products with promising study outcomes, along with newly approved products with significant sales potential, justifies our high level of investment in research and development. In 2017, we plan to invest in the research and development of new pharmaceutical products at a similar level to the year under review, based on our current business structure.

In addition to patent expiry and attacks on patents, the major challenges facing the research-driven pharmaceutical industry are the increasing amount of investment in R&D as well as bigger hurdles and increased costs associated with product approvals. In this context, it is the increasing cost pressure in the healthcare system that should be singled out in particular, leading to decreasing willingness to adequately recognise large amounts invested into the development of new medicines. As a result, there is price pressure in all major markets for prescription medicines. This, in conjunction with longer planning and development cycles for new products, makes business less predictable and requires us to recognise and seize opportunities quickly on the one hand, while subjecting strategies and structures to continual monitoring and adjustments on the other. To this end, we have instigated initiatives over the past few years to accelerate our reaction to change and to reduce organisational complexities as well as to lower

our cost base in order to create potential for investments and to secure the company's long-term success. With the difficult market environment on the one hand, and the potential resulting from the measures we have introduced as well as promising new product launches on the other, we plan to see a 2017 operating income before special factors that is at last year's level, based on our current business structure. As for the results in 2016 we expect a considerable impact of major one-off effects on the 2017 results, essentially due to the sale of our consumer health care business and simultaneously the acquisition of Sanofi's animal health business. Overall, we anticipate a strengthening of the overall Group's financial capability by integrating the Merial business.

As a family-run company, Boehringer Ingelheim's primary aim is to maintain the firm's independence and competitiveness. As such, long-term and sustainable organic growth still takes precedence over short-term profit targets. We are confident that we will achieve our ambitious targets thanks to our great innovative strength based on a comprehensive portfolio of prospective products, our global presence and the support of our highly qualified and motivated employees. Current product launches and expansions in emerging markets will boost growth in all our areas of business. We will stand by our vision "Value through Innovation", research and develop innovative products that offer high medical benefits and bring them to the market. The aim of our endeavours is to make new medicines available that will enable doctors to treat patients more effectively than is currently possible.