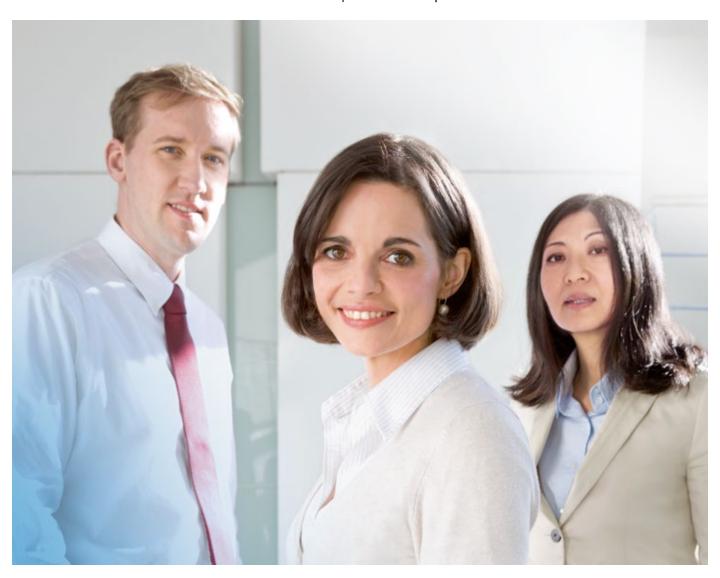


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# **KEY FIGURES**

BIOTEST GROUP		2015	2014	Change in %
Revenue	in € million	589.6	582.0	1.3
thereof:				
Germany	in € million	123.3	106.0	16.3
Rest of world	in € million	466.3	476.0	-2.0
thereof:				
Therapy	in € million	411.4	409.8	0.4
Plasma & Services	in € million	169.7	157.0	8.1
Other Segments	in € million	8.5	15.2	-44.1
EBITDA	in € million	22.4		-73.9
Operating profit (EBIT)	in € million	-71.8	53.4	-234.5
EBIT in % of revenue	%	-12.2	9.2	
Adjusted operating earnings (EBIT)*		91.2	123.2	-26.0
Earnings before taxes	in € million	-74.3	46.9	-258.4
Earnings after taxes	in € million	-82.5	19.2	-529.7
Structure of expenses:				
Personnel expenses	in € million	158.9	138.2	15.0
Research and development costs	in € million	98.8	67.2	47.0
Research and development costs in % of revenue		16.8	11.5	
Capital expenditure in property, plant and equipment and intangible assets	in € million	109.9	47.1	133.3
Financing:				
Cash flow from operating activities	in € million	38.1	-11.4	434.2
Depreciation and amotisation	in € million	94.2	32.5	189.8
Equity (as of 31 December)	in € million	412.3	480.2	-14.1
Equity ratio (as of 31 December)	%	42.8	46.5	
Balance sheet total (as of 31 December)	in € million	962.7	1,032.6	-6.8
Employees (full-time equivalents as of 31 December)	amount	2,271	2,158	5.2
Earnings per share	€	-2.10	0.48	-537.5

<sup>\*</sup> Derivation page 16

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DR BERNHARD EHMER Chairman of the Board of Management



DR MICHAEL RAMROTH Chief Financial Officer





DR GEORG FLOß Chief Operations Officer

# DEAR SHAREHOLDERS,

In recent decades, Biotest has grown vigorously and developed from a family business into an international corporate group. With our innovative capacity and quality products, we have continuously satisfied our customers' needs. However, 2015 has shown that setbacks are part of the work of a researching pharmaceutical company.

After being able to announce increasing sales and achieving the forecast in the first quarter of the last financial year, we had to report unpleasant news in the second and third quarters. Firstly, we did not reach our goal in the clinical development of the monoclonal antibody tregalizumab (BT-061). Secondly, we had to adjust the value of inventories of Bivigam® due to decreasing revenues; given the simultaneously lower market prospects of our development product Civacir® both of which led to an impairment of the manufacturing plant and intangible assets at our US subsidiary.

From a business point of view, we did not reach our targets in the financial year due to the impairment. Compared to the previous year, earnings before interest and taxes (EBIT) decreased from  $\leqslant$  53.4 million to  $\leqslant$  -71.8 million. Revenue increased by 1.3% to  $\leqslant$  589.6 million (previous year:  $\leqslant$  582.0 million). Biotest shows a very solid financial basis: last year, the operative cash flow increased to  $\leqslant$  38.1 million from  $\leqslant$  -11.4 million in the previous year. Our equity ratio is at a stable 42.8%, and all development projects are financed.

The fourth quarter of the past financial year demonstrated that we returned to a profitable growth path. In this period, we achieved sales of  $\in$  171.7 million and earnings of  $\in$  10.2 million. All of us at Biotest have learned from the past year's setbacks; the impairments were painful but also the impetus for a new strategic alignment.

The key of our future growth strategy is our focus on the plasma business and therefore particularly on the initiated expansion project Biotest Next Level. Concerning the monoclonal antibodies, Biotest will push the ongoing pre-clinical and clinical activities to the next milestone in order to identify suitable partners for future development and marketing. Thereby we aim to limit future risks and costs in the area of monoclonal antibodies.

In addition, we plan to achieve further growth by investing in the research and development of new medications. In the past year, we invested € 98.8 million in this area and we were able to achieve considerable progress. One highlight was receiving the Zutectra® marketing authorisation for early use after liver transplantation. This allowed us to further strengthen our market position as the leading supplier of hepatitis B hyperimmunoglobulins. Encouraging results were also achieved for IgM Concentrate, which is to be used in life-threatening lung infections. Furthermore, we were able to initiate the next study phases for other research products. For instance, we started a phase I/III study on fibrinogen as well as the treatment of the first patients in the phase IIa study on BT-063 for the indication systemic lupus erythematosus.

Biotest Next Level is a strategic focus of the company. As part of the project we plan to produce the new plasma-based products at the Dreieich location in the future and thereby to expand our product portfolio.

The new manufacturing plant will generate five instead of three products out of one litre of plasma in the future, and hence reduce the cost of sales ratio and increase our competitiveness. The expansion of the product portfolio for the plasma business will lead to a considerable increase of Biotest's future earnings potential. The implementation of Biotest Next Level is right on course, which is a considerable success in view of the dimensions of this project with an investment volume of  $\in$  250 million. The shell construction was completed in the autumn of 2015 and a roofing ceremony was held. The structural and technical installations are to be completed by mid-2017.

Our success is the result of the great commitment of every Biotest employee. At this point, I would like to thank our employees very much for their motivation, dedication and openness towards new team members. In the context of Biotest Next Level, we plan to hire 300 new employees. In the hiring process, we would like to ensure that new employees share our existing team's attitude of teamspirit, motivation and innovation. This sense of unity will make Biotest Next Level a success, and we will continue to benefit from the strong demand for immunoglobulins.

We strongly believe that with our core business, we can slightly increase sales in the current business year. We aim for an EBIT of  $\in$  30 million.

As the company owners, please let me assure that you are investing in a steadily growing market segment and in a reliable company. Despite our loss in 2015, Biotest is in a stable financial position. Together with my colleagues on the Board, Dr Michael Ramroth and Dr Georg Floß, I would like to thank our shareholders, customers, suppliers, and partners for the confidence placed in us. We would be delighted if you continued with us on our journey.

Cordially yours,

Dr Bernhard Ehmer

Chairman of the Board of Management

# SANGEMENT REPORT

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# GROUP MANAGEMENT REPORT

# A. GROUP PRINCIPLES

# I. BUSINESS MODEL OF THE GROUP

The Biotest Group, with its headquarters in Dreieich, Germany, is an international supplier of biological medicines. Products currently on the market and new developments are obtained from human blood plasma or manufactured using biotechnology methods. The main indication areas are haematology, clinical immunology and intensive care medicine.

The Biotest Group is engaged in research and development in all of these three indication areas. Biotest covers all of the material steps in the value-added chain, from preclinical and clinical development, conducted in some cases in collaboration with international partners, through to global marketing.

# A. CORPORATE STRUCTURE

The consolidated financial statements include the parent company, Biotest AG, together with 16 other fully consolidated companies. The complete list of participating interests of Biotest is provided in Section F10 of the notes to the consolidated financial statements. See the "Management declaration" available on the company website www.biotest.de for detailed information regarding the corporate structure, management and controlling.

# **B. SEGMENTS OF THE BIOTEST GROUP**

The Company's operations are divided into the following segments: Therapy, Plasma & Services, and Other Segments. The Therapy segment includes products and development projects assigned to each of the three indication areas. Plasma sales and toll manufacturing are combined under the Plasma & Services

segment. In Other Segments, Biotest reports on its merchandise business as well as any cross-divisional costs not allocated to the Therapy or Plasma & Services segments.

# C. ADDED VALUE

The Biotest Group covers the entire value chain for production of its main products, plasma proteins, from the collection of human blood plasma as the raw material to marketing and sales. Production takes place both at the headquarters in Dreieich, Germany, as well as in Boca Raton, Florida, USA, where the US subsidiary, Biotest Pharmaceuticals Corporation (BPC), is located. In addition, Biotest maintains its own distribution operations in seven European countries and Brazil, which are responsible for marketing Biotest products in these countries. The Biotest Group is also active in over 70 countries in the world by local partnerships. Their sales and distribution activities are centrally managed strategically from Biotest headquarters in Dreieich.

Human blood plasma is the basis for manufacturing the marketed Biotest products. Biotest currently operates 29 own collection centres in Europe and in the US to obtain this raw material for production as well as for the purposes of selling some of it to contractual partners. In these centres, blood is taken from qualified and strictly monitored healthy donors and the required blood plasma is separated by plasmapheresis (splitting).

This is then processed into the respective Biotest preparations at the production sites or is sold as intermediate product. Regarding the monoclonal antibodies under development, which are manufactured using biotechnology methods and not from human blood plasma, Biotest aims to generate value by further advancing of the projects and by reaching milestones in clinical

development. Biotest covers the essential elements of the value chain at its international locations. Furthermore, resources are supplemented by collaboration with well-known partners. In order to further strengthen the value chain and to exploit the global growth potential the Biotest Next Level project, the largest expansion programme in the Company's history, was started in 2013. The aim is to expand the Biotest product range and simultaneously substantially increase profitability in the future through the acquisition of new plots of land and the construction of further buildings and facilities in Dreieich. In the future, the company aims to produce five instead of three product lines from the same amount of plasma raw material. With the project, Biotest also aims to double production capacities. Building work for Biotest Next Level continued as planned in the past financial year.

# D. PRODUCT PORTFOLIO

Biotest's product portfolio is divided into the indication areas haematology, clinical immunology and intensive care medicine. The portfolio contains products that are already in the market as well as development products that are in various phases of product development. The following table provides an overview of the preparations and indications as well as the current development and marketing status.

# PRODUCTS AND DEVELOPMENT PROJECTS OF THE BIOTEST GROUP

Products	Lead indication	Status
Indication area Haematology		
Haemoctin <sup>®</sup>	Haemophilia A (acute therapy and prophylaxis)	Marketing in Europe, Asia, South America, Near East and other regions
Haemonine®	Haemophilia B (acute therapy and prophylaxis)	Marketing in Europe and other regions
Indatuximab ravtansine	Multiple myeloma	Clinical development; ongoing phase I/II study
(BT-062)*	Solid tumours (breast cancer, bladder cancer)	Clinical development; ongoing phase I/II study
Indication area Clinical Immun	ology	
Bivigam®	Primary immune deficiency (PID)	Marketing in the USA
Cytotect®	Prophylaxis of cytomegalovirus (CMV) infection	Marketing in Europe, Asia and Africa
Fovepta®	Hepatitis B prophylaxis in newborns	Marketing in Asia and Africa
Hepatect®, Nabi-HB®	Prophylaxis of hepatitis B virus reinfection	Marketing in Europe, South America and Asia; new marketing authorisations in Norway, Finland and Iran. Nabi-HB® exclusively for the US market
Intratect® 50 g/l (5%ig)	Primary immune deficiency (PID) and secondary antibody deficiency syndromes and autoimmune diseases	Marketing in Europe, Asia and other regions
Intratect® 100 g/l (10%ig)	Primary immune deficiency (PID) and secondary antibody deficiency syndromes and autoimmune diseases	Marketing in Europe, Near and Middle East and Asia Submitted application for marketing authorisation in additional countries
Varitect®	Varicella zoster virus infection	Marketing in Europe, South America and Asia
Zutectra®	Prophylaxis of hepatitis B reinfection following liver transplantation	Marketing in Europe and Asia
BT-063*	Systemic lupus erythematosus	Clinical development; ongoing phase IIa study
BT-094 (Cytotect 70)*	Prevention of CMV infection of the foetus during pregnancy of CMV-infected mother	Clinical development; ongoing phase III study
Civacir®*	Prophylaxis of hepatitis C reinfection following liver transplantation	Clinical development; ongoing phase III study

### PRODUCTS AND DEVELOPMENT PROJECTS OF THE BIOTEST GROUP

Product	Lead indication	Status
Indication area Intensive Care	Medicine	
Albiomin® (20% and 5%)	Blood volume depletion	Marketing in Europe, South America, Asia and Near East
Biseko®	Volume and serum protein depletion	Marketing in Europe and Asia
Cofact®	Deficiency of clotting factors	Marketing in Germany and Austria
Fibrinogen*	Fibrinogen deficiency	Clinical development; ongoing phase I/III study
IgM Concentrate*	Severe bacterial infection	Clinical development; phase II study completed
Pentaglobin®	Severe bacterial infection	Marketing in South America, Asia, Europe and Near East

<sup>\*</sup> Preparations under development (status: 31 December 2015)

# E. HUMAN RESOURCES

# Change in number of employees

As of 31 December 2015, Biotest employed a staff of 2,271 full-time equivalents. This represents an increase of 5.2% compared to 2,158 full-time equivalents at the end of 2014. The increase is largely due to increased personnel requirements as part of the Biotest Next Level expansion of production capacities in Dreieich and the opening of two new plasma collection centres in the USA. As of 31 December 2015, 922 full-time positions (40.6%, previous year: 40.7%) were assigned to Biotest AG and another 962 full-time positions (42.4%, previous year: 42.2%) to BPC. About half of all employees (49.2%) worked in Germany (previous year: 49.8%).

# Remuneration

The next tranche of the Long Term Incentive Programme for success-based remuneration of management staff was issued on 1 May 2015. This variable remuneration component is based on the achievement of predefined targets. The programme is described in detail in Section F1 (Long Term Incentive Programme) of the consolidated financial statements.

# Human resources and organizational development

As part of the planned expansion of the production capacities at Dreieich, the specialised and management staff needs will also significantly increase over the next few years. For this reason, one focus in 2015 was on wide-ranging information and recruiting activities, which also served to present Biotest as an attractive employer in the region.

Cooperation with the Johann Wolfgang Goethe University Frankfurt am Main was further intensified in the past financial year. For instance, Biotest invited pharmacy students of Frankfurt University to an information event with a factory tour in Dreieich. The event aimed to demonstrate and raise interest in the various tasks and wide range of career opportunities for pharmacists, for instance in quality assurance, production, drug safety and drug approval.

Furthermore, Biotest is continuously providing incentives to enrol in part-time studies through the targeted sponsorship of Bachelor's and Master's degree programmes. In 2015, a total of eight employees were enrolled in scientific and technical studies that Biotest set up, for instance in partnership with the University of Applied Sciences Bingen and Provadis School of International Management and Technology AG, Frankfurt/Main.

In addition, Biotest for the first time participated in the job fair for scientists held by Frankfurt University. For those embarking on their careers, Biotest offers international entry-level programmes to attract well-educated talents. Among other initiatives, four university graduates are currently participating in the "Biopharmaceutical Products" trainee programme.

In addition to the external recruitment of qualified specialised and management staff, (professional and personal) staff development is very important to Biotest. With the "International Leadership & Management Programme", another focus of Biotest staff and organisational development in the financial year 2015 was on promoting cross-functional and international management and leadership skills.

# Promoting women in leadership positions

Having an appropriate share of women in the company's staff and particularly in leadership positions considerably benefits the company. In consideration of the "Gesetz für die gleichberechtigte Teilhabe von Frauen und Männern an Führungspositionen in der Privatwirtschaft und im öffentlichen Dienst" (Law on the equal participation of women and men in leadership positions in the private sector and the public sector), Biotest has defined targets for the share of women in leadership positions that are to be achieved by 30 June 2017.

# Women in the Supervisory Board

The Supervisory Board of Biotest consists of six members, of which four are representatives of the equity holders and two are employee representatives. Since 2004, two women have been members of the Supervisory Board, one as a representative of equity holders and one as an employee representative. This means that the company has met the legally required minimum gender quota of 30% in the membership of the Supervisory Board.

# Women in the Board of Management

The current members of the Board of Management are appointed for a period beyond 30 June 2017. Therefore the Supervisory Board set the target to 0% by 30 June 2017.

# Women in first- and second-level management

The Biotest Group's Board of Management has set a target of 17% women in first-level management. In 2015, the percentage of women in this management level is already 16%. The target for the second level of management was set to 38%, which means that the share of 33% in 2015 is to be further increased. The percentage of female employees at the Biotest AG (949 employees) was 43% as of 31 December 2015.

# Traineeships

Biotest AG has also reinforced its commitment to vocational training over the past year. A total of 66 trainees (previous year: 46) were employed at Biotest in eight professions as of 31 December 2015. Furthermore, Biotest started training three chemical laboratory technicians in September 2015. The quality of the Company's trainee programmes is reflected in the excellent final examination results of the graduates over the past years. In 2015, three of them were honoured by the Offenbach Chamber of Industry and Commerce for their exceptional examination results.

# Family-friendly company

In addition to offering flexible part-time work schemes, Biotest has significantly increased the opportunities for family-friendly work by opening a company day care centre for children. Construction started on the day care centre in spring of 2014. It is located in the immediate vicinity of the Company headquarters in Dreieich and provides places for up to 80 children between the ages of eight months and six years. It opened in July 2015. With opening hours of 6:00 a.m. to 6:00 p.m. and without vacation closings except for the week between Christmas and New Year, Biotest offers employees the opportunity to better balance their professional and family lives.

# F. EXTERNAL FACTORS INFLUENCING THE BUSINESS

# Regulatory environment

Biotest's manufacturing facilities for plasma proteins are subject to mandatory inspection and approval by the Darmstadt Regional Government Commission and the Paul Ehrlich Institute (PEI), Langen as well as by the United States Food and Drug Administration (FDA). In the member states of the European Union, plasma proteins are authorised under the centralised marketing authorisation procedure or by mutual recognition of national marketing authorisations. In the USA the market authorisations for Biotest preparations are subject to the provisions of the FDA. In the international environment the marketing authorisations are issued by the respective national regulatory authorities. The regulatory and authorising agencies for monoclonal antibodies in both Europe and the USA are the same as those for plasma proteins. The legal and regulatory requirements for the marketing authorisation of Biotest preparations are subject to routine and event-driven changes. The marketing authorisation requirements are constantly being tightened in the international environment. These developments led to rising costs in the 2015 financial year for audits in marketing authorisation procedures with national and international authorities.

# II. GROUP STRATEGY

The core element of Biotest's strategy is a clear focus on marketing and the developing of plasma proteins. In addition to continuously advancing its own research and development pipeline, the company is focussing its activities for marketing authorizations on internationalisation and diversification of its portfolio.

In order to continue participating in future global market growth since 2013, the Biotest Group is expanding its production capacity at its headquarters at Dreieich. The product portfolio will be expanded and production capacity will be doubled by 2019/20 due to the Biotest Next Level project. By producing five instead of three product lines from the raw material of plasma in the future, the Company's profitability and hence its competitiveness on the global markets will be further strengthened, thereby laying the foundations for profitable growth.

Biotest is also seeking to enter into strategic partnerships with suitable partners in selected areas. For the monoclonal antibodies in development, Biotest will continue with the current pre-clinical and clinical activities until the next milestones with the aim of advancing the future development and marketing with a suitable partner. Furthermore, Biotest is actively looking for development and/or marketing partners for selected plasma proteins as well.

Biotest strives to achieve extensions of existing marketing authorisations, which was successfully done for Zutectra® in 2015 for instance. In December 2015, the European Commission granted marketing approval to Biotest for the early use of the hepatitis B hyperimmunoglobulin Zutectra® after liver transplantation. While treatment with Zutectra® could previously not be commenced until 6 months after a liver transplantation, Zutectra® can be administered one week after the transplantation from now on. The early administration of subcutaneous hepatitis B hyperimmunoglobulin contributes significantly

to safe, more time efficient and less costly patient care. The successful further development of Zutectra® also supports the role of Biotest AG as the leading provider of hepatitis B hyperimmunoglobulins.

An important factor in implementing the Biotest company strategy is utilising internal resources to cover key portions of the value chain. These include research and development, plasma collection, production, quality assurance and distribution. The existing expertise, especially in the areas of plasma collection and fractionation, is used to offer available capacity to the market in the form of primary and intermediate products as well as toll manufacturing.

A global change process has been initiated to pursue the strategic orientation even more efficiently and effectively. It aims to further optimise collaboration with external customers as well as international and interdisciplinary teamwork, improve work flows and render them more efficient and to implement a uniform, participative leadership culture in the company. In the first step, international members were added to the management team, which shares responsibility with the Board of Management for strategic decisions along the value creation chain.

# III. BUSINESS PERFORMANCE MANAGEMENT

Biotest is managed using both financial and non-financial indicators, whose changes influence the enterprise value in different ways. Financial and non-financial performance indicators are measured continuously and are part of the monthly reports to the Board of Management. These reports include an analysis of actual figures and their variances from budget and previous year figures by segment and company. Additional specific analyses are performed on an event-driven basis.

### A. FINANCIAL PERFORMANCE INDICATORS

The indicators used to manage the business performance of the Biotest Group are shown in the table below:

KEY PERFORMANCE INDICATORS AT THE GROUP LEVEL

Indicator	Calculation method	Value as of 31 December 2015	Value as of 31 December 2014
Return on Capital Employed (RoCE)	EBIT/capital employed	-9.9%	6.9%
EBIT margin	EBIT/sales		9.2%
EBT margin	EBT/sales	-12.6%	8.1%
Contribution margin	(Sales – cost of sales)/sales	24.0%	38.6%
Cash flow from operating activities	See cash flow statement for a detailed calculation	€ 38.1 million	€ – 11.4 million
Cost of sales ratio	Cost of sales/sales	76.0%	61.4%
Distribution expense ratio	Distribution expenses/sales	13.2%	12.7%

At the segment level, operating profit (EBIT) is the primary performance indicator. Other indicators include sales and contribution margin by product and by sales representative. Sales figures are an important indicator of Biotest's share of the overall market or target market segment. In addition, the structure of receivables and their associated risks are continuously analysed. Inventories are measured and verified on a monthly basis.

# **B. NON-FINANCIAL PERFORMANCE INDICATORS**

Control-relevant non-financial performance indicators for the Group are applied to production and are related to the degree of utilisation, cycle times and downtimes, inventory amounts along the production chain and yield per unit of plasma.

### C. MANAGEMENT OF R&D PROJECTS

A regular portfolio analysis is performed for the management of research and development projects. Parameters for development guidelines, costs, probabilities of success, risks, strategic importance, market size as well as the commercial potential, also in the form of a net present value analysis, are used for this. The projects are prioritised on the basis of the portfolio analysis, and the organisation is hence focused on strategically important projects.

# IV. RESEARCH AND DEVELOPMENT (GENERAL)

Research and development are among others the foundations for future growth under the corporate strategy. In this area, the development of existing and new products offers significant potential. Research and development projects are focused on plasma proteins. In addition, Biotest actively pursues the goal of developing products in the field of monoclonal antibodies in collaboration with partners. After the completion of current studies Biotest will continue its efforts only in collaboration with a partner in order to minimise development risks and reduce development costs by synergy effects.

A detailed schedule of the progress achieved in the research and development projects carried out in financial year 2015 is shown in the "Research and development" section of the Economic Report.

Biotest's research and development costs amounted to  $\le$  98.8 million for the 2015 financial year (previous year:  $\le$  67.2 million). Of these costs,  $\le$  48.7 million were related to plasma proteins and  $\le$  50.1 million to monoclonal antibodies. The ratio of these costs to sales amounted to 16.8% compared to 11.5% in the previous year. The number of employees (converted to full-time employees) engaged in research and development was 181 as of 31 December 2015 and has slightly decreased compared to 31 December 2014 (208 full-time employees).

# **B. ECONOMIC REPORT**

# I. BUSINESS AND GENERAL FRAMEWORK

According to the winter forecast of the Kiel Institute for the World Economy (IfW), the expansion of the global economy decreased in 2015. At a rate of only 3.1%, the 2015 global gross domestic product exhibited the lowest growth since the crisis year 2009.¹ According to the IfW, particularly the recent weaker development of the emerging economies is responsible for these results. Lower commodity prices and profound structural problems prevent rapid development. As a result of economic policies, the Chinese economy should initially gain some momentum, but in the long term, the trend toward lower growth rates is likely to continue. According to experts, the global economy will remain vulnerable. Risks are particularly posed by the financial markets, which may exhibit turbulences as a result of monetary policy drifting apart in the large currency areas. For 2016 and 2017, the IfW forecasts a global economic growth of 3.4 respectively 3.8 %.²

The favourable economic outlook for Germany contrasts with the weak development of industrial production. One reason for this phenomenon is that the current upswing is more strongly driven by domestic forces than was the case for previous upswings, and it therefore is felt more strongly in the service sector. According to the IfW, the German gross domestic product grew 1.8% in the year 2015, following a growth of 1.6% in the previous year.<sup>3</sup> The experts expect the German economy to grow by 2.2% and 2.3% in 2016 and 2017, respectively.

According to the IfW forecast, the economy in the euro zone will slowly continue to gain momentum and will expand in the coming two years. The terrorist attacks in Paris signal risks, but in the researchers' opinion, they should have little influence on the economy. According to the economists, the European economy grew by 1.5% in the year 2015. $^4$  The forecast for 2016 is 1.7% and for 2017, 2.0%.

The US Federal Reserve Bank (FED) estimates that the US economy grew by 2.1% last year. For this year, it forecasts an increase of 2.4% and for 2017, an increase of 2.2%. Growth was particularly driven by private consumption in 2015. This should continue to be the case in the coming quarters since the incomes of private households will increase with the growing number of jobs. Therefore, the US economy should continue to grow at a moderate speed in the coming quarters.

In principle, the Biotest Group is only marginally dependent on economic cycles due to the high level of medical need for plasma protein products throughout the world. However, the possibility that the operating business will be impacted by local crises in particular cannot be ruled out.

# II. INDUSTRY-SPECIFIC FRAMEWORK

Immunoglobulins and albumins, the best-selling products of the Biotest Group, are seeing stable growth. This is true in established markets such as the USA and Europe as well as in other regions of the world. For example, industry experts expect the market for intravenous immunoglobulins (IVIG) to see a global increase in demand within a long-term range of 6-7% annually until 2023.7 To meet this heightened demand, the industry is increasingly collecting source plasma. For example, plasma collections in the USA rose by around 8% year-on-year in the first five months of 2015.8 With the rising plasma collection volume, the industry is also preparing for the additional fractionation capacities that are currently arising worldwide. Biotest AG will participate in this growth trend by doubling capacities. Some competitors have already put new plants into operation, and for 2016, the immunoglobulin supply is expected to continue to increase as well. Due to this development, a temporary dampening effect on prices is currently being observed in some regions and distribution channels.9 Price pressure is expected to be temporary; due to the positive

- 1 Institute for Economic Research, Global Economy, winter forecast 2015
- 2 Institute for Economic Research, Global Economy, winter forecast 2015
- 3 Institute for Economic Research, German Economy, winter forecast 2015
- 4 Institute for Economic Research, Global Economy, winter forecast 2015
- 5 Board of the Governors of the Federal Reserve System, minutes of the federal open market committee, 15–16 December 2015
- 6 Commerzbank Research, Konjunktur und Finanzmärkte, January 2016
- 7 Biotest Market Research based on MRB (2013), PPTA (2015), UBS (18 Feb 2015)
- 8 PPTA (2015)
- 9 Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS

market growth, demand will increase again, and a balance is expected to be reached in the medium term.<sup>10</sup>

EU prices for intravenous immunoglobulins (IVIG) are still significantly lower than those in the United States. <sup>11</sup> The market volume for immunoglobulins in the USA has increased slightly in the first half of 2015. <sup>12</sup> Europe has seen considerably stronger growth in market volume than the USA in the first half of 2015. <sup>13</sup> The German market has also recorded positive development in terms of sales volumes — both for practising physicians and hospitals. <sup>14</sup> The average price in German hospitals was stable up to the second quarter and increased very slightly towards the end of the year. <sup>15</sup> With the intravenous immunoglobulin (IVIG) market growth in Germany, the Biotest preparation Intratect <sup>®</sup> was able to record revenue gains and maintain its share of the overall market at a stable level with largely constant prices, as it did in the previous year.

The annual growth of the global albumin market is estimated as 4% until 2020. <sup>16</sup> The demand for human albumin is slightly higher than the supply, which generally causes prices to increase in many countries, in particular in the Near and Middle East. However, prices in Germany and Austria are seeing a slight downward trend.

Demand for plasmatic factor VIII products is also continuing to grow. This development is being driven in particular by factor VIII therapies becoming increasingly established in the emerging economies. In many of these countries, haemophilia patients do not yet have access to treatment with clotting factors. The global market of plasmatic factor VIII preparations is expected to grow by 2 % p. a. until 2020. <sup>17</sup> The recombinant segment is characterised by the introduction of new factor VIII products, which could intensify competition and thereby significantly increase price pressure in the market. In individual high-volume markets, rising price pressure can also be attributed to government public tenders. In these public tenders, often only the drug with the lowest price is authorised in the respective country.

- 10 Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS
- 11 UBS (24 September 2015): Plasma Pharmaceuticals:
  Jun-15 Plasma Price & Supply Survey: We call tight supply inside 2yrs
- 12 PPTA (2015)
- 13 IMS (2015), PPTA (2015)
- 14 IMS (2015)
- 15 IMS (2015)
- 16 Biotest Market Research based on MRB (2015)
- 17 Biotest Market Research based on MRB (2015)

# III. BUSINESS PERFORMANCE

### A. BIOTEST IN 2015

# 2015 goals: Target-performance comparison

Following very sharp increases in sales in the last two years, the Board of Management forecasted an increase in sales in the low single-digit percentage range for 2015. In the 2015 financial year, the Biotest Group generated  $\leqslant$  589.6 million after generating  $\leqslant$  582.0 million in the previous year. This corresponds to a 1.3 % increase.

In the financial year, the EBIT came to € -71.8 million, after a guidance of € 50 million at the beginning of 2015. This deterioration in EBIT is attributable mostly to € 64.9 million in impairment in the third quarter. The impairment was necessary due to the poorer market outlook for the research product Civacir® and the declining revenues of the preparation Bivigam®. Furthermore product impairments and accruals connected to the restructuring of the US-business led to expenses of € 11.6 million. The deterioration in the market prospects for the product Civacir®, which was in development, also led to a re-evaluation of the project and the impairment of intangible assets and inventories in the amount of € 13 million. Due to these two facts, the intrinsic value of the US manufacturing plants was no longer ensured, and these as well as parts of the building and the intangible assets had to be written off (€ 55 million).

In addition to the impairment, additional factors arose throughout the year that burdened results. They include increased research and development costs, particularly in connection with the termination of the cooperation with AbbVie on the development of tregalizumab (BT-061). In June, AbbVie exercised its right to opt out of the global licence, development and commercialisation agreement after the phase Ilb study had not reached the primary endpoint. Additional factors with an adverse effect on earnings were expenses for capacity expansion Biotest Next Level, unabsorbed costs at Biotest Pharmaceuticals Corporation and price pressure in individual product areas and regions.

The core business of the Biotest Group (adjusted EBIT) is lower compared to last year's level. However, the figure is still clearly positive reaching € 91.2 million in 2015.

in € million	2015	2014
EBIT	-71.8	53.4
Impairment and one-time effects	77.2	_
Expenses Biotest Next Level*	23.3	15.4
Expenses monoclonal antibodies	50.1	38.2
Idle capacity costs	12.4	16.2
EBIT (adjusted)	91.2	123.2

<sup>\*</sup> Expenses for research and development, which are allotted to products exclusively producible in the new facility, were added to the expenses for Biotest Next Level.

# Group business strategy and implementation in the 2015 financial year

### Internationalisation

For Biotest, the depreciation and amortisation in the past year were the impetus for strategic re-orientation. On the one hand, the company will further pursue internationalisation. In the past financial year, the Biotest Group expanded its presence in important international markets, opened up new regions by obtaining additional market authorisations and thereby created an even broader base for the Group. The expansion of the Group's international presence led to an increase in marketing and distribution costs.

The Biotest Group continuously expanded its marketable product range with marketing authorisations and sales starts and thereby increased total sales. The Biotest Group recorded slight year-on-year sales growth in 2015. The Group generated revenue of € 589.6 million in the period from January to December 2015. This represents an increase of 1.3% compared to the same period in the previous year (€ 582.0 million).

Particulary in Germany and the Other Asia and Pacific reporting region substantial revenue growth was recorded. In Germany, revenue increased by 16.3% to  $\le 123.3$  million in the period from January to December. In the region Other Asia and Pacific, revenue even increased by 58.0% to  $\le 42.5$  million. Although annual revenue in the USA also rose by 23.4% to  $\le 123.8$  million, this development failed to meet expectations due to the fact that revenue increase was primarily attributable to foreign currency effects. In the world's largest market for immunoglobulins, the USA, the supply situation has changed significantly in recent

months. Supply has increased significantly, making it harder to realise higher prices.

# Focus on the plasma business

With Biotest Next Level, the largest project in company history, the company intends to expand the product range while increasing profitability at the same time. Regarding the expansion of its products, Biotest will focus on its strengths again — on the plasma business, a market that is showing significant growth and a large potential.

# **Cooperation projects**

In future, Biotest intends to focus even more strongly on partnerships. The cooperation agreement for the US sales of Bivigam®, which was entered into with Kedrion Biopharma Inc., Fort Lee, New Jersey, USA (Kedrion Biopharma), is one successful project in this regard. As an established manufacturer and distributor on the US market with a well-developed marketing and distribution organisation, Kedrion Biopharma is an ideal partner for Biotest. Kedrion Biopharma will take over the exclusive distribution of Bivigam® in the USA from BPC until 31 December 2022.

Biotest also plans cooperation projects for the future development and marketing in the area of monoclonal antibodies. Until that time, the company is advancing the ongoing pre-clinical and clinical activities to the next milestone. This is intended to better spread risks and costs in the area of monoclonal antibodies in future.

# Research and development

In 2015, research and development costs increased by 47.0% to  $\in$  98.8 million (same period of the previous year:  $\in$  67.2 million). Of this figure, 50.7% relate to monoclonal antibody development projects (previous year: 56.8%).

# Indication area Haematology

Indatuximab ravtansine (BT-062): In the current phase I/II study (no. 983), in which the safety and efficacy of indatuximab ravtansine (BT-062) in combination with lenalidomide and dexamethasone are being investigated, recruitment has been completed and the treatment of the 47 patients is ongoing. All 17 patients were enrolled in the extension arm of the study investigating the combination with pomalidomide and dexamethasone, and recruitment has been completed. The results of the study to date have shown very good tolerability and efficacy.

In the phase I/II study (no. 989), in which patients with triplenegative metastatic breast cancer and patients with metastatic bladder cancer are treated with indatuximab ravtansine (BT-062), dose escalation was completed, and the maximum tolerated dose has been defined. Recruitment for the second part of the study is in progress. 27 patients have been treated with indatuximab ravtansine (BT-062).

# Indication area Clinical Immunology

Civacir®: Patient recruitment for the clinical phase III study (no. 988) with Civacir® was completed in the third quarter of 2015 with a total of 80 patients. This study investigated Civacir® for preventing hepatitis C virus reinfection in liver transplantation patients. The study was conducted in 24 clinical centres in the USA. Biotest presented positive interim results in April 2015 at the 50th International liver Conference in Vienna, Austria. Another interim analysis was presented at the conference of the American Association for the Study of Liver Diseases (AASLD) in San Francisco, CA, USA, in November 2015. Civacir® was well tolerated, and no serious side effects were observed to date that could be attributed to the Civacir® treatment. Although this interim analysis was promising and the objectives of the study had been achieved to date, Biotest expects the market prospects to be substantially reduced as a result of the newly introduced, highly effective new antivirals whose use shortly after liver transplantation is now being investigated.

BT-063: The clinical trial of the monoclonal antibody BT-063 in the systemic lupus erythematosus (SLE) as lead indication has started with the treatment of the first patients in the phase Ila study (no. 990). SLE is an autoimmune chronic inflammatory disease that can affect various organs of the body with serious to very serious clinical manifestations. Chronic inflammation can occur in different parts of the organism, damaging the tissue and leading to serious and possibly life threatening complications in the medium term. The aim of the Biotest study is to examine the safety and tolerability of the antibody in SLE patients and collect initial data on efficacy.

**Tregalizumab (BT-061):** The phase IIb study (TREAT 2b – Tcell regulating arthritis trial 2b) of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis did not meet the primary endpoint in the second quarter of 2015. Clinical development in rheumatoid arthritis was discontinued. The study data was presented at the ACR (American College of Rheumatology) conference in San Francisco in November. Since mid-2011, the project had been conducted in a development partnership with AbbVie (previously Abbott), a company with

considerable experience in rheumatology. In June 2015, AbbVie exercised its right to opt out of the global licence, development and commercialisation agreement. This meant that the rights to tregalizumab (BT-061) were returned to Biotest. The company is currently using pre-clinical modelling systems to examine potential alternative indications of tregalizumab (BT-061). If successful, potential additional development steps are to be taken within a partnership.

Zutectra®: The product Zutectra® has been approved in the EU since 2009 for the prevention of hepatitis B virus reinfection in patients after liver transplantation due to HBV-induced liver failure. It is the first subcutaneously applied hepatitis B immunoglobulin in a pre-filled syringe that is suitable for self-administration in home treatment worldwide. In December 2015, the European Commission granted marketing approval for the early use of the hepatitis B hyperimmunoglobulin Zutectra® after liver transplantation. While treatment with Zutectra® could previously not be commenced until 6 months after a liver transplantation, Zulectra® can be administered as early as one week after the transplantation from now on. The positive response of the authority is based on the clinical results of the ZEUS study (Zutectra Early Use), which demonstrated the efficient use of Zutectra® in the early treatment phase. The early administration of the subcutaneous hepatitis B hyperimmunoglobulin contributes significantly to safe, more time efficient and less costly patient care. The now-approved earlier application allows initiating home self-administration while the patient is still in hospital. The result is an easier and patient-friendly treatment option. The successful further development of Zutectra® also supports the role of Biotest AG as the leading provider of hepatitis B hyperimmunoglobulins.

# Indication area Intensive Care Medicine

**IgM Concentrate:** The completed phase II study (no. 982) of the IgM enriched immunoglobulin product IgM Concentrate, which was published in late June, showed encouraging results for life-threatening pneumonia in terms of reducing the time spent on artificial ventilation as well as mortality rates. The randomised, double-blind, placebo-controlled phase II study was conducted with 160 patients with severe community-acquired pneumonia (sCAP). This subgroup of patients has a high mortality rate and includes seriously ill patients in intensive care. The study was conducted in Germany, Spain and the United Kingdom. The final results of the study are currently being evaluated. Publication of the data is scheduled for the second quarter of 2016.

**Fibrinogen:** Recruitment has been completed for the first part of the clinical phase I/II study (no. 984) of fibrinogen that is under development. This part of the study examined the effects of the product in the patient's body. In the next part of the study, patients will be treated as required, i.e. in the case of haemorrhage or when undergoing operations. The Paul Ehrlich Institute recently approved the extension of this study into a phase III study with the existing treatment plan and higher number of patients. On the basis of the results of this study, a marketing authorisation application can be submitted.

**Pentaglobin®:** Pentaglobin® has now been on the market for 30 years and is used in combination with antibiotics for the treatment of severe bacterial infections. In the last two years, various pre-clinical studies have been conducted with respect to the efficacy of Pentaglobin® on antibiotic-resistant bacteria. In future, these bacteria will be one of the biggest challenges for health systems. "In vitro" and "in vivo" testing has led to convincing results. In addition, two retrospective studies in Italy and Greece showed a significant survival benefit with Pentaglobin® in patients with severe sepsis or septic shock caused by multiresistant pathogens. Biotest believes that Pentaglobin® offers considerable future potential in terms of use on antibiotic-resistant

bacteria. Pentaglobin® also recently showed impressive results in the treatment of donor-specific antibodies after lung transplantation. The relative reduction in mortality rate was over 70%. In lung transplantation, the development of donor-specific antibodies (DSA) increases the mortality risk and the risk of organ rejection. The recently published study of the Medizinische Hochschule Hannover (Hanover Medical School) showed that patients with early DSA development after lung transplantation who were treated with Pentaglobin (IgM/IgA-enriched immunoglobulin) had a significantly higher survival rate than patients treated with therapeutic plasma exchange.

**RI-002:** In the third quarter, ADMA Biologics, Inc., New Jersey, USA (ADMA) and Biotest AG decided to continue their cooperation on the respiratory syncytial virus (RSV) hyperimmunoglobulin product RI-002. RI-002 is a hyperimmunoglobulin derived from human plasma with naturally occurring antibodies against respiratory syncytial virus (RSV). The virus is responsible for most of the cases of acute bronchitis in neonates and small children. Biotest has acquired the distribution licence for Europe and other selected international markets from ADMA. Following the successful phase III study, ADMA submitted the application for approval for RI-002 to the United States Food and Drug Administration (FDA).

# OVERVIEW OF CLINICAL STUDIES

Type of study	Study number	Dosage/ study design	Number of study participants	Status as of 31 December 2015
Indication area Haematology				
Indatuximab ravtansine (BT-062)				
Phase I Multiple myeloma	969	Repeated single dose, intravenously every 21 days, 10–200 mg/m²	32	Study completed
Phase I/II Multiple myeloma	975	Repeated multiple dosing, intravenously on day 1, 8 and 15; every 28 days, dose escalation from 40 mg/m²	35	Study completed
Phase I/II Multiple myeloma	983	Combination with lenalidomide and dexamethasone based on 975 design (repeated multiple dosing);	47	Patient recruitment completed
		Combination with pomalidomide and dexamethasone	17	Patient recruitment completed
Phase I/IIa Breast cancer, bladder cancer	989	Repeated multiple dosing, intravenously on day 1, 8 and 15; every 28 days, dose escalation from 100 mg/m²	80 planned	Patient recruitment ongoing

# OVERVIEW OF CLINICAL STUDIES

Patient recruitment ongoing
Patient recruitment completed
Patient recruitment completed
Study completed, marketing autho- risation received in December 2015
Patient recruitment ongoing
Patient recruitment completed

# Marketing and distribution

# Indication area Clinical Immunology

Fovepta®, a hyperimmunoglobulin for newborns, is used immediately after birth and offers effective protection for babies of mothers suffering from hepatitis B. In the first quarter of 2015, the preparation received marketing authorisation in India. In addition, successful deliveries have already been made to Vietnam and Algeria. In 2016, Fovepta® will be introduced in additional Asian markets.

In Mexico, Intratect® 50 g/l (5%) and Intratect® 100 g/l (10%) were introduced in the private pharmaceutical sector. Further, the product Intratect® 100 g/l (10%) is currently in the registration process in a number of countries, including the promising Near and Middle East regions as well as Australia, Colombia and

Algeria. In the latter countries, the product Intratect® 50 g/l (5%) is primarily sold through tenders, a purchasing process for pharmaceutical products in which potential suppliers are invited to submit bids. Price is typically a central criterion for acceptance of the bid. In addition, product quality, supplier reliability and delivery modalities can be relevant in the decision-making process.

Hepatect® and Zutectra® were introduced in new markets in the year 2015. The new markets for Zutectra® included Israel and Singapore. Zutectra® sales are developing positively in France and Spain.

A number of scientific papers have given new impetus to the discussion on the use of Cytotect® to prevent cytomegalovirus (CMV) infection in heart and lung transplantations. This data could lead to Cytotect® being used to protect transplanted organs from CMV reinfection to a greater extent in the future.

# Indication area Intensive Care Medicine

The Biotest product Albiomin® 20% (200 g/l) received marketing authorisation in both Sweden and Norway in the first half of the year. The initial delivery of Albiomin® to China has been initiated and will take place in the first quarter of 2016.

# Indication area Haematology

The plasmatic product Haemoctin® is continuing to record stable growth on the German market. Other key markets include North Africa, Turkey and Asia. Biotest won the government tender in Singapore once again. Biotest also achieved initial success in hospital tenders in Thailand.

# Plasma and Services

In 2015, Biotest opened two new plasma collection centres in the USA – in Conway, Arkansas, and Jacksonville, North Carolina. The United States Food and Drug Administration (FDA) granted Biotest the necessary approvals for the start-up in early 2016. With the two new centres Biotest now has a total of 18 plasma collection centres in the USA. Biotest is also planning to open another three or four centres over the course of 2016.

# Social responsibility

With its products and their indications, the Biotest Group operates in a highly ethical environment. Biotest's products help to save lives and confer a degree of normality on the daily lives of patients with chronic illness. Furthermore, the company is engaged in various scientific medical initiatives, research projects and measures taken by patient organisations. In the year 2015, the humanitarian "Project Recovery", which Biotest is running together with the Canadian Blood Service, Grifols and the World Federation of Hemophilia (WFH), was successfully advanced. The recipients were haemophilia patients without other access to treatments for bleeding. "Project Recovery" aims to provide haemophilia patients world-wide with urgently needed treatment. Haemophilia is a lifelong, inherited bleeding disorder that affects about one in 10,000 people worldwide. Close to 75 % of patients receive little or no treatment. Through the WFH Humanitarian Aid Programme, Haemoctin® will be provided free of charge to patients in developing countries by "Project Recovery". In addition to production Biotest is also responsible for the entire coordination process and shipping logistics.

In the past year Biotest has continued to support the "International Patient Organisation for Primary Immunodeficiency" (IPOPI) in its work to improve diagnostics for patients with immunological diseases and the access of patients to appropriate therapy. Finally, Biotest is also working at the political

level, amongst other things, as part of the "Plasma Protein Therapeutics Association" (PPTA) to improve the situation of patients suffering from rare diseases and on a general arrangement for the cross-border and necessary treatment of these target groups.

In addition, Biotest supports activities of the University of Frankfurt. For instance, the company finances scholarships and is one of the sponsors of the "Night of Science". In the latter, the general population and students of other subject areas are familiarised primarily with scientific subjects.

# IV. PRESENTATION OF RESULTS OF OPERATIONS, FINANCIAL POSITION AND CASH FLOWS

# A. RESULTS OF OPERATIONS

In the 2015 financial year the Biotest Group generated revenue of  $\in$  589.6 million. This amounts to an increase of 1.3 % compared to the previous year, in which sales of  $\in$  582.0 million were achieved. At segment level, the Biotest Group increased its revenue mainly in the segment Plasma & Services. Here, revenue for the year increased by 8.1 % from  $\in$  157.0 million to  $\in$  169.7 million. While revenue in the core segment Therapy rose slightly from  $\in$  409.8 million to  $\in$  411.4 million, Other Segments had to report a decrease of  $\in$  6.7 million.

SALES BY SEGMENT

in € million	2015	2014	Change in %
Therapy	411.4	409.8	0.4
Plasma & Services	169.7	157.0	8.1
Other Segments	8.5	15.2	-44.1
Biotest Group	589.6	582.0	1.3

The Biotest Group is still an international company. The Biotest Group's sales growth in 2015 was generated primarily in the USA, in the Group's domestic market of Germany and in the Asia and Pacific region. The US achieved growth of 23.4%, which is mainly attributable to foreign currency effects. At € 123.8 million, this region contributed a slightly higher share of sales than the domestic market of Germany (€ 123.3 million). Sales growth here amounted to 16.3%. In the Asia and Pacific region sales increased by 58.0% to € 42.5 million in the period under review. There was a strong relative increase of 44.0% in Central and South America. This represents an increase of € 3.7 million.

Sales decreases were posted in Middle East and Africa (-22.4%) and Rest of Europe (-9.8%) regions. The latter was attributable to the continuing price pressure in individual product areas and regions, as well as negative exchange rate effects. Due to the positive trend in Germany, the breakdown of Group sales has shifted in 2015 slightly towards the domestic market. In the period between January and December 2015 the Biotest Group generated 79.1% of its sales outside of Germany (previous year: 81.8%).

# SALES BY REGIONS

in € million	2015	2014	Change in %
Germany	123.3	106.0	16.3
Rest of Europe	169.7	188.1	-9.8
USA	123.8	100.3	23.4
Central and South America	12.1	8.4	44.0
Middle East and Africa	118.2	152.3	-22.4
Other Asia and Pacific	42.5	26.9	58.0
Biotest Group	589.6	582.0	1.3

The cost of sales increased from € 357.5 million to € 448.3 million in the 2015 financial year. This includes the write-downs due to the impairment test in the third quarter, resulting in depreciation and amortisation of intangible assets and property, plant and equipment. The cost of sales ratio rose extraordinarily to 76.0% (previous year: 61.4%). Marketing and distribution costs increased to now € 77.8 million (share of sales: 13.2%). In the previous year € 74.2 million was spent in this area (ratio to sales: 12.7%).

Administrative expenses increased from € 31.6 million to currently € 35.6 million. The administrative expense ratio climbed to 6% after 5.4% in the previous year. Biotest hired additional employees in the past year as part of the Biotest Next Level expansion project.

The research and development cost increased to  $\leqslant$  98.8 million in 2015 after  $\leqslant$  67.2 million in the 2014 financial year. This item accounted for 16.8% of sales and therefore a higher share than in 2014. This was due to increased expenses for the preproduction of tregalizumab (BT-061) in the first half of 2015 and the impairment recognised in the third quarter, which related in particular to the product Civacir®.

Other operating expenses decreased from  $\le$  5.1 million in the 2014 financial year to  $\le$  3.6 million. Other operating income amounted to  $\le$  2.7 million and remained below the previous year's amount of  $\le$  7.0 million.

Due to the impairment in the financial year, operating profit (EBIT) decreased to € -71.8 million after € 53.4 million in the previous year. The EBIT margin for 2015 was -12.2% after 9.2% in the previous year. The impairment was triggered by the deteriorated market prospects for the preparation in development Civacir® and declining revenue for the preparation Bivigam® in the third quarter. As a result, Biotest recognised write-downs on Bivigam® inventory and also on intangible assets and inventories in the amount of € 13 million owing to the deteriorated marketing prospects for Civacir®. As a result of these two facts, the intrinsic value of the US manufacturing plants was no longer ensured, and these as well as parts of the building and the intangible assets had to be written off (€ 55 million). Additional factors with an adverse effect on earnings were expenses for capacity expansion Biotest Next Level, unabsorbed costs at Biotest Pharmaceuticals Corporation and price pressure in individual product areas and regions.

# PRIMARY COST POOLS OF THE BIOTEST GROUP\*

in € million	2015	% of sales	2014	% of sales
Cost of sales	-448.3	76.0	-357.5	61.4
Marketing and distribution costs		13.2		12.7
Administrative expenses		6.0		5.4
Research and development costs	-98.8	16.8	-67.2	11.5
Other operating income and expenses		0.2	1.9	0.3
Financial result		0.8	-6.5	1.1

<sup>\*</sup> Costs/expenses are denoted with a negative sign

EBIT in the Therapy segment declined to € -97.2 million in 2015 after € 27.5 million in the previous year. The result in the segment Therapy was not only influenced by the impairment and inventory write-downs mentioned earlier, but also by the expenses connected to the project Biotest Next Level and the termination of the cooperation with AbbVie. In the Plasma & Services segment EBIT climbed from € 27.0 million in the previous year to € 27.6 million for 2015. In Other Segments EBIT decreased to € -2.2 million after € -1.1 million in the previous year.

The financial result amounted to € -4.5 million compared to € -6.5 million in the previous year. This resulted in earnings before taxes (EBT) of € -74.3 million for the Biotest Group compared with € 46.9 million in the previous year. Earnings after taxes (EAT) amounted to € -82.5 million after € 19.2 million in the previous year. This corresponds to earnings per share of € -2.10 after € 0.48 in the previous year.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	2015	2014
EBIT	-71.8	53.4
EBT	-74.3	46.9
EAT	-82.5	19.2
Earnings per share in €	-2.10	0.48

# **B. FINANCIAL POSITION**

Essentially as a result of impairment in the third quarter, total assets were down from € 1,032.6 million as at 31 December 2014 to € 962.7 million as at 31 December 2015.

On the assets side, non-current assets increased from € 353.3 million in the previous year to € 375.9 million. Property, plant and equipment increased from € 282.3 million to € 317.2 million. Despite significant depreciation on the manufacturing plant in the USA, there was an increase due to further capital expenditure under the Biotest Next Level expansion project. Other non-current financial assets declined from € 5.2 million to currently € 0.8 million. The decrease results from a change in

reporting in financial fixed assets whose time to maturity as at 31 December 2015 was less than one year. They are now included in the other current financial assets position together with all other interest-bearing financial assets for short-term financial disposition. Other current financial assets increased from € 55.7 million to € 120.8 million in the 2015 financial year.

Current assets decreased by 13.6% to € 586.8 million as at 31 December 2015 (31 December 2014: € 679.3 million). Inventories fell to € 218.7 million (31 December 2014: € 246.0 million).

Trade receivables decreased to € 173.9 million as at 31 December 2015 (31 December 2014: € 181.6 million). Cash and cash equivalents amounted to € 53.8 million at the end of the year (31 December 2014: € 179.4 million). Their planned reduction resulted essentially from payments for capital expenditure and the investment of short-term funds, which are reported under other financial assets.

Under equity and liabilities, equity decreased to € 412.3 million due to the consolidated net loss (31 December 2014: € 480.2 million). The equity ratio was slightly below the previous year's level at 42.8% (31 December 2014: 46.5%).

Total liabilities decreased slightly in the past year to € 550.4 million (31 December 2014: € 552.4 million). While non-current liabilities increased minimally from € 423.5 million to € 424.6 million, current liabilities decreased from € 128.9 million to € 125.8 million. The Biotest Group currently has loans of € 335.5 million available over the long term.

Pension provisions amounted to € 72.6 million as at 31 December 2015 after € 77.5 million in the previous year. Trade payables decreased slightly from € 55.5 million to € 53.1 million. Other current liabilities also decreased to € 31.8 million (31 December 2014: € 32.7 million).

The capital available to the company over the long term (equity, pension provisions and non-current liabilities to banks) covers 85.2% of total assets as at 31 December 2015 (previous year: 85.6%). Net debt increased from € 92.8 million to € 170.9 million as at 31 December 2015.

### C. CASH FLOWS

Cash flow from operating activities amounted to € 38.1 million in the 2015 financial year. An amount of € -11.4 million was reported here in the same period of the previous year. Cash flow from changes in working capital climbed to € 28.5 million after € -77.3 million in the previous year. The interest and taxes paid amounted to € -21.4 million after € -25.2 million in the previous year. The lower taxes are a result of the lower earnings.

Cash flow from investing activities amounted to € -160.1 million for the period between January and December 2015 compared to € -102.4 million in the previous year. Adjusted for the included outflows in other current financial assets, cash flow from investing activities increased from € -42.7 million to € -100.0 million due to higher capital expenditure in 2015 on account of the Biotest Next Level project.

In the 2015 financial year, including the dividend paid out in the second quarter of  $\in$  8.3 million, the Biotest Group reported a cash flow from financing activities of  $\in$  -4.6 million after  $\in$  87.4 million in the previous year. Considerable funds were borrowed in the 2014 financial year to finance the Biotest Next Level expansion project.

Cash and cash equivalents amounted to  $\le$  53.8 million at the end of 2015 compared to  $\le$  179.4 million as at 31 December 2014.

# Financing strategy

The Biotest Group's financing strategy is designed to ensure the liquidity of the Group at all times, adequate options are available for financing growth in its operating business and all capital expenditure is fully financed. Biotest uses both equity and debt financing with the aim of maintaining a solid and conservative financing structure. The target equity ratio is at least 40.0%. With an equity ratio of 42.8% as of 31 December 2015 Biotest continues to have an excellent basis for financing its future investments. In addition, Biotest was able to obtain in 2014 an energy efficiency loan totalling € 100.5 million from the Reconstruction Loan Corporation

(Kreditanstalt für Wiederaufbau, KfW) for the construction of the new plasma goods receipt area and new production facility, which ensures that this project is financed at advantageous conditions. The total of equity and the non-current components of debt financing should cover non-current assets. The capital structure is described in Section E13 and F6 of the Notes.

# V. OVERALL ASSESSMENT OF THE COMPANY'S BUSINESS SITUATION

The Biotest Group continued its growth course in the 2015 financial year in terms of sales. Sales increased by 1.3 % compared to the previous year. The cash flow from operating activities was € 38.1 million.

Overall, Biotest has the resources to drive forward the operating business and the research and development activities as planned. Due to the competitive environment sales of Bivigam® in the USA in 2015 were below expectations. Following the better-than-expected development in the first half of 2015 the write-down was recognised in respect of inventory at risk of expiry due to the unexpected downturn in revenue in the third quarter.

The 2015 financial year was negatively affected by the end of the cooperation with AbbVie, the deterioration of the market prospects for the Civacir® preparation and the associated impairment loss on the production facility in the USA.

Additional profit potential is provided by the market entry of plasma protein preparations into other lucrative regions that has already occurred or is upcoming as well as further developments in the area of monoclonal antibodies over the medium- and long-term.

The financial position that has been sustainably strengthened by the successful capital measures implemented in 2013 and the balanced financing structure are a solid foundation for the planned future growth of the Biotest Group.

# C. SUPPLEMENTARY REPORT

On 19 January 2016, Biotest AG announced that the US subsidiary Biotest Pharmaceuticals Corporation, Boca Raton, Florida, USA (BPC) and Kedrion Biopharma Inc., Fort Lee, New Jersey, USA (Kedrion Biopharma) entered into a seven-year cooperation agreement for the distribution of Bivigam® in the USA.

Kedrion Biopharma is an established manufacturer and distributor on the US market with a well-developed marketing and distribution organisation and will take over the distribution of Bivigam® in the USA from BPC until 31 December 2022.

The agreement stipulates mandatory minimum purchase quantities for both parties that increase over time. On non-fulfilment of the associated supply obligations by BPC or of the purchase obligations by Kedrion Biopharma Inc., the contract provides for appropriate compensation payments. Biotest AG has provided Kedrion Biopharma Inc. with a guarantee for the fulfilment of BPC's contractual obligations.

# D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

# I. OUTLOOK

# A. GENERAL STATEMENT BY THE BOARD OF MANAGEMENT REGARDING GROUP PERFORMANCE

The Board of Management is predicting a positive development of the Biotest Group for the year 2016. The demand for plasma protein preparations is on a constant growth curve throughout the world. In addition, the start of the marketing of new as well as existing products will create further sales potential over the short and medium term. However, price pressure on immunoglobulins in the USA and Europe, which is likely to continue in 2016, as well as the continued tense situation in the crisis regions of the world could present a challenge.

With the course set for the research and development activities and the further progress made in expanding production capacity at the Group headquarters in Dreieich, the essential foundation for the future development of the Group will be laid in 2016. In the opinion of the Board of Management, the Biotest Group will continue to remain on its growth path in the current financial year from this very strong base.

# B. DIRECTION OF THE GROUP IN THE 2016 FINANCIAL YEAR

The general direction of the Biotest Group will not change in the 2016 financial year. In future, Biotest will focus on the plasma business and on the Biotest Next Level expansion project, which has already been started, as a central component of this strategy. Biotest Next Level aims to expand the product range, double capacities and hence substantially increase profitability. Furthermore Biotest is seeking strategic partnerships with suitable cooperation partners in selected areas and specific business segments.

# C. DEVELOPMENTS IN THE MARKET ENVIRONMENT

# **Target markets**

According to current studies, global demand for immuno-globulins (lgG) will continue to increase by 7% annually over the coming years. The prices of these preparations remained largely unchanged in the past year, but some regions and distribution channels are currently characterised by increasing price pressure. Among other things, this is due to additional fractionation capacities generated at various plasma companies worldwide which are coming onto the market. An additional supply is expected for 2016 as well, which could have a further negative effect on prices. Price pressure is expected to be temporary; due to the positive market growth, demand will further increase, and a balance is expected to be reached in the medium term.

The Biotest Group also expects the global market volume for plasmatic clotting factors to increase by around 2% p. a. until 2020.<sup>21</sup> The start of sales of Albiomin® 20% in China offers new medium-term sales potential in a market that is expected to see average annual growth of 10% until 2020.<sup>22</sup> There is significant future sales potential for the Biotest Group in the area of monoclonal antibodies. Preparations to treat multiple myeloma (Biotest development project indatuximab ravtansine (BT-062)) generated global sales of USD 8 billion in 2015. Increased sales across all product groups are forecasted up to 2018 in connection with new and extended marketing

- 18 Biotest Market Research based on MRB (2015)
- 19 IMS Health (2015), Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS
- 20 Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS
- 21 Biotest Market Research based on MRB (2015)
- 22 MRB (2015)

authorisations. Furthermore, the treatment of various solid tumours with indatuximab ravtansine (BT-062) offers additional sales potential following marketing authorisation for corresponding indications.

# D. EXPECTED PERFORMANCE OF THE BIOTEST GROUP

# Expected business and earnings situation of the Biotest Group

For 2016, the Board of Management expects sales growth in the low single-digit range. Profitability will be influenced by various factors in 2016. Steadily growing quality and safety requirements will require additional expenses in this area in the amount of  $\in$  3 to 5 million. The costs of the Biotest Next Level expansion project, which has already been started, are estimated at  $\in$  10–15 million for 2016, and the research and development costs for monoclonal antibodies are expected to be  $\in$  12 million. Additional expenses in the amount of  $\in$  8 to 12 million arise from unabsorbed costs resulting from unused capacities. Despite these factors, the Biotest Group expects EBIT of  $\in$  30 million in the 2016 financial year. As a result, the Board of Management expects a return on capital employed (RoCE) of approximately 4% and cash flow from operating activities of circa  $\in$  5 million to be generated for 2016.

# Expected financial position and cash flows of the Biotest Group

The main focus of the Biotest Group will be on a balanced financing structure, both in terms of the ratio of debt to equity and the ratio of short-term to long-term debt financing. The Group will use a substantial portion of the cash and cash equivalents received over the last few years for the "Biotest Next Level" project to pay for the expansion of capacity at Dreieich. Furthermore, the increase in current assets required for the sales growth must be financed. Capital expenditure of up to € 156.6 million is planned for the Biotest Group for the 2016 financial year, of which a substantial portion is attributable to the Biotest Next Level project. However, further capital expenditure will be incurred for the expansion of existing and the building of new plasma centres in the USA for BPC.

In addition to the organic growth described above and the financing thereof, the in-licensing of market-ready products could represent a future strategic option. There are sufficient financial resources available to cover the higher level of capital expenditure, the sales growth and the associated increase in working capital. The company's growth programme has solid financing available for the long term.

# **Expected development in the segments**

# Therapy segment

The following significant advances and developments are expected in the therapy segment in the current 2016 financial year:

# Indication area Haematology

Indatuximab ravtansine (BT-062): For the phase I/II study (no. 975) of indatuximab ravtansine (BT-062) for monotherapy of multiple myeloma, a malignant disease of the bone marrow, data analysis was completed and the final clinical study report was generated. Because of promising results, a treatment arm in combination with pomalidomide and dexamethasone was added to the phase I/II study (no. 983), in which the safety and efficacy of indatuximab ravtansine (BT-062) in combination with lenalidomide and dexamethasone are being investigated. Patient recruitment was completed, and the treatment of patients continues.

Biotest is also testing indatuximab ravtansine (BT-062) in CD138-positive solid tumours. In the phase I/II clinical monotherapy study (no. 989), patients with triple-negative metastatic breast cancer (that is, tumours that would not react to treatment with oestrogen-, progesterone- or HER 2-directed therapies) and patients with metastatic bladder cancer will be treated with indatuximab ravtansine (BT-062), and the preparation will be studied for efficacy and safety. The phase I part of the study was successfully completed with the determination of the maximum tolerated dose. Patient recruitment in the phase II part of the study is continuing. The authorities (EMA and PEI) have confirmed the pre-clinical development strategy.

# Indication area Clinical Immunology

BT-063: A phase IIa study (no. 990) of the treatment of patients diagnosed with systemic lupus erythematosus (SLE) was started with the inclusion of the first patients in the 3rd quarter of 2015. In this study, which is conducted in several European countries, 36 SLE patients are to be treated for three months with BT-063 or placebo. The aim of this study is to examine the safety and tolerability of the substance in SLE patients. In addition, initial efficacy data is collected on SLE patients. Initial results are expected from an interim analysis in the second half of 2016. The study is being accompanied by specialised pharmacological investigations designed to further characterise the mechanism of action of BT-063. Together with the patient data, such investigations are the basis for the effective and safe planning of subsequent clinical studies and hence for initial discussions with potential partners.

**Civacir®:** The phase III study (no. 988) is scheduled to be completed in 2016. Final study results on efficacy and safety will be presented to a scientific audience.

**Fovepta®:** The first non-European marketing authorisation was granted in 2015, and other applications for marketing authorisation have been submitted. In 2016, marketing authorisation will be sought in other countries, especially in Asia and the Near East.

Intratect® 100g/l (10% ig): Successful marketing is already ongoing in Germany and other European countries as well as in the Near and Middle East. Marketing authorisation was applied for in other countries

**Zutectra®:** The phase III study ZEUS (Zutectra Early Use, no. 987) was completed as scheduled in the fourth quarter of 2014, and study data was submitted to the European Medicines Agency (EMA) in April 2015 to expand the marketing authorisation. After the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of EMA, issued a positive recommendation on extension of the indication, a European marketing authorisation was granted in December 2015. Under the granted EU marketing authorisation, the administration of Zutectra® is permissible as early as eight days after transplantation.

### Indication area Intensive Care Medicine

**Fibrinogen:** The phase I/II study (no. 984) was intended to collect pharmacokinetic parameters as well as to prevent haemorrhage in patients with congenital fibrinogen deficiency. The pharmacokinetic part of the study has been successfully completed, while patient treatment is being continued in case of acute need. As the national regulatory authority, the Paul Ehrlich Institute has approved the expansion of the ongoing study into a phase III study. The implementation is in the planning stages.

**IgM Concentrate:** The results of the phase II study (no. 982) in the indication severe community acquired pneumonia (sCAP) were encouraging. On the basis of this data, a suitable patient population is being identified and the design for a phase III study correspondingly developed and then discussed with the authorities.

**Pentaglobin®:** Marketing is ongoing in South America, Asia, Europe and Near East.

# Segment Plasma & Services

The objective of the Company strategy within the Plasma & Services segment is to achieve maximum utilisation of the existing plasma production capacities. Plasma not required is sold by Biotest to third parties. Available plasma is processed to Biotest products or sold, as needed. Due to the constant high demand for Biotest products and planned significant increase in production capacity as part of Biotest Next Level it is expected that toll manufacturing will remain at about the same level as in 2015. With growing capacities in the Biotest Group, sales in the Plasma & Services segment will continue to grow in the medium term over the next few years, while profitability remains steady.

# II. RISK REPORT

As a global Group in a highly advanced field of technology, Biotest is subject to a variety of risk factors that could negatively impact business activities and can therefore result in negative forecast and target variances. When and where risks resulting from its business activities or external factors will materialise – if at all – cannot always be predicted and may be partially or completely beyond the control of Biotest. Sales and profits, along with the Group's financial position and cash flows, may be negatively affected. The risk report describes the risks to which Biotest is exposed, both as a Group and at the segment level. At the same time it explains how the Group deals with these risks and how they are controlled and managed. An assessment by the Board of Management of the likelihood that any of the individual risks described will materialise is given below.

# A. RISK STRATEGY

As defined by the Board of Management and Supervisory Board in their joint risk strategy report, the Company may take controlled risks in order to generate prospects for long-term profitable growth. The risk strategy is aimed at ensuring the Company's continued existence and enhancing its value sustainably and systematically. This is also reflected in the forecasts of the Board of Management that are based on the neutral occurrence of the risk events mentioned below.

# **B. RISK MANAGEMENT AND CONTROLLING**

Biotest systematically identifies and evaluates operational and strategic risks. All risks with fundamental implications and a reasonable likelihood of arising are closely monitored. Risk management processes are documented in detail, and the relevant documents are stored in the risk management system.

The implemented risk management system is aimed at identifying and evaluating risks that might negatively impact the compliance of the consolidated financial statements with the rules. Furthermore, any risks identified are limited, with the involvement of external specialists if required. Lastly, the risk management system is used to evaluate the impact of identified risks on the consolidated financial statements and to map these risks.

Major potential risks are elements of monthly internal reports. In addition, every six months the Risk Management Committee reviews the current risk situation in all segments and drafts a detailed risk report, which is submitted to the Board of Management. This report covers the following risk areas: market risks, process and production risks, financial risks, personnel risks and organisational risks. Strategic risks are also regularly discussed with the Supervisory Board.

In the period between the meetings of the Risk Management Committee the managers brief the Board of Management at regularly held Board meetings on the current risk situation in their respective areas of responsibility. At the same time the Board of Management is informed of the current risk situation as part of forecasts to the year end. In the event of a sudden change in the risk position, the Board of Management is notified at short notice and directly about this.

All Biotest employees must behave in a risk-conscious manner within the scope of their responsibilities. The management staff is responsible for controlling and managing risks. There are about 60 risk reporters within the Group who cover all potential risks. All risk reporters are subject to binding principles for dealing with risks.

The Internal Audit department reviews risk management and controlling standards and procedures regularly for appropriateness and effectiveness. The last audit took place in 2015. Biotest has taken out insurance policies to limit the financial consequences of liability risks and material damage to plant and machinery. The level of protection afforded by the insurance is reviewed regularly and adjusted where necessary.

# C. INTERNAL CONTROL SYSTEMS FOR ACCOUNTING PROCESSES

Biotest has implemented an accounting-related internal control system that covers all main business processes at Biotest AG and all of its subsidiaries. The aim of the accounting-related internal control system is to ensure with adequate certainty through a series of checks that, despite any risks identified, the consolidated financial statements are prepared in accordance with applicable accounting standards and policies. The relevant guidelines are summarised in an organisational manual to which all employees have access.

Biotest AG's accounting manual conforms to IFRS standards (International Financial Reporting Standards). This manual is binding for all Group companies and covers all relevant accounting standards to Biotest. It is updated continuously to reflect any changes to IFRS. All managers in charge of financial accounting are continuously informed of and trained in relevant accounting practices.

The accounting and reporting at Biotest AG and all subsidiaries included in the consolidated financial statements are performed in accordance with strict schedules and procedures, in which all the necessary activities are set forth in detail.

Single entity and consolidated financial statements are prepared using recognised systems. Internal control processes have been established in each Group company through organisational procedures and clear responsibilities, including separation of duties through the dual control principle.

Companies enter data for the consolidated financial statements into a standardised, detailed reporting package, the content of which is agreed upon on a monthly basis by the departments responsible for finance and controlling. All single entity financial statements prepared by Group companies undergo plausibility checks, and any differences in consolidation processes are analysed and corrected where necessary.

Measures undertaken in the preparation of the consolidated financial statements are subject to electronic and manual checks. Further checks at the consolidated financial statement level include target performance comparisons and analyses of changes in items on the statement of financial position and statement of income.

Confidential data and documents are protected against access by unauthorised persons. This applies to access to the company campus (access control) as well as the (accounting-related) IT systems (access rights, passwords).

The single-entity and consolidated financial statements are either audited or reviewed by external auditors.

The Internal Audit department reviews business processes in all segments and subsidiaries. Its powers, duties and position within the Group are laid down in the internal audit guidelines. Audits are conducted in accordance with an annual internal audit plan established by the Board of Management and the Supervisory Board's Audit Committee. Individual audit findings are submitted to the Board of Management in a timely manner. In addition, once a year the Internal Audit department submits a detailed report to the Board of Management and the members of the Audit Committee.

# D. RISK MANAGEMENT SYSTEM FOR FINANCIAL INSTRUMENTS

Biotest uses derivative financial instruments to hedge currency and interest rate positions. The corresponding contracts are concluded taking due account of the defined risk limits. Section F4 of the Notes to the consolidated financial statements contains a detailed description of the risk management system with regard to financial instruments.

### E. DESCRIPTION OF SIGNIFICANT RISK CATEGORIES

The material risks known to the Biotest Group are described below together with an assessment of the respective risks by the Board of Management. However, Biotest may be exposed to additional risks and uncertainties which are still unknown or which are currently considered minor. These risks could also have an adverse effect on the financial position, cash flows and results of operations of the Biotest Group. The order in which the risks below are listed is in no way indicative of the probability of their occurrence.

# **Environmental and industry risks**

# Economic risks

Biotest would not be able to permanently escape the consequences of a far-reaching, long-lasting recession, even if its direct effects were limited. The risk of a downturn in sales may result from lower demand and rising pressure from customers to reduce prices. Another potentially dampening effect is the possibility that Biotest will be forced to reduce or discontinue supplies to individual markets. This could be the case if the Company is unable to adequately hedge against default on corresponding receivables or only at much less favourable terms. If a country's overall economic position deteriorates to such an extent that serious consequences for its solvency and its health care system are feared, Biotest may be forced to discontinue deliveries to such countries in order to reduce risk. The Board of Management considers the economic risks to be slightly elevated and is closely monitoring developments.

### Sales market risks

Sales market risks consist of risks associated with price, quantity, substitution and payment default. The Biotest Group is reducing the risk of short-term fluctuations in sales volumes and prices by expanding into additional international markets and establishing longer-term supply agreements. Nevertheless, the risk remains, especially in the case of individual tendered contracts in the Therapy segment, that the volume of sales could be lower than planned.

The risk of sharp price decreases for plasma proteins has not increased based on the price trend of the past few years. However, it continues to be classified as high. Cost pressure is becoming increasingly important in highly developed health care markets — also in the wake of the financial crisis. Countries are increasingly adopting enforcement measures in order to reduce drug prices. Examples of this are manufacturer discounts and price moratoria in Germany and Austria as well as mandatory discounts in Greece, Romania and Italy. In addition, efforts of countries to reduce prices in their own country by referring to countries with lower prices are increasing. Such efforts also exist at an EU level.

The upcoming EU Council Presidency (Netherlands) has announced increased collaboration among member states regarding medication pricing as one of its priorities.

Based on the observations of the Biotest Group, the relationship between globally used plasmatic and recombinant clotting factors has been largely stable, although the demand for plasmatic clotting factors is likely to grow less strongly over the next few years than that for recombinant factors. Nevertheless, the Board of Management of Biotest considers further substitution risks to be manageable.

Default risk continues to be high due to the lower credit standing of companies and governments in some regions. Biotest has set up an active receivables management system and takes necessary measures to minimise risk such as, for example, a delivery stop. Furthermore, credit insurance is taken out for many countries and customers. Political changes to the legal framework can also entail a sales market risk. Ceilings that were also below the previous year's amount were set for the first time in 2013 for the consumption of pharmaceutical drugs in Italy. Companies are thereby required to reimburse the health authority 100% of the amount sold above the specified ceiling. This

could result in Biotest generating sales in Italy only up to this ceiling. In this connection Biotest Italia S.r.l. is currently obtaining a judicial declaration regarding the claims asserted by the Italian health authorities against it for the reimbursement of Zutectra® sales for the years 2011 to 2012. In January 2014 the position of Biotest Italia S.r.l. was confirmed in a first instance ruling.

Entry into a market is associated with high costs for marketing authorisations of products as well as infrastructure costs such as the formation of a subsidiary. If countries undergoing economic development change their regulatory framework and bureaucratic procedures, this can cause unexpected delays with regard to market entry. In this case, Biotest tries, with the involvement of experts in the relevant market, to assess the situation regarding the risks and to minimise these risks where necessary. The market entries and marketing authorisation efforts in China and Brazil are examples of such an approach.

### Procurement market risks

Biotest needs special raw materials and excipients to manufacture its biological and biotechnological products. If these materials were to become scarcer or increase substantially in price, Biotest's ability to manufacture or supply might be restricted. Biotest procures a large amount of its basic materials from its own sources, which are being gradually expanded. The Company has also entered into long-term supply agreements. Therefore, in the Company's assessment, procurement market risks are very low.

# Political risks

Biotest generates a portion of its sales via tender business. In certain countries, business of this kind may be subject to a high level of political influence, which may in certain cases be to Biotest's disadvantage. Because Biotest acts with a high level of risk awareness in this market sector, the associated risk may be regarded as minor. Biotest maintains relationships with companies all over the world. In unfavourable circumstances, a destabilisation of the political situation in individual countries could impair business relationships and prospects. In extreme cases, the political and economic system of individual countries may be subject to destabilising effects. These may include currency export restrictions or import and export bans, which could threaten business relationships between Biotest and typically government-run institutions in such countries.

The situation in several countries in the Near and Middle East has destabilised further in some cases in 2015. Because Biotest is represented in these countries, it is exposed to increased risk. An additional risk worth mentioning is the continuing difficulty to collect payment for product deliveries currently excluded from embargo and sanction measures, from countries that are otherwise subject to an embargo. Biotest is trying to minimise these difficulties through intensive contact with its banks and by explaining the underlying transactions. Biotest continuously monitors all political risks. The potential economic consequences of an occurrence of such risks are closely analysed in order to implement appropriate measures.

# Corporate strategy risks

# Research and development risks

New medications undergo several preclinical trials and clinical studies prior to marketing authorisation and market launch. There is a risk that a previously assumed therapeutic effect may not be confirmed or that unexpected medical risks will negatively impact the benefit/risk balance. As development programmes must be adjusted, where necessary, to take account of new information, the associated costs cannot always be exactly predicted — unexpected additional costs may be incurred. Changes to the environment such as the requirements for marketing authorisation or later reimbursement for new medications can influence the development tasks.

For example, constantly increasing requirements to prove the additional benefits of new products compared to already existing products, or demonstrate health economic benefit, are playing an increasingly important role in the development of medications. Proving these benefits is necessary as early as possible during the product development stage, as otherwise there is a high risk that the company will not be able to obtain a sufficiently high price on the market to cover the costs of development.

The progress of development projects is constantly monitored through milestone planning. New data obtained from clinical and preclinical development is evaluated in regular interim analyses to create a reliable basis for decisions on the further course of these projects.

### Performance-related risks

# Process and production risks

Process and production risks include those that could impair the ability to provide efficient and environmentally friendly goods and services due to inefficient structures or production processes or material damage to plant and machinery. Personnel risks in production arise from possible deliberate or accidental misconduct by employees that might negatively affect production efficiency or safety.

Biotest constantly monitors and analyses its production processes in order to take early action against any risks that may arise. All employees involved in production become familiar with production workflows by reviewing our operating procedures. To combat possible risks, comprehensive, precisely documented standards and operating procedures are maintained, and staff members regularly attend training sessions. Increased risk is not currently evident in this area.

# Supplier relationship risk

There is a risk that individual business or cooperation partners may fail to duly meet their obligations or may terminate existing agreements. The Biotest Group is also at risk of claims brought against it for possible breach of duty on the part of its partners. Given that its business relationships generally last many years and in view of the close dialogue maintained with suppliers, the Board of Management believes that the probability that these risks will materialise is very low.

# Risks relating to plasma as a raw material

There is a very low risk that plasma contaminated with currently known but undetected, or previously unknown bacteria, viruses or prions will enter the production cycle. This could lead to contamination of end products. Possible consequences include a recall of individual batches from the market or restriction or suspension of marketing authorisation by the authorities. In addition, contamination caused by previously unknown bacteria, viruses or prions could result in tighter legislative controls on plasma-based drugs. In the event of reports from the market of suspected contaminated end products, these will be entered and analysed as part of the pharmacovigilance system. In the very

unlikely case of a confirmed contamination this would result in a risk-minimising measure being taken, e.g. recall of the batch. This is not considered an increased risk. The test procedures employed by Biotest are in line with the latest scientific standards. The manufacturing process includes several steps for viral inactivation or viral depletion. Contamination of end products is thus highly unlikely.

# Compliance

There is a fundamental risk of corruption in competing for supply contracts and in procurement. Biotest Group employees could improperly influence the awarding of contract by granting or accepting undue advantages. The Biotest Group has again strengthened its compliance measures in the 2015 financial year in order to counteract this risk. An international compliance system, which takes country-specific features into account and is periodically adjusted in accordance with current requirements, has been established for this purpose in close collaboration with the Company's Compliance, Legal and IT departments. Local compliance regulations were updated as well as standard agreements and clauses. Furthermore, a publication part was added to the compliance creditor process created in the 2014 financial year, through which data for the planned publication from 2016 on of all monetary contributions paid to all "Health Care Professionals" and "Health Care Organisations" since the beginning of 2015 can be documented and then published from the middle of 2016 onwards. This will also meet the transparency rules within the meaning of the Code of Conduct of the "Arzneimittel und Kooperation im Gesundheitswesen" (AKG e.V.) (Organisation for Medicinal Products and Cooperation within the Health Sector).

For the Biotest Group as well as for the larger affiliated companies, the electronic Compliance Training System (CTS) was introduced for advanced training in 2015. In November 2015, the Biotest code of conduct and ethics was presented to the companies affiliated with Biotest. The introduction was associated with a training-the-trainer program to ensure solid implementation in the organisation.

Employees in all departments of the Biotest Group regularly receive training on current developments in the compliance

field (e.g. transparency rules). All employees regularly receive basic training. The heads of Group companies may only undertake business transactions with a material effect on the Group's financial position, cash flows and results of operations or the Group's risk position with the approval of Group management. For distributors and agents, the respective area meetings included information events on compliance-related topics and on the code of conduct and ethics.

In Italy, the Naples public prosecutor's office has now charged 16 people with unlawful price-fixing. Two of the 16 accused are employees of Biotest Italia S.r.l. The trial started in early November. The subsidiary is not the subject of the investigation.

The preliminary proceedings by the Frankfurt am Main public prosecutor's office in May 2012 in terms of the suspicion of bribery, embezzlement and tax evasion in connection with the Biotest business in Russia and other eastern European countries continues. The affected persons as well as Biotest consider this suspicion to be unfounded. With regard to the investigation initiated by the Frankfurt am Main public prosecutor's office in late 2011 concerning Biotest's business in Russia, the criminal proceedings against the former head of Biotest's representative office in Moscow and her husband are ongoing. In connection with this investigation, the fiscal authorities have examined the business expenses claimed by Biotest in the period 2005 – 2008. This could potentially lead to additional charges for taxes and interest of up to € 16 million, although the legality of any such payments would naturally be carefully reviewed. If the accusations of the public prosecutor's office should be justified or if it comes to an agreement with the determination authorities to avoid a long-term process, this could lead to a sanctioning through fines or comparable measures, which could strain the result of the group.

The defence costs arising in connection with the proceedings are covered by appropriate provisions. Notwithstanding the ongoing proceedings, Biotest has continued to further expand its compliance management system. The compliance regulations were amended and updated as a result of changed regulations in the codes of conduct or new statutory regulations of various countries. The standard agreements and standard clauses were amended accordingly.

### Personnel risks

Other risks include the possibility that Biotest will not be in a position to retain employees in key positions or not be able to find suitable candidates for such positions. Biotest combats this risk through continuous and targeted staff continuing education, targeted training programmes and performance-based remuneration of specialised and management staff.

# IT risks

Many production and other business processes at Biotest rely on IT support. The Group has been using an integrated standard business software package, SAP ERP Business Suite, since 2008. The security of the technology used is a top priority. This applies both to the stability of the IT systems and backup solutions as well as to protection against unauthorised thirdparty access and possible attacks from the Internet. Production and administration operate on separate IT networks. Biotest is continuously increasing its already comprehensive use of IT systems and is enhancing the corresponding security systems in parallel in the same way. The system functionality is constantly being enhanced in the areas of production, quality control and quality assurance in order to reduce risks and ensure product quality. However, redundant systems cannot be maintained in all areas for protection. The proper handling of systems and data is governed by the working instructions and is ensured through appropriate training.

# Financial and currency risks

In 2014 Biotest AG concluded energy efficiency loans with funds provided by the Reconstruction Loan Corporation (Kreditanstalt für Wiederaufbau, KfW). The loan note was issued without collateral and financial ratio covenants. Financial risks can also result from the unexpected cancellation of credit lines. Biotest AG has entered into long-term agreements for a large part of its debt financing. A significant portion of the promissory notes issued in 2013 bears interest at a variable rate. Biotest AG has concluded long-term interest rate hedging transactions to limit the interest rate risk.

Biotest counteracts currency risks through the use of derivative financial instruments wherever advisable. Sales in US dollars are also offset by purchases in the same currency. However, despite these measures, the massive devaluation of individual currencies could greatly impact consolidated results. Possible currency risks are therefore monitored continuously and appropriate hedges entered into where necessary. As a general rule, only underlying transactions already executed are hedged. If the business incurs losses as a result of a currency depreciation (e.g. in Russia and Turkey), those sales that can no longer be generated cannot be hedged.

# Other risks

# Risks resulting from side effects or interactions, quality defects

Unexpectedly severe, more frequent or hitherto unknown side effects or interactions with other medicines can result when taking drugs. Inappropriate handling, storage or application of our products may also give rise to significant adverse effects for customers and patients. Furthermore, suspected cases of quality defects may emanate from the market. Reported suspected cases of side effects, interactions or quality defects are recorded, investigated and analysed and further risk-based risk minimisation measures added as part of the pharmacovigilance system. The measures to be adopted in agreement with regulatory authorities for these cases range from recall of individual lots to restriction or withdrawal of the marketing authorisation. Increased risk is not currently evident in this area.

# Risks caused by defects in the pharmacovigilance system

The pharmacovigilance system for which the marketing authorisation holder is responsible ensures that national and international requirements (Good Vigilance Practise (GVP)) for monitoring product use and drug safety are met as a prerequisite for the receipt and maintenance of marketing authorisations for drugs. The Corporate Drug Safety department is responsible for its implementation in the Company.

Defects in the pharmacovigilance system, especially the improper handling of suspected cases of side effects, interactions or quality defects could damage not only Biotest's reputation with the supervisory and regulatory authorities but also be subject to a fine for the territory of the EU (up to a maximum of 5% of the annual sales in the EU per defect). Furthermore, they could result in the withdrawal of the drug marketing authorisation in severe, repeated cases. Biotest ensures a very high level of reliability in this area by continuously developing transparent processes and through interdepartmental and international training courses for staff who deal with these subjects. Our high reliability has been consistently confirmed by routine inspections conducted by international authorities. Moreover, intensive dialogue with clinics, practising physicians and pharmacists ensures that we are informed promptly about possible newly identified side effects and interactions.

# Risks arising from ongoing legal proceedings and tax risks

Risks relating to the deductibility of defence costs, any assumption of monetary conditions as well as possible retroactive tax payments could result from the above-described public prosecutor investigation proceedings. A monetary fine could also be considered a further risk. All identifiable risks from employment law and other ongoing proceedings are covered through provisions. Furthermore, tax risks could result from tax audits of previous years. This would be the case if the fiscal authorities assess tax items in a different way than that applied by Biotest companies.

# F. GENERAL STATEMENT ON THE GROUP'S RISK POSITION

In the Board of Management's opinion, Biotest is not currently subject to any risks exceeding those that are an inevitable part of its business operations. All material risks are monitored continuously. Wherever possible and reasonable, the necessary precautions are taken to prevent any potential financial consequences. There are currently no identifiable risks that might jeopardise Biotest's financial stability.

# III. OPPORTUNITIES REPORT

Biotest views risks and opportunities from an integrated management perspective. By continuously monitoring developments in sales markets and regulatory conditions, the Company is able to identify opportunities at an early stage. Current opportunities are the subject of regular reports to the Board of Management. In the event of a change in opportunities requiring immediate action, the Board of Management is notified directly and at short notice. Biotest thoroughly evaluates any identified opportunities and makes decisions regarding possible investments based on the results of the evaluation. This evaluation may include the use of risk-adjusted net present values or comparisons of multiple scenarios. Possible risks are also considered in assessing opportunities. Finally, the potential project must be in line with the strategic orientation of the segment and the Group.

# A. OPPORTUNITIES ARISING FROM DEVELOPMENT OF THE PRODUCT PORTFOLIO

The extension of the application of existing products or development projects to additional indications might open up further marketing potential for the Biotest Group in the immunoglobulins area as well as in monoclonal antibodies.

In addition, extended indication areas may also result from improved or more widely used diagnostic methods, leading to better detection of potentially treatable diseases which can be treated by the administration of immunoglobulins. Additional potential also results from the consistent product and life cycle management of existing products. By developing products already on the market, by establishing additional concentrations or pharmaceutical forms, among other things, the product portfolio will be further differentiated, thus enabling other market segments to be addressed. In addition to the development projects that lead to new products or extended indications, projects to improve process yield and to achieve additional cost-reducing measures continue to be conducted.

# B. OPPORTUNITIES ARISING FROM CORPORATE STRATEGY

The internationalisation strategy of the Group offers potential for the future growth of the Company. The marketing authorisation for Albiomin® 20% (200g/l) in China as well as numerous other new marketing authorisations in international markets confirm this development. In addition, other regions in Central and South America as well as in Asia are to be opened up. In numerous emerging countries, more funds are being provided for health care systems, health insurance is being introduced and patient care improved as a result. This positive trend is marked in Tunisia and Algeria as well as in Turkey and Central and South America – countries in which Biotest already operates and can benefit from these trends. The same trend was previously seen in the Gulf States and particularly in Saudi Arabia as well, but due to falling oil prices, it is currently unreliable in that region. Competitive advantages and therefore opportunities could also arise in the future from further strategic research and development as well as distribution cooperation agreements. Numerous opportunities, which will raise the Biotest Group to a new level, will result from the increased productivity and doubling of production capacities by 2019/2020 that are planned as part of the Biotest Next Level project. Furthermore, hyperimmunoglobulins offer Biotest an opportunity to extend application to further indications or to achieve sales in additional countries. The selection depends on market requirements and local circumstances.

# C. PERFORMANCE-RELATED OPPORTUNITIES

Biotest has invested heavily in recent years in expanding its resources and expertise in the fields of drug development and marketing authorisation. In addition, the Group is moving into a new dimension through the planned doubling of production capacity. In the future, it will also maintain the benefits of its efficiently managed corporate headquarters in Dreieich, where all of the major business departments are concentrated. The resulting synergies and potential will continue to be used to conduct research and development projects more quickly and cost-effectively and to improve the efficiency of production.

# E. REMUNERATION REPORT

This remuneration report describes the remuneration system for the members of the Board of Management and Supervisory Board of Biotest. First the composition of the different remuneration components is addressed, and then the individual amounts are shown.

The remuneration report is based on the recommendations of the German Corporate Governance Code (GCGC) and contains information in accordance with the provisions of the German Commercial Code (HGB), the German Accounting Standards (DRS) and the International Financial Reporting Standards (IFRS). The remuneration report is an integral part of the Group Management Report.

# Explanatory notes on the remuneration system for members of the Board of Management

The Supervisory Board determines the remuneration of the members of the Board of Management. It consists of a fixed salary, an annual bonus and a component incorporating a long-term incentive effect and risk features. Added to this are benefits in kind.

The criteria for determining appropriate remuneration take into account the duties of the individual Board Member, his personal performance, the economic situation, the success and future prospects of the Company as well as typical remuneration at peer companies and the remuneration structure that otherwise applies at the Company.

# Non-performance-based remuneration components

# Fixed remuneration

The non-performance-based remuneration of the Board of Management members consists of fixed salary and benefits in kind. The amount is based on the economic situation and future prospects of Biotest as well as on remuneration levels paid by the competition. The annual fixed salary is set for the entire term of the respective employment contract and is payable in twelve monthly installments.

#### Benefits in kind

Board of Management members receive benefits in kind in addition to the fixed salary. Board of Management members are covered professionally and privately under Biotest AG's collective accident insurance policy. They are also covered for personal liability under the existing employer's liability insurance policy. In addition, the Board of Management members receive an allowance towards their social security and direct insurance contributions

Biotest AG has concluded a directors' and officers' liability insurance policy (D&O insurance) with an appropriate deductible. The deductible is 10% of the insured event and is limited to 150% of the fixed annual remuneration of the respective Board of Management member and meets the requirements of Section 93 (2) clause 3 of the German Stock Corporation Act (AktG). All Board of Management members are provided with a top-of-the-range company car free of charge; personal use of the car is permitted.

Furthermore, lawyer's fees and income tax payable thereon incurred in connection with the ongoing investigation proceedings regarding Biotest AG were paid on behalf of a Board of Management member.

#### Performance-based remuneration components

#### Annual variable remuneration

The performance-based remuneration component is calculated based on the achievement of corporate and personal targets. In calculating bonuses, the EBIT and operative cash flow are each weighted at 25%, the return on capital employed (RoCE) at 10% and the achievement of personal targets set in the past financial year at 40%.

# Remuneration component with long-term incentive effect and risk features

The remuneration component with a long-term incentive effect and risk features is based on Biotest AG's Long Term Incentive Programme (LTIP). In addition to Board of Management members, selected managers who have a significant impact on the Company's success due to their position in the Group, their leadership and actions also participate in the programme.

This programme is designed in accordance with established capital markets criteria for a system of this type and complies with the requirements of the GCGC. Participation in the programme requires a personal investment by the participant in the form of a purchase of preference shares of Biotest AG. The

programme is described in detail in Section F1 of the Notes to the consolidated financial statements, including the process for calculating incentive payments. It is anticipated that the incentive component will be paid in May of the year following the expiry of the tranche.

#### Pension commitments

Board of Management members are covered by the company pension scheme of Biotest AG. Members have been given individual commitments in accordance with the terms of the Biotest AG pension plan. Provisions are recognised for these in accordance with IFRS. The amount of the entitlement is dependent on the length of service, pensionable salary and applicable benefits scale below and above the contribution limits of Germany's statutory pension scheme.

The valuation is based on the actuarial reports prepared by an independent actuary in accordance with the projected unit credit method.

### Commitments in connection with the termination of a Board Member's activities

A supplementary agreement to the Board of Management employment contract of all active Board of Management members contains a severance pay clause that becomes effective in the event of the early termination of such contract as a result of a clearly defined change of control. The severance payment includes the fixed remuneration up to the end of the term and is limited to a maximum of three times the annual fixed salary. Pro-rata variable remuneration components that are calculated on the basis of the average for the previous two financial years plus compensation for the value in use of the Company vehicle provided are also paid. In addition to these claims, the severance payment also includes up to twice the annual fixed salary. In total, however, the severance payment amount must not exceed triple the annual fixed salary.

There shall be no entitlement if the Board of Management employment contract is terminated for good cause, illness or incapacity to work or if the Board of Management member at the time of the termination has already completed the age of 60 or receives monetary or non-monetary benefits in connection with the change of control.

No other one-off or recurring commitments exist in the event of termination of a Board of Management assignment.

#### Remuneration for the current financial year

Total remuneration of the Board of Management members in office as of 31 December 2015

		Dr Bern	hard Ehmer			Dr Mich	ael Ramrotl	1		Dr G	eorg Floß	
in € thousand	2014	2015	2015 minimum	2015 maximum	2014	2015	2015 minimum	2015 maximum	2014	2015	2015 minimum	2015 maximum
Non-performance- based												
Fixed remuneration	60	385	385	385	300	325	325	325	260	285	285	285
Benefits in kind	5	31	31	31	233	214	34	214	35	35	35	35
Total non-performance- based components	65	416	416	416	533	539	359	539	295	320	320	320
Performance-based												
Excluding long-term incentive effect (not share-based)												
Annual variable remune- ration – cash portion	10	119		227	123	166		242	110	136		218
With long-term incentive effect (share-based):												
Variable remuneration (LTIP) – cash portion	135	78		347	112	66	_	293	97	58	_	257
Total performance- based components	145	197		574	235	232	_	535	207	194	_	475
Pension expense (service cost)		521	521	521	152	271	271	271	144	199	199	199
Total remuneration (GCGC)	210	1,134	937	1,511	920	1,042	630	1,345	646	713	519	994
Less pension expense (service cost)		521	521	521	152	271	271	271	144	199	199	199
Total remuneration (DRS 17)	210	613	416	990	768	771	359	1,074	502	514	320	795

This overview shows the calculation of the total remuneration for each Board of Management member together with the amounts granted in the 2015 financial year for the different remuneration components.

The maximum amounts for performance-based remuneration show the maximum possible amount on the date such remuneration is granted. Depending on the share price this amount may be higher on the date such remuneration is received.

Total remuneration of Board of Management members is  $\in$  1,898 thousand (previous year:  $\in$  1,480 thousand) for the 2015 financial year calculated on the basis of DRS 17. Pension expense is not included in this amount.

# Remuneration received by Board of Management members in office at 31 December 2015

The following table provides an overview of the amounts received for the current financial year broken down by Board of Management members. Total remuneration is also broken down by the different remuneration components. This analysis shows the multi-year variable remuneration that was granted in previous years and paid in this financial year.

	Dr Bernhard	Ehmer	<b>Dr Michael Ramroth</b>		Dr Georg Floß	
in € thousand	2015	2014	2015	2014	2015	2014
Non-performance-based						
Fixed remuneration	385	60	325	300	285	260
Benefits in kind	31	5	214	233	35	35
Total non-performance-based components	416	65	539	533	320	295
Performance-based						
Excluding long-term incentive effect (not share-based)						
Annual variable remuneration – cash portion	17	_	135	177	104	158
With long-term incentive effect (share-based):	_     _					
Variable remuneration (LTIP 2012) – cash portion	_	_	316		130	-
Variable remuneration (LTIP 2011) – cash portion	_	_		270		111
Total of the multi-year variable remuneration	_	_	316	270	130	111
Total performance-based components	17	_	451	447	234	269
Pension expense (service cost)	_     _	_				_
Total remuneration (GCGC)	433	65	990	980	554	564

# Overview of pension commitments for Board of Management members in office as of 31 December 2015

in € thousand	Present value commitmen deferred rer	ts excluding	Present value of deferred remuneration		
	Present value in <b>2015</b>	Present value in 2014	Present value in <b>2015</b>	Present value in 2014	
Dr Bernhard Ehmer	684	425			
Dr Michael Ramroth	2,360	2,410	365	308	
Dr Georg Floß	1,729	1,481			
	4,773	4,316	365	308	

Assets amounting to  $\leqslant$  1,186 thousand (previous year:  $\leqslant$  1,177 thousand) were transferred to Biotest Vorsorge Trust e.V. for the purposes of protecting the pension entitlements against insolvency.

# Remuneration system for former Board of Management members and their dependants

Contractually agreed pension benefits are paid to former Board of Management members and their dependants. Pension provisions of € 6,683 thousand (previous year: € 7,437 thousand) have been established for this. The pension provisions were measured in accordance with IAS 19 Accounting and Reporting by Retirement Benefit Plans.

In the 2015 financial year, former members of the Board of Management were also paid  $\in$  487 thousand as part of profit-sharing and the LTIP 2012.

As of 31 December 2015, provisions for former members of the Board of Management as part of LTIP have been established in the amount of  $\le$  40 thousand.

The information on Prof. Georg Schulz, who entered planned retirement on 31 December 2014, will be reported in the 2015 annual financial statement in the information on former members of the Board of Management; the values for the previous year were correspondingly adapted.

# Long Term Incentive Programme for Board of Management members

Participation by members of the Board of Management in the Long Term Incentive Programme is included in total remuneration and is as follows:

in € thousand	Personal invest- ment in preference shares (in number of shares)	Fair value of options as of 31 December	Total cost of the stock option plan in the financial year
<b>2015</b> (2013, 2014 and 2015 tranches)			
Dr Bernhard Ehmer	1,800	55	-142
Dr Michael Ramroth	1,800	46	-126
Dr Georg Floß	1,800	40	-109
	5,400	141	-377
2014 (2012, 2013 and 2014 tranches)			
Dr Bernhard Ehmer	1,800	162	37
Dr Michael Ramroth	1,800	655	182
Dr Georg Floß	1,800	436	122
	5,400	1,253	341

The 2012 tranche of the Long Term Incentive Programme was disbursed in financial year 2015; Dr Michael Ramroth received € 316 thousand and Dr Georg Floß € 130 thousand.

### Explanatory comments on the remuneration system for Supervisory Board members

The remuneration of the Supervisory Board is laid down in the Articles of Association. Each Supervisory Board member receives an annual fixed remuneration of € 20 thousand (previous year: € 15 thousand). The Chairman of the Supervisory Board receives triple this amount and his/her deputy one-and-a-half times this sum. In addition, € 4 thousand is paid for any work carried out in a committee, the Chairman of the Audit Committee receives € 10 thousand and the Chairmen of the other committees € 7.5 thousand. Biotest AG reimburses the value added tax payable on Supervisory Board remuneration. Supervisory Board members also receive a variable remuneration of € 1 thousand for every € 0.0033 by which the dividend paid for the financial year exceeds € 0.08. The variable remuneration is limited to a maximum amount of € 10 thousand.

The members of Biotest AG's Supervisory Board are, like members of the Board of Management, covered by the Group's professional indemnity insurance (D&O liability insurance). Biotest pays the related insurance premiums for all Supervisory Board members. One Supervisory Board member also receives personal liability coverage under the existing employer's liability insurance. No other non-cash benefits are granted.

The amounts disclosed for the remuneration of the Supervisory Board include in some cases the reimbursement of value added tax payable on the Supervisory Board remuneration.

#### Remuneration for the current financial year

The Supervisory Board members received the following remuneration for their activities in financial year 2015:

in € thousand <b>2015</b>	Fixed salary	Variable remune- ration	Total remune- ration
Dr Alessandro Banchi	76		76
Dr Cathrin Schleussner	41		41
Kerstin Birkhahn	20		20
Thomas Jakob	24		24
Jürgen Heilmann	24	_	24
Dr Christoph Schröder	34	_	34
	219	_	219

The members of the Supervisory Board were paid the following remuneration for financial year 2014:

64		
	25	89
31	15	46
15	10	25
19	10	29
19	10	29
29	10	39
177	80	257
	29	29 10

In addition to the listed Supervisory Board remuneration, additional amounts paid in financial years 2015 and 2014 to employee representatives on the Supervisory Board under their employment agreements were also recognised as an expense. These amounts were based on collective bargaining agreements and/or company pay rates for non-pay-scale employees.

### F. INFORMATION CONCERNING TAKEOVERS IN ACCORDANCE WITH SECTION 315 (4) OF THE GERMAN COMMERCIAL CODE (HGB)

In accordance with the Articles of Association the subscribed capital of Biotest AG amounts to € 39,571,452.00. It is divided into 19,785,726 ordinary shares and 19,785,726 preference shares. The ordinary shares are bearer shares; the preference shares do not carry any voting rights.

OGEL GmbH notified us on 12 February 2008 that it holds 50.03% of Biotest AG's ordinary shares. The Company is controlled by Dr Cathrin Schleussner, who is a member of Biotest AG's Supervisory Board. Based on the new rules under Section 41 Paragraph 4d of the German Securities Act (WpHG) in effect from 1 February 2012, Dr Martin Schleussner, Renate Schleussner and Dr Hans Schleussner notified us on 22 February 2012 that, effective 1 February 2012, they each held a 50.27% share in Biotest AG with voting rights reportable under Section 41 Paragraph 4d of the WpHG. The district of Biberach notified us on 26 March 2014 that it holds 19.95% of Biotest AG's ordinary shares. The shares are assignable to the district in accordance with Section 22 (1) sentence 1 of the WpHG and are held by the Kreissparkasse Biberach.

Furthermore, the Board of Management is not aware of any direct or indirect shareholdings in the Company exceeding 10% of the voting rights. There are no holders of shares with special rights conferring powers of control.

Members of the Board of Management are appointed and dismissed by the Supervisory Board in accordance with Sections 84 and 85 of the German Stock Corporation Act (AktG) and Section 7 (2) of the Articles of Association. In accordance with Section 179 (1) of the AktG any amendment to the Articles of Association requires a resolution of the Annual Shareholders' Meeting (Section 133 AktG). Authorisation to amend the Articles of Association affecting only the wording thereof has been transferred to the Supervisory Board in accordance with Section 27 of the Articles of Association in accordance with Section 179 (1) clause 2 of the AktG.

Pursuant to the resolutions of the Annual Shareholders' Meeting of 7 May 2015 the Company is authorised to acquire under Section 71 (1) no. 8 of the AktG ordinary bearer shares and/ or preference bearer shares up to 10% of the share capital of € 33,767,639.04 outstanding at the time of the Annual Shareholders' Meeting. At no time may the shares acquired together with other Treasury shares held by the Company or ascribed to

it under Sections 71d and 71e of the AktG represent more than 10% of the share capital. This authorisation is valid until 6 May 2020 and has not been made use of to date by the Company.

Biotest AG has entered into material arrangements with third parties regarding agreements for the long-term financing of Biotest AG, and also the Group in this regard, which take effect in the event of a change of control. The financial agreements give the right to the creditors under the loan note and the lending banks to terminate the agreement in the event of a change of control, if, in their view, this change of control would make the continuation of the contract unacceptable.

A supplementary agreement to the Board of Management employment contract of all Board of Management members contains a severance pay clause that becomes effective in the event of the early termination of such contract as a result of a clearly defined change of control. The severance payment includes the fixed remuneration up to the end of the term and is limited to a maximum of three times the annual fixed salary. Pro-rata bonuses calculated on the basis of the average for the previous two financial years plus compensation for the value in use of the Company vehicle provided are also paid. In addition to these claims, the severance payment also includes up to twice the annual fixed salary provided the severance payment with regard to total fixed salary does not exceed three times the annual fixed salary.

There shall be no entitlement if the Board of Management employment contract is terminated for good cause, illness or incapacity to work or if the Board of Management member receives monetary or non-monetary benefits in connection with the change of control.

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### CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 December 2015

in € million	Note	2015	2014*
Revenue	D1	589.6	582.0
Cost of sales		-448.3	-357.5
Gross profit		141.3	224.5
Other operating income	D5	2.7	7.0
Marketing and distribution costs		-77.8	-74.2
Administrative expenses		-35.6	-31.6
Research and development costs	D4	-98.8	-67.2
Other operating expenses	D6	-3.6	-5.1
Operating profit		-71.8	53.4
Financial income	D7	38.4	21.4
Financial expenses	D8	-42.9	-27.9
Financial result		-4.5	-6.5
Income from associated companies	D 9	2.0	
Earnings before taxes		-74.3	46.9
Income taxes	D10	-8.2	-27.7
Earnings after taxes		-82.5	19.2
Attributable to:			
Equity holders of the parent		-82.5	19.2
Non-controlling interests			_
Earnings per ordinary share in €	E10	-2.10	0.48
Additional dividend rights per preference share in €	E10	0.02	0.02
Earnings per preference share in €	E10	-2.08	0.50

<sup>\*</sup>The earnings per share were adjusted due to IAS 33.26.

### CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 31 December 2015

2015	2014
-82.5	19.2
17.6	19.8
_	_
17.6	19.8
7.6	-16.3
-2.3	4.7
5.3	-11.6
22.9	8.2
	27.4
-59.6	27.4
_	_
	7.6 -2.3 -5.6 -2.9 -59.6

### CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 December 2015

in € million	Note	31 December 2015	31 December 2014*
ASSETS			
Non-current assets			
Intangible assets	<u>E1</u>	44.7	50.2
Property, plant and equipment	<u>E2</u>	317.2	282.3
Investments in associates	E3	3.5	1.3
Other assets	E8	1.0	0.8
Other financial assets	<u>E4</u>	0.8	5.2
Deferred tax assets	E 5	8.7	13.5
Total non-current assets		375.9	353.3
Current assets			
Inventories	E 6	218.7	246.0
Trade receivables	E 7	173.9	181.6
Current income tax assets		5.8	4.6
Other assets	E8	13.8	12.0
Other financial assets	E4	120.8	55.7
Cash and cash equivalents	E 9	53.8	179.4
Total current assets		586.8	679,3
TOTAL ASSETS		962.7	1,032.6
EQUITY AND LIABILITIES			
Equity			
Subscribed capital		39.6	33.8
Share premium		219.8	225.6
Retained earnings		235.3	201.5
Shares of profit or loss attributable to equity holders of the parent		-82.5	19.2
Equity attributable to equity holders of the parent	E10	412.2	480.1
Non-controlling interests		0.1	0.1
Total equity	E10	412.3	480.2
Non-current liabilities			
Provisions for pensions and similar obligations	E 11	72.6	77.5
Other provisions	E 12	6.6	6.3
Financial liabilities	E13	335.5	325.8
Other liabilities	E14	2.2	2.5
Deferred tax liabilities	E 5	7.7	11.4
Total non-current liabilities		424.6	423.5
Current liabilities			
Other provisions	E12	27.5	23.5
Current income tax liabilities		4.3	8.6
Financial liabilities	E13	9.1	6.1
Trade payables		53.1	55.5
Other liabilities	E 14	31.8	32.7
Liabilities from deferred revenue			2.5
Total current liabilities		125.8	128.9
Total liabilities		550.4	552.4
TOTAL EQUITY AND LIABILITIES		962.7	1,032.6

<sup>\*</sup> Some amounts shown differ from the amounts in the consolidated financial statements for the 2014 financial year due to adjustments made (see Note "Changes in recognition and measurement methods")

### CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 December 2015

in € million	Note Note	2015	2014
Earnings before taxes			46.9
Depreciation, amortisation and impairment of intangible assets and property, plant and equipment	E 1, E 2	94.2	32.5
Other non-cash income and expense items		6.5	4.9
Income from associated companies	D9	-2.0	_
Losses from the disposal of fixed assets		0.7	0.4
Changes in pension provisions	E11	1.4	-0.1
Financial result		4.5	6.5
Operating cash flow before changes in working capital		31.0	91.1
Changes in other provisions	E12	3.5	-1.0
Changes in inventories, receivables and other assets		45.9	-70.3
Changes in liabilities from deferred revenue		-2.5	-6.9
Changes in trade payables and other liabilities		-18.4	0.9
Cash flow from changes in working capital		28.5	-77.3
Interest paid		-6.1	-5.6
Taxes paid		-15.3	-19.6
Cash flow from operating activities		38.1	-11.4
Cash received on the disposal of fixed assets		0.1	0.8
Payments for investments in fixed assets		-100.7	-44.7
Payments for other financial assets		-60.1	-59.7
Interest received		0.6	1.2
Cash flow from investing activities		-160.1	-102.4
Dividend payments for the previous year	E10	-8.3	-7.9
Proceeds from the assumption of financial liabilities	E13	10.5	100.5
Payments for the redemption of financial liabilities	E13	-6.8	-5.2
Cash flow from financing activities		-4.6	87.4
Cash changes in cash and cash equivalents		-126.6	-26.4
Exchange rate-related changes in cash and cash equivalents		1.0	1.4
Cash and cash equivalents on 1 January	E9	179.4	204.4
Cash and cash equivalents on 31 December	E9	53.8	179.4

### CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January 2014 to 31 December 2015

in € million	Subscribed capital	Share premium	Accumulated differences from currency translation	Retained earnings	Equity attributable to equity holders of the parent	Non- controlling interests	Total equity
Balance on 31 December 2013	33.8	225.6	-0.4	201.6	460.6	0.1	460.7
Gains/losses recognised directly in equity		_	19.8	-11.6	8.2	_	8.2
Profit for the period		_		19.2	19.2	_	19.2
Total comprehensive income	_	_	19.8	7.6	27.4	_	27.4
Dividend payments		_		-7.9	-7.9	_	-7.9
Balance on 31 December 2014	33.8	225.6	19.4	201.3	480.1	0.1	480.2
Gains/losses recognised directly in equity			17.6	5.3	22.9		22.9
Profit for the period	<u>-</u>			-82.5	-82.5		-82.5
Total comprehensive income			17.6	-77.2	-59.6		-59.6
Dividend payments		_		-8.3	-8.3	_	-8.3
Capital increase from company funds	5.8	-5.8					
Balance on 31 December 2015	39.6	219.8	37.0	115.8	412.2	0.1	412.3

#### **NOTES**

#### A. GENERAL INFORMATION

The Biotest Group consists of the parent company, Biotest Aktiengesellschaft (Biotest AG), with its registered office in Dreieich, Germany, and its domestic and foreign subsidiaries. The Group's headquarters are located at Landsteinerstrasse 5, 63303 Dreieich, Germany. Biotest AG is registered in the Commercial Register of the District Court of Offenbach am Main under HRB 42396. Biotest is a provider and developer of biological and biotechnological pharmaceutical products. With a value added chain that ranges from pre-clinical and clinical development to worldwide sales, Biotest has specialised primarily in the indication areas of clinical immunology, haematology and intensive care medicine.

The Biotest Group is divided into the following segments: Therapy, Plasma & Services and Other Segments.

The **Therapy segment** essentially combines the former Plasma Proteins and Biotherapeutics segments. It therefore comprises the development and production of blood plasma-based immunoglobulins, clotting factors and albumins, which are used for diseases of the immune system, haematological diseases and in intensive care medicine. It also includes the preclinical and clinical development of monoclonal antibodies, indications for which include rheumatoid arthritis and blood cancers among others.

The **Plasma & Services segment** includes the areas of plasma sales and toll manufacturing.

**Other Segments** include retail business and costs that cannot be allocated to either the Therapy segment or the Plasma & Services segment.

The Biotest Group employed 2,443 staff worldwide as of the reporting date (previous year: 2,332).

The financial statements of Biotest AG and its subsidiaries have been prepared in accordance with the International Financial Reporting Standards (IFRS) which are mandatory in the European Union. The IFRS comprise the International Financial Reporting Standards (IFRS) and International Accounting Standards (IAS) as well as the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) and the interpretations of the Standing Interpretation Committee (SIC). The accounts of the Biotest Group are prepared in accordance with those IFRS that are mandatory for financial years beginning on or after 1 January 2015.

In their present version, the consolidated financial statements comply with the provisions of Section 315a of the German Commercial Code (HGB). These provisions form the legal basis in Germany for consolidated accounting in accordance with international standards in conjunction with Regulation (EC) No. 1606/2002 on the application of International Accounting Standards issued by the European Parliament and Council on 19 July 2002.

Unless otherwise noted, all amounts are stated in million euros (€ million). The financial statements have been prepared in euros.

The Board of Management of Biotest AG will submit the consolidated financial statements to the Supervisory Board on 10 March 2016. The Supervisory Board will decide on the release of the consolidated financial statements for publication on 15 March 2016.

### CHANGES IN RECOGNITION AND MEASUREMENT METHODS

The accounting and measurement methods applied are the same as those of the previous year, with the exception of the standards presented below that were applied for the first time and the change in the presentation of other financial assets.

# IFRS Improvements Cycle (2010–2012) / IFRS Improvements Cycle (2011–2013)

IFRS Improvements Cycle 2011–2013 and IFRS Improvements Cycle 2010–2012 are collective standards, which were published in December 2013 and address amendments made to different IFRS, the majority of which are to be applied in financial years beginning on or after 1 July 2014. The first-time adoption of the amendments had no impact on the presentation of the Group's financial position, results of operation and cash flows.

# IAS 19 Employee Benefits – Defined Benefit Plans: Employee Contributions (amended)

The amendment to IAS 19 was published in November 2013 and is to be adopted for the first time for the financial year beginning on or after 1 February 2015. The Group adopted the amendment prematurely in these consolidated financial statements. The amendment governs the recognition of contributions from employees or third parties to the pension plan as a reduction in service cost, provided these reflect the service rendered in the reporting period. The first-time adoption of the amendments had no impact on the presentation of the Group's financial position, results of operation and cash flows.

#### Change in the presentation of other financial assets

To improve the clarity of the balance sheet disclosure, the other financial assets previously recognised under other assets are now shown in a separate item on the statement of financial position. This relates to "financial assets as part of the short-term financial disposition", "receivables from associated companies" and "derivative financial instruments". The disclosure for the previous year was adjusted accordingly and current other financial assets of € 55.7 million reclassified.

### Recently released accounting pronouncements – not yet implemented

Standards that are issued, but not yet mandatory up to the date of issuance of the consolidated financial statements are listed below. This list is based on published standards and interpretations that the Group reasonably expects will be applicable in the future. The Biotest Group intends to adopt these standards if applicable, when they become mandatory.

#### **IFRS 9 Financial Instruments**

In July 2014, the IASB published the final version of IFRS 9 Financial Instruments, which replaces IAS 39 Financial Instruments: Recognition and Measurement and all previous versions of IFRS 9. IFRS 9 brings together the three project phases regarding the recognition of financial instruments, "Classification and Measurement", "Impairment" and "Hedge Accounting". IFRS 9 applies for the first time for financial years beginning on or after 1 January 2018. Earlier application is permitted. With the exception of hedge accounting, the standard is to be applied retrospectively, but comparative information does not have to be disclosed. The hedge accounting requirements are generally to be applied prospectively, with a few exceptions.

The classification and measurement requirements as well as the amended requirements for impairment losses are not expected to have a material impact on the Group's financial position, results of operations and cash flows. The designation of hedging relationships and effectiveness test are significantly simplified in the hedge accounting rules.

### IFRS 15 Revenue from Contracts with Customers

IFRS 15 was published in May 2014 and introduces a five-step model for the recognition of revenue from contracts with customers. According to IFRS 15, revenue is recognised at the amount of the consideration an entity can expect for transferring goods or services to a customer (transaction price as defined by IFRS 15). The new revenue standard will supersede all current requirements on revenue recognition according to IFRS. For annual periods beginning on or after 1 January 2018, either complete retrospective adoption or modified retrospective adoption is required with early application permitted. The Group has started to analyse its income streams in accordance with the requirements of IFRS 15. A final statement regarding the impact cannot be made yet.

### Amendment to IAS 16 and IAS 38: Clarification of Acceptable Methods of Depreciation and Amortisation

The amendments specify the principle contained in IAS 16 and IAS 38 that revenue reflects the operation of a business (to which an asset belongs) rather than the consumption of the economic benefit of an asset. As a result, a revenue-based method cannot be applied for the depreciation of property, plant and equipment, but only — and only in very limited circumstances — for the amortisation of intangible assets. The amendments are to be adopted prospectively for annual periods beginning on or after 1 January 2016 with early application permitted. The Group expects that the first-time adoption of the amendment will not have a material impact on the financial position, cash flows and results of operations.

#### Amendments to IAS 1: Disclosure Initiative

The amendments to IAS 1 Presentation of Financial Statements are more of a clarification than a substantial amendment of the existing requirements of IAS 1. The amendments specify the following:

- The materiality considerations in IAS 1.
- Certain items in the consolidated statement of income, the consolidated statement of comprehensive income and the statement of financial position can be disaggregated.
- Entities may freely choose in which order to present the disclosures in the notes.

The shares of equity-accounted associates and joint ventures in other comprehensive income should each be presented in single line items, subdivided according to whether or not it these items will subsequently be reclassified to profit or loss. In addition, the amendments clarify which requirements apply for the presentation of additional subtotals in the statement of financial position, the consolidated statement of income and in other comprehensive income. These amendments are to be adopted for financial years beginning on or after 1 January 2016 with early application permitted. These amendments primarily include conceptual clarification and are therefore not expected to affect the consolidated financial statements.

#### IFRS Improvements Cycle (2012-2014)

IFRS Improvements Cycle 2012—2014 is a collective standard, which was published in September 2014 and addresses amendments made to different IFRS. The amendments from this project are to be adopted for the first time for financial years beginning on or after 1 January 2016. The Group expects that the first-time adoption of the amendment will not have a material impact on the financial position, cash flows and results of operation.

#### IFRS 16 Leases

In January 2016, the IASB issued the new standard on lease accounting. This requires lessees to recognise the right of use to the leased asset and a corresponding lease liability for most leases. For lessors, however, there are only minor changes to the classification and recognition of leases required under IAS 17. IFRS 16 requires additional disclosures both for lessees and lessors. IFRS 16 applies for the first time for financial years beginning on or after 1 January 2019. Early adoption is permitted provided that IFRS 15 Revenue from Contracts with Customers is already applied or applied at the same time as IFRS 16. The Group intends to adopt the new standard when it becomes mandatory. The application is expected to result in an increase in total assets. However, the precise scope of the effects is yet to be determined.

### B. MATERIAL RECOGNITION AND MEASUREMENT PRINCIPLES

#### 1 SCOPE OF CONSOLIDATION

The consolidated financial statements of Biotest AG include all material subsidiaries, which consist of three (previous year: three) domestic and 13 (previous year: 13) foreign companies, in which Biotest AG directly or indirectly holds the majority of voting rights.

As in the previous year, BioDarou P.J.S. Co., with its registered offices in Tehran, Iran, is included in the consolidated financial statements as an associate and recognised at equity.

The shareholdings of Biotest AG as defined under Section 313 (2) of the German Commercial Code (HGB) are listed in Section F10 Participating interests.

#### 2 CONSOLIDATION METHODS

The closing date for Biotest AG and all companies included in the financial statements is 31 December 2015. The financial statements of the consolidated companies were prepared using uniform accounting and measurement methods as prescribed by Biotest AG.

Intra-Group sales, expenses and income as well as all receivables and liabilities between consolidated companies have been eliminated.

The Group controls an investee if and only if it has all of the following elements:

- power over the investee (i.e. the Group has the ability on the basis of existing rights to direct those activities of the investee that significantly affect its returns),
- exposure, or rights, to variable returns from its involvement with the investee, and
- ability to exert power over the investee to affect the amount of the investee's returns.

If the Group does not hold a majority of the voting rights or similar rights in the investee, it takes all facts and circumstances into account in assessing whether it has power over this investee. These include:

- contractual arrangements with other holders of voting rights,
- rights arising from other contractual arrangements,
- · voting rights and potential voting rights of the Group.

A subsidiary is consolidated from the date on which the Group acquires control of the subsidiary. It is deconsolidated if the Group loses control of the subsidiary. Assets, liabilities, income and expense of a subsidiary acquired or disposed during the reporting period are recognised in the statement of financial

position and consolidated statement of comprehensive income from the date on which the Group acquires control of the subsidiary until the date on which control is lost.

Any change in the ownership interest in a subsidiary that does not result in a loss of control is accounted for as an equity transaction. If a parent loses control of a subsidiary, the following steps are carried out:

- derecognition of the assets (including goodwill) and liabilities of the subsidiary,
- derecognition of the carrying amount of the non-controlling interests in the former subsidiary,
- derecognition of the cumulative exchange differences recognised directly in equity,
- recognition of the fair value of the consideration received,
- · recognition of the fair value of the investment retained,
- recognition of surpluses and deficits through profit or loss,
- reclassification to profit or loss, or transfer directly to retained earnings, of the components of other comprehensive income attributable to the parent as would be required if the Group had directly disposed of the related assets and liabilities.

Business combinations entered into after 1 January 2010 are consolidated using the purchase method in accordance with IFRS 3 (revised 2008). Under this method, the cost of a business combination is measured as the sum of the consideration transferred, measured at fair value at the acquisition date, and the non-controlling interest in the acquiree. For each business combination, the acquirer measures the non-controlling interests in the acquiree either at fair value or its corresponding share of the identifiable net assets of the acquired company. Costs incurred in connection with the business combination are expensed. The agreed contingent consideration is recognised at fair value at the acquisition date. Subsequent changes in the fair value of contingent consideration representing an asset or liability are recognised either through profit or loss or directly in equity as accumulated other comprehensive income. Contingent consideration classified as equity is not remeasured and its subsequent

settlement is accounted for in equity. For successive business combinations, equity in the acquiree previously held by the acquirer is remeasured at fair value at the time of acquisition and the resulting profit or loss is recognised in income.

Non-controlling interests are the portions of profit or loss for the period and of the net assets of Biotest Grundstücksverwaltungs GmbH attributable to interests not wholly owned by Biotest Group. Non-controlling interests are disclosed as a separate item in the consolidated statement of income and the statement of financial position.

Investments in associates are recognised using the equity method in accordance with IAS 28. Under the equity method, investments in associates are recognised on the statement of financial position at cost plus post-acquisition changes in the shares held by the Group in the net assets of the company accounted for under the equity method.

The Group's share in the success of the associate is reported separately in the profit for the period. Changes disclosed directly in the equity of the associate are recognised by the Group in the amount of its share and, if applicable, in the consolidated statement of changes in equity. Goodwill arising on the acquisition of an associate is included in the amortised carrying amount of the associate or jointly-controlled entity and is neither amortised nor tested separately for impairment.

After applying the equity method, the Group determines whether it is necessary to record an additional impairment on investments in associates. On each reporting date, the Group determines whether objective evidence exists that the investments in associates could be impaired. If this is the case, the difference between the fair value of the investment and the carrying amount of the investment is recognised in income as an impairment loss.

According to IAS 28 "Investments in Associates", the amount recognised for the investment should include the cost of purchase and any other financial exposure (such as loans).

#### **3 CURRENCY TRANSLATION**

The functional currency concept applies to currency translation. The subsidiaries included in the Biotest Group conduct their operations independently and the functional currency of these companies is therefore the respective local currency. When translating the annual financial statements of the subsidiaries whose functional currency is not the euro, assets and liabilities are translated using the mean rate of exchange prevailing as of the reporting date, and income and expense are translated at the average annual rate. The resultant accumulated differences are recognised directly in a separate item in equity, which is disclosed under reserves in the statement of financial position.

Under IAS 21 "The Effects of Changes in Foreign Exchange Rates", goodwill as asset of the economically independent foreign subsidiaries is translated using the prevailing exchange rate as of the reporting date.

The following exchange rates were applied to currency translation within the Biotest Group:

	Average exchange rates		Closing	rates
1 euro equals	2015	2014	31. 12. 2015	31. 12.2014
US dollar	1.1096	1.3288	1.0887	1.2141
UK pound	0.7260	0.8064	0.7340	0.7789
Russian ruble	68.0068	51.0113	80.6736	72.3370
Swiss franc	1.0676	1.2146	1.0835	1.2024
Hungarian forint	309.90	308.71	315.98	315.54
Brazilian real	3.6916	3.1228	4.3117	3.2207

Monetary items (cash and cash equivalents, receivables and liabilities) denominated in foreign currency in the consolidated companies' individual statements of financial position are recognised in local currency at the exchange rate as of the reporting date. Income and expense resulting from currency translation are reported as financial expense or financial income.

An exception is the recognition directly in equity of exchange differences arising on a net investment in a foreign operation in accordance with IAS 21.15, 21.32 and 21.33.

Non-monetary items denominated in foreign currencies are recognised at historical cost.

#### **4 INTANGIBLE FIXED ASSETS**

#### A) GOODWILL

Goodwill arises in the acquisition of companies or shares in companies and is the difference between the cost of purchase (purchase price) and the fair values of the assets and liabilities acquired. Goodwill is recognised at cost of purchase. The goodwill disclosed is tested at least annually for impairment and, if appropriate, written down in accordance with IAS 36 "Impairment of Assets". Whenever there is concrete evidence of impairment, an additional test for impairment is performed.

Goodwill is allocated to a group of cash-generating units. These groups of cash-generating units are equivalent to the segments and projects of the Biotest Group. In cases where goodwill represents a portion of the cash-generating unit and a part of the business division of this unit is sold, goodwill attributable to the divested business division is included in the carrying amount of the business division when determining the net income from the sale of the division. The value of the divested portion of goodwill is determined based on the relative values of the divested business and the remaining portion of the cash-generating unit.

An impairment loss is recognised through profit or loss if the recoverable amount of the asset or the cash-generating unit is below the carrying amount. The recoverable amount is the maximum of fair value, less selling costs and value in use. For the purpose of impairment testing, the allocable future cash flows of the cash generating units are used to calculate their value in use on the basis of the discounted cash flow method. Under this method, cash flows are discounted based on multi-year business projections and a long-term growth rate forecast. The growth rate depends on the business under review. The discount rates applied after tax are based on the relevant WACC (Weighted Average Cost of Capital). Any write-downs required are determined by comparing the carrying amount of the cash

generating unit with the recoverable amount. An appropriate valuation model based on the discounting of future cash flows is used to determine fair value less selling costs. In order to ensure that the results are objective, valuation multiples, stock quotes, exchange-traded shares in companies or other available indicators are used to determine fair value.

#### B) OTHER INTANGIBLE FIXED ASSETS

Other intangible assets acquired are recognised at cost and divided into assets with a finite useful life and assets with an indefinite useful life. Assets with a finite useful life are amortised on a straight line basis over their estimated useful life. If necessary, impairment losses are recognised in accordance with IAS 36. Useful life applied in this case ranges from 3 to 10 years.

The amortisation period and the amortisation method applied to an intangible asset with a finite useful life are reviewed at the end of each financial year at least. If there is a change in the anticipated useful life of the asset or anticipated amortisation period of the asset, another amortisation period or amortisation method is to be selected. Such changes are treated as changes to estimates. Amortisation of intangible assets with a finite useful life is recorded in the consolidated statement of income under the expense category corresponding to the function of the intangible asset.

Intangible assets with an indefinite useful life or intangible assets whose amortisation period has not yet begun are subject to an impairment test at least once a year at the cash generating unit level. Whenever there is concrete evidence of impairment, an additional test for impairment is performed. These assets are not subject to scheduled amortisation. The useful life of these intangible assets is to be reviewed at least once a year to ensure that the indefinite useful life assessment is still justified. If this is not the case, the indefinite useful life is reassessed as a finite useful life on a prospective basis.

Impairment testing is performed on the basis of future cash flows allocated to the cash generating units; to test impairment, their recoverable amount is calculated as the value in use using the discounted cash flow method. Under this method, cash flows are discounted based on multi-year business projections and a long-term growth rate forecast. The growth rate depends on the business under review. The discount rates applied after tax are based on the relevant WACC (Weighted Average Cost of Capital). Any write-downs required are determined by comparing the carrying amount of the cash generating unit with the recoverable amount.

#### 5 PROPERTY, PLANT & EQUIPMENT

Property, plant and equipment are recognised in accordance with the cost of purchase model at cost of purchase or production cost less accumulated scheduled depreciation and amortisation and accumulated impairment losses. Depreciation is allocated on a straight line basis over the expected useful life, which is estimated as follows:

Buildings	up to 50 years
Technical equipment and machinery	5–12 years
Operating and office equipment	3-10 years

If necessary, an impairment loss is recognised in accordance with IAS 36. If impairment is indicated, the carrying amounts of property, plant and equipment are compared against the corresponding recoverable amounts.

Production costs for self-constructed property, plant and equipment include material and personnel costs as well as an appropriate share of overhead costs. Ongoing repair and maintenance expenses are recognised through profit or loss when incurred. Extensions and material improvements are capitalised. Interest

on borrowed funds is recognised as an expense provided it is not applicable to the production of qualified assets in accordance with IAS 23. Government grants reduce cost of purchase or production costs.

#### 6 LEASING

Whether or not an agreement constitutes or contains a leasing relationship is determined based on its economic content. For this purpose, an assessment is required as to whether fulfilment of the contractual agreement is dependent on the use of a specific asset or specific assets and whether the agreement grants the right to use the asset (IFRIC 4).

If fixed assets are rented or leased and the Biotest Group bears a substantial portion of the risks and rewards associated with the leased assets, such contracts are classified as finance leases. These are recognised in accordance with IAS 17 "Leases" at the lower of fair value or the present value of the minimum lease payments at the time the agreement is concluded. Amortisation and depreciation are recognised over the expected useful life or shorter contract term. If necessary, impairment losses are recognised in accordance with IAS 36. Future lease payment obligations are recognised as liabilities accordingly. The interest element of lease payments is recognised through profit or loss as interest expense over the term of the lease agreement.

If all of the relevant risks and rewards associated with the leased item are not transferred to the Biotest Group under the lease agreement, the lease is classified by the lessor as an operating lease. In this case, lease payments are amortised over the term of the lease on a straight-line basis through profit or loss.

#### 7 IMPAIRMENT

Should facts or circumstances indicate a need for impairment of long-lived assets or should an annual impairment test of an asset be required, the recoverable amount, which represents the higher of either the net realisable value or value in use, is determined

The recoverable amount is determined for each individual asset, unless the asset does not generate cash flows independently (to the greatest extent possible) of cash flows from other assets or other groups of assets.

To determine the value in use, the estimated future cash flows are discounted to their present value at a pre-tax discount rate reflecting current market expectations with regard to the interest rate effect and the specific risks of the asset.

If the recoverable amount is below the carrying amount, the value of the asset is considered impaired and is written down to the recoverable amount.

Impairment expenses are recognised in the expense categories corresponding to the function of the impaired asset.

If the estimated recoverable amount is higher than the carrying amount, impairments are reversed up to an amount not greater than the amortised cost of purchase or production costs, except in the case of goodwill.

#### **8 INVENTORIES**

Inventories are recognised at cost of purchase or production costs or the lower net realisable value as of the reporting date. The latter corresponds to the estimated selling price which may be recovered in the course of ordinary business, reduced by expected completion or selling costs. Production costs are determined using the "first in first out" or weighted average method. In addition to directly allocable individual costs, pursuant to IAS 2 "Inventories", production costs include an appropriate share of overhead costs directly allocable to the production process. These are based on the normal capacity of the manufacturing plants excluding costs for borrowed capital.

#### 9 TRADE RECEIVABLES AND OTHER ASSETS

Trade receivables and other assets are recognised at their nominal value. Accounts receivable denominated in foreign currencies are translated at the closing rates prevailing as of the reporting date. Foreign exchange gains or losses are recognised through profit or loss. Default and transfer risks are accounted for through the recognition of allowances. These allowances are determined on the basis of experience and individual risk assessments. An allowance is recognised if there is an objective and substantial indication that the Group will not be in a position to collect all or part of the receivables. Receivables are written off as soon as they become irrecoverable.

Accounts receivable that arise through the application of the percentage of completion method are disclosed less payments on account if the production costs already incurred, including the profit portion, exceed the payments on account received.

#### 10 OTHER FINANCIAL ASSETS

Financial assets are measured at fair value or cost of purchase at the time of initial recognition. In the case of financial assets that are not subsequently measured at fair value through profit or loss, the transaction costs attributable to the acquisition are capitalised. The fair values recognised in the statement of financial position generally correspond to the market prices of the financial assets. Where these are not readily available, fair values are calculated applying recognised valuation models and are based on current market parameters. Already established cash flows or those calculated based on forward rates using the current yield curve are discounted to the reporting date using discount factors determined on the basis of the yield curve applicable on the reporting date. The mean rates are applied.

#### 11 CASH AND CASH EQUIVALENTS

Cash and cash equivalents comprise cash and current account balances, cheques and financial investments realisable at short notice with original maturities of less than three months and are recognised at their nominal value.

#### 12 PENSION PROVISIONS

The Biotest Group operates several defined contribution and defined benefit pension plans.

Commitments under defined contribution plans are determined by contributions to be made in the period, so that in this case no actuarial assumptions are required.

Defined benefit plans are measured on the basis of actuarial opinions in accordance with the projected unit credit method. The pension costs for the financial year are forecasted at the beginning of the financial year based on approaches determined at that time. The included parameters (interest rate, staff turnover rate, salary increases, etc.) are anticipated values.

All actuarial gains and losses are recognised directly in equity in accordance with IAS 19.

Past service cost arising during a financial year as a result of a retroactive change to pension commitments is recognised immediately and in full.

#### 13 OTHER PROVISIONS

In accordance with IAS 37, provisions are recognised when there is a present (legal or constructive) obligation arising out of a past event and it is probable that this will result in an outflow of resources to settle the obligation and a reliable estimate can be made of the outflow of resources. Provisions are measured at the most probable amount. Provisions with an expected time for settlement of more than twelve months after the reporting date are recognised at their present value.

Provisions are discounted using a pre-tax interest rate reflecting the specific risks of the liability. Increases in provisions due to the passage of time are recorded as interest expense.

In addition, obligations under the Biotest Group's share-based remuneration system, which are recognised in accordance with IFRS 2, are disclosed under other provisions. Costs incurred as a result of cash-settled transactions are initially measured using a Monte Carlo simulation at fair value at the time incurred. Fair value is distributed through profit or loss over the period until the date of first possible exercise as a corresponding liability. The liability is remeasured at each reporting date and on the settlement date. Changes in fair value are allocated to the functional area costs.

#### 14 FINANCIAL LIABILITIES

Financial liabilities are recognised at the loan amount less transaction costs and subsequently measured at amortised acquisition cost using the effective interest rate method. Any difference between the net loan amount and the repayment value is recognised in the consolidated statement of income over the term of the financial liability.

In the case of an interest subsidy the financial liability is recognised at its net present value without taking the interest subsidy into account. The difference is accrued and amortised over the term in accordance with IAS 20.

#### 15 FINANCIAL INSTRUMENTS

A financial instrument is a contract which results in a financial asset for one company and a financial liability or equity instrument for another company.

Financial assets comprise cash and cash equivalents, trade receivables, other loans granted and accounts receivable, financial investments held to maturity as well as original and derivative financial assets held for trading.

Financial liabilities regularly serve as the basis for repayment claims in cash or cash equivalents or another financial asset. This includes, in particular, bonds and other securitised liabilities, trade payables, liabilities to banks, liabilities from finance leases, promissory notes and derivative financial instruments.

The Biotest Group uses derivative financial instruments such as currency forward transactions and payer swaps to hedge against interest rate and currency risks. Derivative financial instruments are not acquired for trading purposes.

Derivative financial instruments are measured at fair value. The measurement takes both the counterparty default risk and the Group's own default risk into account. The market value is calculated on the basis of market information valid and available on the reporting date.

As the stringent formal criteria for hedge accounting are not met in the Biotest Group, all derivative financial instruments are recognised in accordance with the rules for trading derivatives, despite a hedge being in place from an economic point of view. Derivative financial instruments are initially recognised at cost of purchase, excluding incidental charges, and subsequently measured at market value. Changes in market values are recognised through profit or loss in the consolidated statement of income

A financial asset is derecognised when one of the following conditions is met:

- Contractual rights to cash flows from a financial asset have expired.
- The Group has transferred its rights to receive cash flows from that asset to a third party or has taken on a contractual obligation to immediately pass on cash flows to a third party under a so-called pass-through agreement and thus has either (a) transferred all material opportunities and risks associated with ownership of the financial asset or (b) neither transferred nor withheld material opportunities and risks associated with the financial asset but transferred control of the asset.

If the Group transfers its contractual rights to cash flows from an asset or enters into a pass-through agreement, thus neither transferring nor withholding all material opportunities and risks associated with ownership of that asset but retaining control of the asset, the Group recognises the asset to the extent of its continuing involvement.

#### **16 REVENUE**

#### Sale of goods:

Revenue from the sale of products is recognised at the time of transfer of economic ownership, that is at the time of transfer of the risks and rewards to the purchaser, based on the corresponding contractual agreements less any discounts and VAT.

#### Provision of services:

Sales from the services business are recorded by the Biotest Group at the time the services are rendered. Service agreements from which the result can be reliably estimated are recognised using the percentage of completion method in accordance with IAS 18 "Revenue". The service provided, including the pro rata result, is recognised as revenue based on percentage of completion. The percentage of completion to be recognised is determined based on expenses incurred (cost to cost method). Contracts are disclosed under receivables or liabilities using the percentage of completion method.

In individual cases where accumulated performance (contract cost and contract result) exceeds payments received on account, construction contracts are disclosed as assets under receivables using the percentage of completion method. Any negative balances remaining after deducting payments received are disclosed as liabilities under construction contracts using the percentage of completion method. Anticipated contract losses determined on the basis of discernible risks are covered by write-downs or provisions.

Revenue from non-repayable fees for providing technology, fees for the use of technology and licence fees have been accounted for using the percentage of completion method.

# Revenue recognition for multiple-component agreements:

Sales of products and services may include multiple delivery and service components. In these cases, the Company will determine whether more than one accounting item exists. A transaction will be separated if (1) the delivered component(s) offer an independent benefit for the customer, (2) the fair value of the still-undelivered component(s) can be reliably measured and (3) in the case of a general right to return the delivered component(s), delivery or performance of the still-undelivered component(s) is likely and essentially controllable by the Company. If all three criteria are met, Biotest will use the revenue recognition method applicable to each separate accounting item.

# 17 RESEARCH AND DEVELOPMENT COSTS

Research costs are recognised as expenses at the time incurred. Development costs are also generally recorded as expenses at the time incurred, as it is not sufficiently certain that products will be marketable or that production processes can be used until they have been approved by the authorities, and such authorisation is typically granted only at the end of the development process. Therefore, the requirements for capitalisation pursuant to IAS 38 "Intangible Assets" are not met entirely. Development expenses incurred after approval is received by the authorities are not material.

#### **18 GOVERNMENT GRANTS**

Government grants are recognised if there is reasonable assurance that the grant will be received and the entity will comply with any attached conditions. Cost-based grants are recognised systematically as income over the same period as the related costs, intended to compensate, them. Grants for an asset are recognised through profit and loss over the estimated useful life of the related asset.

### 19 FINANCIAL INCOME AND FINANCIAL EXPENSES

Interest is recognised as expense or income at the time incurred. The interest component of lease payments under finance leases is determined using the effective interest rate method and recognised as interest expense. The effective interest rate method uses the rate that discounts the future cash flows over the expected life of the financial instrument to the net carrying amount of the financial asset. All income and expenses arising from currency translation are recognised in the financial result. In accordance with IFRS 7, interest on financial instruments is also disclosed separately.

#### 20 TAXES

Actual tax assets and tax liabilities for the current period and for earlier periods are to be measured at the amount of the expected refund from or payment to the tax authorities. The amount is calculated based on tax rates and tax legislation reflecting the respective national tax regulations of the countries in which Biotest Group companies operate.

Deferred taxes are recognised for all deductible temporary differences, so far unused tax loss carryforwards and unused tax credits to the extent that it is probable that taxable income will be available against which the deductible temporary differences and so far unused tax loss carryforwards and tax credits can be offset.

The carrying amount of deferred tax assets is reviewed on each reporting date and reduced by the amount by which it is no longer probable that sufficient taxable income will be available to at least partially offset the deferred tax asset. In addition, unrecognised deferred tax assets are reviewed on each reporting date and recognised to the amount to which it has become probable that future taxable income will allow the deferred tax asset to be realised.

Current tax rates or rates already adopted by parliament are used to determine both current tax expense and deferred taxes.

Deferred tax assets and deferred tax liabilities are offset against each other if there are enforceable claims for offsetting actual tax refund claims against actual tax liabilities and these claims apply to income taxes of the same tax subject levied by the same tax authority.

#### 21 DETERMINATION OF FAIR VALUE

The Group measures financial instruments, for example derivatives, at fair value at each reporting date. Fair values of financial instruments measured at amortised cost are shown in Section F3 Determination of fair value.

Fair value is the amount for which an asset could be exchanged, or a liability settled, in an arm's length transaction on the measurement date. In determining the fair value it is assumed that the transaction under which the asset is sold or the liability is transferred occurs in either

- the principal market for the asset or liability, or
- the most advantageous market for the asset or liability in the absence of a principal market.

The Group must have access to the principal market or most advantageous market.

The fair value of an asset is measured based on assumptions that market participants would use when pricing the asset or liability. This assumes that market participants act in their best economic interests.

The measurement of a non-financial asset must reflect the market participant's ability to generate economic benefits through the highest and best use of the asset or through its sale to another market participant who finds the highest and best use for the asset.

The Group uses valuation techniques that are appropriate in the prevailing circumstances and for which sufficient data is available for determining the fair value. The use of crucial observable inputs is to be kept as high as possible and that of unobservable inputs as low as possible.

The financial instruments recognised at fair value in the statement of financial position are to be assigned under IFRS 7.27A to a three-level fair value measurement hierarchy. The level reflects the proximity to the market of the data used to calculate fair value. The fair value hierarchy levels are described below:

- **Level 1:** quoted prices for identical assets or liabilities in active markets.
- **Level 2:** information other than quoted prices that is directly (such as prices) or indirectly (such as derived from prices) observable, and
- **Level 3:** information on assets and liabilities that is not based on observable market data.

In the case of assets and liabilities recognised in the financial statements on a recurring basis, the Group determines whether reclassifications between the hierarchy levels have occurred by reviewing the classification (based on the input parameter of the lowest level that is material as a whole for fair value measurement) at the end of each reporting period.

In order to meet the fair value disclosure requirements, the Group has established groups of assets and liabilities based on their nature, characteristics and risks as well as on the fair value hierarchy levels explained above.

### 22 UNCERTAIN ESTIMATES AND ACCOUNTING JUDGEMENTS

Preparation of the financial statements requires certain estimates to be made as part of the recognition and measurement of assets and liabilities under IFRS. These estimates affect the amount and disclosure of assets and liabilities and income and expenses recognised during the reporting period. Estimates and assumptions represent judgements by the management. These are reviewed on an ongoing basis. Changes are prospectively recognised in the reporting period or in future periods. Assumptions and estimates are made particularly in connection with the measurement of goodwill, provisions, allowances for bad debt and inventories, the write-off of receivables under factoring agreements, the measurement of share-based payments as well as the determination of fair values.

In making judgements, the management relies on past experience, assessments by experts (lawyers, rating agencies, trade associations) and the results of a careful weighing of different scenarios. Developments that deviate from these assumptions and are beyond the management's control may cause actual amounts to differ from original estimates. If actual developments deviate from anticipated developments, assumptions and, if necessary, the carrying amounts of the assets and liabilities in question are adjusted accordingly. The management has indicated that future events often vary from forecasts and that estimates require routine adjustment.

The key assumptions and parameters underlying the estimates and judgements made are explained in the notes for each situation.

#### C. SEGMENT REPORTING

The information disclosed in the segment report has been prepared in accordance with IFRS 8 "Operating Segments". Segmentation at the Biotest Group is carried out on the basis of products and services in accordance with the internal reporting system. At Biotest AG, the chief operating decision maker within the meaning of IFRS 8 is the Board of Management.

Segment information made available to the chief operation decision maker in the course of the year is based on IFRS amounts and primarily comprises information up to and including operating profit (EBIT). Operating profit is used as a measure of segment performance.

The Biotest Group is divided into the following segments: Therapy, Plasma & Services and Other Segments.

The business segments of the Biotest Group are as follows:

The **Therapy segment** essentially combines the former Plasma Proteins and Biotherapeutics segments. It therefore comprises the development and production of blood plasma-based immunoglobulins, clotting factors and albumins, which are used for diseases of the immune system, haematological diseases and in intensive care medicine. It also includes the preclinical and clinical development of monoclonal antibodies, for the treatment of rheumatoid arthritis and multiple myeloma amongst others.

The **Plasma & Services segment** includes the areas of plasma sales and toll manufacturing.

Other Segments is a reporting segment divided into an operationally active Merchandise business segment and a non-operational Corporate segment. Expenses for the overall management of the Group as well as other income and expenses, which by their nature cannot be allocated to the segments Therapy or Plasma & Services, are combined under Corporate.

The Biotest Group currently receives income from service and rental agreements with Bio-Rad Medical Diagnostics GmbH, Dreieich, Germany, for a previously sold business division. The income and expenses from these services and rental agreements are disclosed in the current financial year under Other Segments.

#### SEGMENT INFORMATION BY BUSINESS SEGMENT

in € million		Therapy	Plasma & Services	Other Segments	Total
Revenue with third parties	2015	411.4	169.7	8.5	589.6
	2014	409.8	157.0	15.2	582.0
Operating profit (EBIT)	2015	-97.2	27.6	-2.2	-71.8
	2014	27.5	27.0	-1.1	53.4
Investments in associates	2015	3.5	-	_	3.5
	2014	1.3			1.3
Capital expenditure	2015	108.7	1.2	_	109.9
	2014	44.4	2.4	0.3	47.1
Depreciation and amortisation	2015	23.9	4.0	1.4	29.3
	2014	26.2	4.8	1.5	32.5
Impairment	2015	64.9	_		64.9
	2014	_	_	_	_

# RECONCILIATION OF TOTAL SEGMENT RESULTS TO EARNINGS AFTER TAXES OF THE BIOTEST GROUP

in € million	2015	2014
Operating profit (EBIT)	-71.8	53.4
Financial income	38.4	21.4
Financial expenses	-42.9	-27.9
Income from associated companies	2.0	_
Earnings before taxes (EBT)	-74.3	46.9
Income taxes	-8.2	-27.7
Earnings after taxes (EAT)	-82.5	19.2

#### SEGMENT INFORMATION BY REGION

		Revenue with third parties by customer's geographical location		Revenue with third parties based on company's headquarters	
in € million	2015	2014	2015	2014	
Europe	293.0	294.1	421.2	461.7	
Americas	135.9	108.7	168.4	120.3	
Other Asia and Pacific	42.5	26.9	_	_	
Middle East and Africa	118.2	152.3			
Biotest Group	589.6	582.0	589.6	582.0	
thereof:					
Germany	123.3	106.0	345.3	380.6	
Rest of world	466.3	476.0	244.3	201.4	
thereof USA	123.8	100.3	167.6	119.7	

There is no significant trade between the individual segments.

# D. EXPLANATORY NOTES TO THE CONSOLIDATED STATEMENT OF INCOME

#### 1 REVENUE

in € million	2015	2014
Products of the Biotest Group	534.5	494.0
Toll manufacturing	44.0	64.2
Merchandise	8.5	15.2
Revenue from cooperation agreements	2.5	8.5
Other	0.1	0.1
	589.6	582.0

The revenue from cooperation agreements results from an upfront payment received under the agreement for the worldwide development and marketing of the monoclonal antibody tregalizumab (BT-061), which was terminated by AbbVie in June 2015. As the upfront payment of USD 85.0 million relates primarily to research activities still to be carried out, most of the amount was recognised as deferred revenue. Income is recognised under the percentage of completion method. The Biotest Group recognised  $\in$  2.5 million through profit and loss for research services provided in the 2015 financial year (previous year:  $\in$  6.9 million). In the previous year, income realised from the production of clinical trial material in the amount of  $\in$  1.6 million was also included in revenue from cooperation agreements.

Revenue from products of the Biotest Group also includes revenue from the sale of plasma.

### 2 COST OF MATERIALS

in € million	2015	2014
Raw materials and supplies	208.5	186.5
Services purchased	33.9	33.5
	242.4	220.0

#### **3 PERSONNEL EXPENSES**

in € million	2015	2014
Wages and salaries	129.7	113.7
Social security contributions	24.2	20.3
Pension costs	5.0	4.2
	158.9	138.2

Personnel expenses include expenses resulting from the termination of employment in the amount of  $\leq$  2.3 million (previous year:  $\leq$  1.0 million).

The average number of employees, converted to full-time equivalents, is 2,224 in the 2015 financial year (previous year: 2,129). The Biotest Group employs 2,271 staff, converted to full-time equivalents, as of 31 December 2015 (previous year: 2,158).

The Biotest Group had 2,443 employees as of 31 December 2015 (previous year: 2,332).

Employees are allocated to the operating divisions as follows:

in full time equivalents	2015	2014
Production	1,612	1,516
Administration	265	231
Distribution	213	203
Research and development	181	208
	2,271	2,158

#### **4 RESEARCH AND DEVELOPMENT COSTS**

Expenses for research and development totalling € 98.8 million (previous year: 67.2 million) are recognised in full in the consolidated statement of income.

#### 5 OTHER OPERATING INCOME

in € million	2015	2014
Income from service agreements	1.6	2.6
Insurance reimbursements and other refunds	0.3	0.4
Reversal of other provisions	0.2	0.7
Reversal of write-downs	0.1	0.1
Gains from the disposal of fixed assets		0.3
Derecognition of liabilities		0.9
Other	0.5	2.0
	2.7	7.0

Income from service agreements primarily relates to a contract signed after the sale of the former Medical Diagnostics division.

In the 2015 financial year, the Biotest Group recognised through profit and loss government grants of  $\in$  0.4 million (previous year:  $\in$  0.6 million), of which  $\in$  0.3 million (previous year:  $\in$  0.2 million) relate to wage subsidies and wage replacement benefits and  $\in$  0.1 million (previous year:  $\in$  0.4 million) to grants for research and development projects. Grants for research and development projects are included in research and development costs.

The Biotest Group as lessor generated € 0.2 million in income from operating leases in the 2015 financial year (previous year: € 0.6 million). Lease agreements in force until 2015 give rise to future lease income of € 0.1 million for the 2016 financial year. From today's perspective, no further lease income will incur for the subsequent four financial years (2017 to 2020) nor for the period from 2021. Income from operating leases mainly results from the temporary leasing of land and buildings currently not used in a business context.

#### 6 OTHER OPERATING EXPENSES

in € million	2015	2014
Expenses incurred in connection with service agreements	2.2	3.9
Losses from the disposal of fixed assets	0.7	0.5
Donations	0.4	0.4
Additions to provisions		0.1
Other	0.3	0.2
	3.6	5.1

#### **7 FINANCIAL INCOME**

in € million	2015	2014
Income from currency translation	36.7	19.9
Interest income	1.3	1.3
Other	0.4	0.2
	38.4	21.4
Thereof: financial instruments of measurement categories according to IAS 39:		
Loans and receivables (LaR)	11.3	0.7
Financial liabilities measured at amortised cost (FLAC)	1.2	0.1
Financial assets held for trading (FAHfT)	1.5	0.4
Financial liabilities held for trading (FLHfT)	3.3	0.4

Income from currency translation includes income from realised foreign exchange gains in connection with foreign currency receivables and payables, income from foreign currency hedging and income from the measurement of foreign currency positions as of the reporting date.

#### **8 FINANCIAL EXPENSES**

in € million	2015	2014
Currency translation expenses	33.4	14.3
Interest expenses	7.3	9.2
Net interest expenses – for pensions	1.3	2.0
Interest rate hedging costs	0.6	1.9
Other	0.3	0.5
	42.9	27.9
Thereof: financial instruments of measurement categories according to IAS 39:		
Financial liabilities measured at amortised cost (FLAC)	10.2	6.7
Financial assets held for trading (FAHfT)	0.8	0.4
Financial liabilities held for trading (FLHfT)	5.2	2.9
Loans and receivables (LaR)	5.6	3.0

Expenses from currency translation include expenses from realised foreign exchange losses in connection with foreign currency receivables and payables as well as expenses from foreign currency hedging.

Reported interest rate hedging expenses include expenses from the measurement of interest rate hedges at fair value, payments on interest rate hedging transactions and fees incurred.

### 9 INCOME FROM ASSOCIATED COMPANIES

Income from associated companies of € 2.0 million (previous year: € 0.0 million) was generated in the 2015 financial year.

### **10 INCOME TAXES**

in € million	2015	2014
Current tax expenses related to the financial year	7.6	14.9
Current tax expenses related to previous years (previous years tax income)	2.2	-0.3
Current taxes	9.8	14.6
Deferred taxes		13.1
Income tax expense	8.2	27.7

Deferred tax expense arising on items credited directly to equity amounted to € 2.3 million (previous year: income of € 4.7 million).

Applying the nominal income tax rate of 29.0 % (previous year: 28.8 %), the expected tax expense for the 2015 financial year differs from the effective amount as follows:

in € million	2015	2014
Earnings before taxes	-74.3	46.9
Expected tax expense	-21.6	13.5
Effect of losses not recognised in the financial year	4.9	2.9
Unrecognised deferred tax assets on temporary differences	28.2	_
Write-downs of deferred tax assets	0.5	9.9
Current tax expenses related to previous years (previous year: tax income)	2.2	-0.3
Tax effect of adjustments to deferred taxes from previous years	-0.5	_
Tax effect of non-deductible expenses	1.7	2.6
Tax effect of the application of foreign tax rates and use of foreign tax losses carried forward	-6.7	-0.6
Tax effect of tax-free income	-0.5	-0.4
Other effects		0.1
Income tax disclosed in the statement		
of income	8.2	27.7

The calculated tax rate of 29.0% is based on a corporation tax rate of 15%, a solidarity surcharge of 5.5% and the weighted trade tax rates of the municipalities of the business premises of Biotest AG.

#### 11 AUDITORS' FEES

On 7 May 2015 the Annual Shareholders' Meeting of Biotest AG appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft as auditor for the 2015 financial year.

Fees payable to the external auditors, Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, totalled € 0.5 million for the 2015 financial year (previous year: € 0.6 million), of which € 0.1 million (previous year: € 0.1 million) relate to the previous year. The fees of € 0.5 million (previous year: € 0.6 million) relate to the financial statement audit, of which € 0.1 million (previous year: € 0.1 million) relate to the previous year.

# E. EXPLANATORY NOTES TO THE STATEMENT OF FINANCIAL POSITION

#### 1 INTANGIBLE ASSETS

All intangible assets are allocated to non-current assets.

		Patents, licenses	Leased	Payments in	
in € million	Goodwill	and similar rights	assets	advance	Total
Cost of purchase					
Balance as of 31 December 2013	29.9	57.7	9.6	2.0	99.2
Additions		0.9		1.6	2.5
Disposals		-2.0			
Book transfers	<u> </u>	0.7		-0.7	
Effect of foreign currency translation differences	3.9	5.6		<u>_</u>	9.5
Balance as of 31 December 2014	33.8	62.9	9.6	2.9	109.2
Additions		1.1		2.5	3.6
Disposals	<u> </u>	-0.2		<u> </u>	
Book transfers	_	1.1	_	-1.2	-0.1
Effect of foreign currency translation differences	3.5	5.2	_	_	8.7
Balance as of 31 December 2015	37.3	70.1	9.6	4.2	121.2
Accumulated depreciation					
Balance as of 31 December 2013	1.1	40.4	9.6	_	51.1
Depreciation for the financial year	_	5.7		_	5.7
Disposals	_	-1.9	_	_	-1.9
Effect of foreign currency translation differences	_	4.1	_	_	4.1
Balance as of 31 December 2014	1.1	48.3	9.6	_	59.0
Depreciation for the financial year	_	1.8		_	1.8
Disposals	_	-0.1	_	_	-0.1
Impairment —	_	12.0		_	12.0
Effect of foreign currency translation differences	-0.3	4.1		_	3.8
Balance as of 31 December 2015	0.8	66.1	9.6	_	76.5
Carrying amount as of					
31 December 2014	32.7	14.6		2.9	50.2
31 December 2015	36.5	4.0		4.2	44.7

Two development projects were acquired in connection with the purchase of the plasma protein division of Nabi Biopharmaceuticals in the 2007 financial year and recognised in the consolidated financial statements as intangible assets. These included a project regarding the intravenous immunoglobulin Bivigam®, which received marketing authorisation in

December 2012, as well as Civacir®, a drug designed to prevent re-infection in the case of liver transplants made necessary due to hepatitis C. Both intangible assets were written off amounting to € 12.0 million (previous year: € 0.0 million) in the 2015 financial year.

The impairment was due firstly to the worse market prospects for the hepatitis C preparation under development Civacir®. Although the interim results of the phase III study for Civacir® were promising and the objectives of the study had been achieved to date, Biotest now expects the market prospects to be substantially reduced, because highly effective antivirals have since been introduced that reduce reinfection rates after a liver transplantation to much less than 30% and that may also be used earlier after a transplantation. Both developments therefore significantly reduce the possible applications of Civacir®. Secondly, impairment was also triggered by declining revenue from the preparation Bivigam® in the months following the better-than-expected development in the first half of 2015. Bivigam® is a polyvalent immunoglobulin from the subsidiary Biotest Pharmaceuticals Corporation, Boca Raton, Florida, USA, which is manufactured and marketed exclusively in the USA. Due to the poor sales, stocks with shorter product shelf-life were written down. These products date back to pre-production for the US market entry Biotest expected two years ago. As a result of the reduced sales, Biotest has already reduced the production of Bivigam® and expects it to take a while until the manufacturing plant is working to capacity. Civacir® was also supposed to be manufactured in the same plant. As significantly lower demand is expected here, Civacir® production also failed to utilise the plant to capacity in the short term. Biotest therefore had to write down manufacturing plants, parts of the buildings and of the intangible assets.

The recoverable amount of the cash generating unit is determined by calculating the value in use based on cash flow forecasts. Finally, in order to determine any need for impairment, the carrying amount of the cash-generating unit is compared to its recoverable amount.

For the impairment test of the goodwill of the Therapy segment a discount rate before tax of 10.30% (previous year: 8.00%) was applied, which is based on the relevant WACC (weighted average cost of capital). A discount rate before tax of 8.15% (previous year: 6.22%) was used for the Plasma & Services segment. Expected cash flows were calculated on the basis of five-year financial forecasts made by management. With regards to value contribution the perpetual annuities will be

added from the year 2021 onwards. Perpetual annuities are based on average values for the years 2016 to 2020. A growth rate of 0.5% (previous year: 1.00%) was applied to perpetual annuities.

The impact of changes in the discount factor applied and a change in the assumed growth rate for the development projects was determined by means of sensitivity analyses. No realistic change in the value of the parameters would lead to impairment of development projects or goodwill.

The carrying amounts of intangible assets subject to an impairment test refer to the following cash generating units:

Cash generating unit	Intangible asset	Carrying amount as of 31 December 2015 in € million	Carrying amount as of 31 December 2014 in € million
Therapy segment	Goodwill	28.2	25.2
Segment Plasma & Services	Goodwill	8.3	7.5
Project	Patents, licenses and similar rights		9.1
		36.5	41.8

Amortisation and impairment losses on intangible assets for the financial year are included in the following items of the consolidated statement of income:

in € million	2015	2014
Cost of sales	2.4	4.2
Marketing and distribution costs	0.1	0.1
Administrative expenses	1.2	1.4
Research and development costs	10.1	
	13.8	5.7

In the 2015 financial year, amortisation of intangible assets includes an impairment of  $\leqslant$  12.0 million (previous year:  $\leqslant$  0.0 million).

### 2 PROPERTY, PLANT AND EQUIPMENT

All assets listed below are allocated to non-current assets.

in € million	Land and buildings	Technical equipment and machinery	Other facilities, office furniture and equipment	Leased assets	Payments in advance	Total
Cost/production cost						
Balance as of 31 December 2013	182.1	172.2	84.6	1.4	17.8	458.1
Additions	3.9	5.1	4.8	<u> </u>	30.8	44.6
Book transfers	8.2	5.2	3.8	-0.6	-16.6	
Disposals	-1.4	-4.6	-6.6			-12.6
Effect of foreign currency translation differences	7.3	6.8	1.4	<u> </u>	0.4	15.9
Balance as of 31 December 2014	200.1	184.7	88.0	0.8	32.4	506.0
Additions	11.5	4.2	6.1	3.8	80.7	106.3
Book transfers	8.3	3.3	4.4	_	-15.9	0.1
Disposals	-0.8	-0.2	-1.2		_	-2.2
Effect of foreign currency translation differences	6.9	7.1	1.8	_	0.3	16.1
Balance as of 31 December 2015	226.0	199.1	99.1	4.6	97.5	626.3
Accumulated depreciation						
Balance as of 31 December 2013	55.7	91.1	55.0	1.4	_	203.2
Depreciation for the financial year	4.7	15.2	6.9	_	_	26.8
Book transfers	_		0.6	-0.6	_	
Disposals	-0.9	-4.3	-6.3	_	_	-11.5
Effect of foreign currency translation differences	0.7	4.0	0.5	_		5.2
Balance as of 31 December 2014	60.2	106.0	56.7	0.8	_	223.7
Depreciation for the financial year	4.7	15.0	7.4	0.1	0.3	27.5
Disposals	-0.3	-0.1	-1.1	_	_	-1.5
Impairment	29.0	20.6	0.7	_	2.6	52.9
Effect of foreign currency translation differences	1.4	4.5	0.6	_	_	6.5
Balance as of 31 December 2015	95.0	146.0	64.3	0.9	2.9	309.1
Carrying amount as of						
31 December 2014	139.9	78.7	31.3		32.4	282.3
31 December 2015	131.0	53.1	34.8	3.7	94.6	317.2

Payments in advance in the financial year 2015 mainly include capital expenditure incurred as part of the expansion of capacity at Dreieich.

The Biotest Group had entered into commitments to acquire fixed assets of € 141.0 million as of 31 December 2015 (previous year: € 33.2 million).

Government grants for the acquisition or production of assets reduce the acquisition cost or production cost. In the financial year,  $\leqslant$  0.0 million (previous year:  $\leqslant$  0.1 million) of this was recognised in profit or loss.

Depreciation of property, plant and equipment for the financial year is included in the following items of the consolidated statement of income:

in € million	2015	2014
Cost of sales	69.0	19.3
Marketing and distribution costs	0.6	0.5
Administrative expenses	6.1	5.8
Research and development costs	4.7	1.2
	80.4	26.8

In the 2015 financial year, depreciation of property, plant and equipment includes impairment of € 52.9 million (previous year: € 0.0 million). The details are described in Section E1.

#### **3 INVESTMENTS IN ASSOCIATES**

Investments in associates relate to a 49% shareholding held by Biotest Pharma GmbH in BioDarou P.J.S. Co., whose registered offices are in Tehran, Iran, and are evaluated using the equity method.

The purpose of the company is to collect plasma, to process it into immunoglobulins, factors and human albumin via Biotest AG and to sell the finished products in Iran.

The investors intend to gradually provide the company with up to € 4.0 million of equity capital. The shareholder resolutions required for this are adopted separately based on financial requirements. To date, Biotest Pharma GmbH has contributed € 1.6 million in capital. The capital of BioDarou P.J.S. Co. amounts to 37.5 billion rials as of 31 December 2015 (previous year: 37.5 billion rials) and is fully paid-in.

As no audited financial statements of BioDarou P.J.S. were available when the consolidated financial statements were prepared, the previous year figures of BioDarou P.J.S. Co. as of 31 December 2014 are reported.

The earnings forecast for BioDarou P.J.S. Co. for the 2015 financial year shows positive results. The appreciation of the rial resulted in a foreign exchange gain of  $\in$  0.5 million (previous year:  $\in$  -0.1 million), which was recognised in other comprehensive income.

The associate had the following assets and liabilities as of the 2014 reporting date:

The value of non-current and current assets amounted to  $\leqslant$  1.0 million (previous year:  $\leqslant$  1.1 million) and  $\leqslant$  21.6 million (previous year:  $\leqslant$  12.5 million), respectively on 31 December 2014.

Non-current and current liabilities were measured at € 0.3 million (previous year: € 0.2 million) and € 15.2 million (previous year: € 10.7 million), respectively on 31 December 2014.

Sales revenue amounted to € 27.5 million (previous year: € 15.9 million) and net income of the company was € 4.2 million (previous year: € 0.0 million) for the 2014 financial year.

BioDarou P.J.S. Co. holds a 60% share of Plasma Gostar Pars (PJS) based in Tehran, Iran.

The political situation in Iran cooled off somewhat in 2015 with the easing of sanctions. The difficult payment situation improved only slightly in the 2015 financial year despite the relaxing of sanctions. The Biotest Group does not expect a permanent restriction on sales of pharmaceutical products in Iran, especially since the sanctions were lifted completely at 16 January 2016.

#### **4 OTHER FINANCIAL ASSETS**

	20	15	20:	14
		thereof non-		thereof non-
in € million	Total	current	Total	current
Promissory notes (Loans and receivables)	20.0		5.0	5.0
Time deposit (Loans and receivables)	65.0	-	-	_
Financial assets as part of the short-term financial disposition (Loans and receivables)	34.9	_	54.7	_
Loans to associated companies (Loans and receivables)	0.7	0.7		_
Receivables from associated companies (Loans and receivables)	0.5	-	1.0	_
Derivative financial instruments (Financial assets held for trading)	0.4			_
Bond funds (Financial assets at fair value through				
profit and loss)	0.1	0.1	0.2	0.2
	121.6	0.8	60.9	5.2

The loans and receivables category contains non-current promissory notes, time deposit, loans to associated companies and financial assets as part of the short-term financial disposition recognised at cost. The financial assets at fair value through profit and loss category include fund units, whose market value as of the reporting date is notified in writing by the custodian bank.

#### 5 DEFERRED TAX ASSETS AND LIABILITIES

Deferred tax assets and liabilities relate to the following items on the statement of financial position:

	Asse	ets	Equity and	liabilities	Recognised profit o	
in € million	2015	2014	2015	2014	2015	2014
Intangible assets	_	_	5.2	2.6	2.2	2.7
Property, plant and equipment	_	_	8.6	11.3	-3.0	-2.8
Other financial assets	1.2	1.1			-0.1	-0.1
Inventories	9.9	11.4	0.1	0.1	1.6	-0.8
Trade receivables	0.1	0.1	11.7	11.5	0.2	9.3
Other provisions	1.1	1.6			0.5	1.1
Financial liabilities	3.6	1.2	0.2	0.3	-2.4	-1.1
Pension provisions	8.5	10.2	0.1		-0.5	0.1
Other liabilities	2.9	3.1	0.9	1.1	0.1	-2.6
Other financial position items	0.4	0.2			-0.2	0.2
Tax credits						4.7
Tax value of the recognised loss carried forward	0.1	0.1				2.4
Total deferred taxes	27.8	29.0	26.8	26.9	-1.6	13.1
Less netting of deferred tax assets and liabilities	-19.1	-15.5	-19.1	-15.5		
Deferred tax assets/liabilities	8.7	13.5	7.7	11.4		

The Group has tax loss carryforwards of € 0.8 million (previous year: € 0.8 million), which are available to various Group companies with and without time limits and can be offset against expected future taxable income of this company or other Group companies. € 0.3 million (previous year: € 0.3 million) of the loss carryforwards recognised are attributable to a tax rate of 31.4% and € 0.5 million (previous year: € 0.5 million) to tax categories with a tax rate of 10.0%.

Deferred taxes are not recognised for tax loss carryforwards of € 37.2 million (previous year: € 23.8 million), as the utilisation of these carryforwards is not sufficiently certain at this time. The unrecognised tax loss carryforwards relate solely to foreign companies. Foreign loss carryforwards of € 2.6 million (previous year: € 3.0 million) may be carried forward indefinitely. Furthermore, € 2.4 million (previous year: € 2.4 million) may be carried forward for up to five years and € 32.2 million (previous year: € 18.4 million) for over five years.

In some countries, the Biotest Group has not yet been issued a final tax assessment by tax authorities for several years. Adequate provisions for pending tax assessments have therefore been recognised.

No deferred tax liabilities (previous year: none) were recognised as of 31 December 2015 for taxes on non-distributed earnings of subsidiaries or associates of the Biotest Group. The Biotest Group has decided not to distribute any undistributed profits of its subsidiaries and associates in the foreseeable future. This is because the Biotest Group has entered an agreement under which the profits of associates will not be distributed until the Biotest Group has granted permission to do so. As of the reporting date, the parent company does not intend to grant such permission. Furthermore, an associate of the Group may only distribute its profits when it has received permission to do so from all shareholders.

Temporary differences relating to investments in subsidiaries and associates for which no deferred taxes are recognised amount to  $\in$  -0.5 million (previous year:  $\in$  0.5 million).

#### **6 INVENTORIES**

in € million	2015	2014
Raw materials and supplies	25.8	42.8
Work in progress	103.8	100.9
Finished goods and merchandise	89.1	102.3
	218.7	246.0

As in the previous year, the Biotest Group has no inventories with a turnover rate of more than one year as of the reporting date

Impairment losses recognised on inventories amounted to  $\in$  39.1 million (previous year:  $\in$  13.1 million); the residual carrying amount of the related inventories was  $\in$  81.3 million (previous year:  $\in$  78.5 million) after write-down to their net realisable value.

#### 7 TRADE RECEIVABLES

Trade receivables are typically due within one year. As in the previous year, none of the receivables totalling € 173.9 million (previous year: € 181.6 million) were classified as non-current. Trade receivables are allocated to the loans and receivables (LaR) category. They are broken down as follows:

in € million	2015	2014
Trade receivables (gross)	188.2	200.3
Sale of trade receivables		
Allowance for bad debts	-3.6	-2.2
Trade receivables (net)	173.9	181.6

The allowance for bad debts is calculated as the difference between the nominal amount of the accounts receivable and the estimated net recoverable amount. For this estimate the Biotest Group uses empirical values relating to the payment behaviour of specific customers and knowledge about country-specific circumstances. When testing the impairment of trade receivables, every change in credit ratings is taken into account since the payment target was granted and up to the reporting date. This applies to changes in country risk and specific customer risk. The Biotest Group only uses specific bad debt charges for determining the allowance for bad debts for trade receivables. A general allowance for bad debts is not recognised.

As of the reporting date, Biotest AG has sold trade receivables totalling € 8.6 million (previous year: € 8.5 million) under factoring agreements. The factoring programme provides for the sale of domestic and foreign receivables of Biotest AG, with each customer having an individual credit limit. Provided that the receivables are legally valid, the factor carries the risk of the customer's inability to pay the receivables purchased.

Biotest Italia S.r.l. sells some of its receivables from Italian customers. Provided that the receivables are legally valid, the factor carries the risk of the customer's inability to pay the receivables purchased (del credere). Receivables of the Italian company totalling  $\in$  2.1 million (previous year:  $\in$  8.0 million) had been sold as of the reporting date. As in the previous year, these receivables were fully derecognised in accordance with IAS 39.

Trade receivables include receivables accounted for the percentage of completion method amounting to  $\in$  30.8 million (previous year:  $\in$  30.7 million). These relate to customer-specific production contracts valued at the related production costs incurred plus a pro rata profit provided that it can be reliably estimated.

Changes in the allowance for bad debts for trade receivables were as follows:

in € million	2015	2014
Balance as of 1 January	2.2	2.4
Additions	1.5	_
Utilisation	-0.1	-0.1
Releases		-0.1
Balance as of 31 December	3.6	2.2

An analysis of the ageing structure of trade receivables shows the following picture:

in € million	2015	2014
Carrying amount	173.9	181.6
Unimpaired and not past due as of the reporting date		142.4
Unimpaired as of the reporting date and past due in the following time bands	_	
< 90 days past due	14.5	24.9
91–180 days past due	3.0	6.8
181 – 365 days past due	1.2	5.3
> 1 year past due	0.6	2.2

The past due receivables of the Biotest Group in the 2015 financial year comprise receivables due to Biotest AG of € 8.9 million (previous year: € 26.4 million), receivables due to Biotest Pharmaceuticals Corp., USA, of € 4.4 million (previous year: € 2.3 million), receivables due to Biotest Medical S.L.U, Spain, of € 2.5 million (previous year: € 3.8 million), receivables due to Biotest Italia S.r.l., Italy, of € 2.0 million (previous year: € 4.8 million) and receivables due to Biotest Hungaria Kft., Hungary, of € 0.5 million (previous year: € 1.5 million).

Net trade receivables are denominated in the following currencies:

in € million	2015	2014
EUR	90.2	97.5
USD	77.4	76.4
GBP	2.1	2.2
RUB	1.6	2.1
HUF	1.3	2.4
Other currencies	1.3	1.0
Trade receivables (net)	173.9	181.6

#### **8 OTHER ASSETS**

	20	015	20	)14
in € million	Total	thereof non- current	Total	thereof non- current
Value-added and other tax receivables	6.6		3.0	
Deferred items	3.9	0.2	4.5	0.1
Payments in advance	1.4	0.2	1.6	0.1
Other assets	2.9	0.6	3.7	0.6
	14.8	1.0	12.8	0.8

Impairment losses recognised on other assets were as follows:

in € million	20	15	2014
Balance as of 1 January		_	0.8
Utilisation			-0.8
Balance as of 31 December		_	

An analysis of the ageing structure of other assets shows the following picture:

2015	2014
14.8	12.8
14.7	12.8
0.1	
_	_
_	_
_	_
	14.8

Other assets are denominated in the following currencies:

in € million	2015	2014
EUR	9.3	7.3
USD	4.6	4.5
GBP	0.1	0.1
HUF	0.5	0.7
Other currencies	0.3	0.2
	14.8	12.8

### 9 CASH AND CASH EQUIVALENTS

in € million	2015	2014
Bank balances	33.6	92.7
Short-term deposits	20.0	86.5
Cash in hand	0.2	0.2
	53.8	179.4

Please refer to the Biotest Group's cash flow statement for details regarding the changes in cash and cash equivalents.

Short-term deposits are time deposits with original maturities of up to three months.

#### 10 EQUITY

At the annual shareholders' meeting on 7 May 2015, Biotest AG adopted a resolution regarding a capital increase from company funds, the redivision of the share capital (share split) and the corresponding amendment to the articles of association. This was carried out as planned in the 2015 financial year. The number of shares in the portfolio holdings was automatically converted to a ratio of 1:3. The trading of the new shares began on 15 July 2015.

Subscribed capital is fully paid in and amounts to € 39,571,452 on 31 December 2015 (previous year: € 33,767,639.04), comprising ordinary shares of € 19,785,726 (previous year: € 16,883,819.52) and preference shares of € 19,785,726 (previous year: € 16,883,819.52). As of 31 December 2015 it was divided into 19,785,726 no-par value ordinary shares and 19,785,726 no-par value preference shares without voting rights. Certification of shares is excluded. The theoretical par value of each share is therefore € 1.00 per share class. Profit distributions in any financial year are based on the net profit of Biotest AG as defined under the German Commercial Code.

In her letter dated 12 February 2008, Dr Cathrin Schleussner advised the Biotest Group that her voting rights interest as of that date was 50.03%. These voting rights are held via OGEL GmbH, Frankfurt/Main. OGEL GmbH is controlled by Dr Cathrin Schleussner. Based on the new rules under Section 41 Paragraph 4d of the German Securities Act (WpHG) in effect from 1 February 2012, Dr Martin Schleussner, Renate Schleussner and Dr Hans Schleussner notified the Biotest Group on 22 February 2012 that, effective 1 February 2012, they each held a 50.27% share in Biotest AG with voting rights reportable under Section 41 Paragraph 4d of the WpHG. The district of Biberach notified the Biotest Group on 26 March 2014 that it holds 19.95% of Biotest AG's ordinary shares. The shares are assignable to the district in accordance with Section 22 (1) sentence 1, No. 1 of the WpHG and are held by the Kreissparkasse Biberach.

The proposed appropriation of net profit for the year 2015 provides for dividend payments of  $\in$  1.2 million (previous year:  $\in$  8.3 million). A dividend of  $\in$  0.02 per share (previous year:  $\in$  0.20 per share) will be paid on the ordinary shares and a dividend of  $\in$  0.04 per share (previous year:  $\in$  0.22 per share) on the preference shares. After the 1:3 share split on 15 July 2015, the previous year's figure for the dividend per share was calculated on the basis of the current number of shares in order to make the figures comparable. In accordance with a resolution passed by the Annual Shareholders' Meeting regarding dividend

payments, preference shares are entitled to have a dividend of  $\in$  0.04 per share if the annual shareholder meeting decides to pay a dividend. Additionally, if holders of ordinary shares receive a dividend of more than  $\in$  0.03 per share, holders of preference shares receive an additional dividend of  $\in$  0.02 per share. If no dividend is paid on preference shares in one year, it shall be paid in the following year. If a dividend is not paid in the second year, preference shares shall receive voting rights (cf. Section 140 (2) of the German Stock Corporation Act (AktG)).

By resolution of the Annual Shareholders' Meeting of 7 May 2015, the Board of Management of Biotest AG was authorised to purchase ordinary and/or preference shares under Section 71 (1) No. 8 of the German Stock Corporation Act (AktG) until 6 May 2020 up to 10% of the share capital as it then was of € 33.8 million.

The share premium amounts to  $\in$  219.8 million (previous year:  $\in$  225.6 million). The change in the share premium is due to the capital increase from company funds carried out in connection with the share split.

Diluted and basic earnings per share are calculated by dividing the profit attributable to shareholders of the parent company by the weighted average number of shares outstanding. Diluted earnings are equivalent to basic earnings at Biotest AG.

in € million	2015	2014
Earnings after taxes	-82.5	19.2
Additional dividend on preference shares	-0.4	-0.4
Profit adjusted for additional dividend rights	-82.9	18.8
Number of shares outstanding (weighted average)	39,571,452	39,571,452
Basic and diluted earnings per ordinary share in €	-2.10	0.48
Additional dividend rights per preference share in €	0.02	0.02
Basic and diluted earnings per preference share in €		0.50

After the 1:3 share split on 15 July 2015, the previous year's figure for the earnings per share in accordance with IAS 33.26 was calculated on the basis of the current number of shares.

No additional transactions involving ordinary shares or potential ordinary shares occurred in the period between the reporting date and the approval of the consolidated financial statements.

## 11 PROVISIONS FOR PENSIONS AND SIMILAR OBLIGATIONS

Benefits are based on the employee's length of service and salary. Retirement benefit obligations relate mainly to employees of the Group's German companies. Similar obligations are foreign obligations payable in a lump sum on retirement and obligations of the Biotest pension savings plan. These plans are voluntary pension plans not subject to statutory or legal obligations. The amount of the pension obligations depends on interest rate movements and life expectancy of the participants.

Assets of € 3.1 million (previous year: € 2.8 million) were held by a trustee, Biotest Vorsorge Trust e.V., during the 2015 financial year under a contractual trust arrangement (CTA) as external insolvency insurance for portions of the occupational pension scheme. Since the transferred funds qualify as plan assets in accordance with IAS 19, provisions for pensions and similar obligations were netted with the transferred assets. As a result, provisions for pensions and similar obligations were reduced accordingly.

The liability arising from the defined pension obligation comprises the following:

in € million	2015	2014
Net present value of defined benefit obligations		
Pension plans	71.0	76.2
Similar obligations	5.6	5.1
	76.6	81.3
Fair value of plan assets		
Pension plans	2.4	2.4
Similar obligations	1.6	1.4
	4.0	3.8
Net defined benefit liability		
Pension plans	68.6	73.8
Similar obligations	4.0	3.7
	72.6	77.5

The costs for the defined benefit plans consist of the following components:

in € million	2015	2014
Current service cost	4.3	3.5
Past service cost	0.7	0.7
Net interest expenses	1.3	2.0
Total expense recognised in profit and loss	6.3	6.2
Actuarial losses/gains due to experience adjustments	-1.6	0.8
Actuarial losses/gains due to changes in financial assumptions	-6.1	15.4
Return on plan assets (excluding amounts included in net interest expenses)	0.1	0.1
Revaluations recognised directly in the statement of comprehensive income	-7.6	16.3
Defined benefit costs	-1.3	22.5

Actuarial gains of € 7.6 million (previous year: losses of € 16.3 million) were recognised directly in equity in the 2015 financial year. Actuarial losses totalling € 25.2 million (previous year: € 32.8 million) had previously been recognised directly in equity.

The following table shows the reconciliation of the present value of the defined benefit obligation (DBO):

in € million	2015	2014
Defined benefit obligation as of 1 January	81.3	61.4
Current service cost	4.3	3.5
Past service cost	0.7	0.7
Interest expense	1.4	2.1
Expenses recognised in the consolidated statement of income	6.4	6.3
Actuarial gains (previous year: losses) due to experience adjustments	-1.6	0.8
Actuarial gains (previous year: losses) due to changes in financial assumptions	-6.1	15.4
Revaluations recognised directly in the consolidated statement of comprehensive income	-7.7	16.2
Pension benefits paid	-3.4	-2.2
Book transfers	_	-0.4
Defined benefit obligation as of 31 December	76.6	81.3

The following table shows the reconciliation of the fair value of plan assets:

in € million	2015	2014
Fair value of plan assets as of 1 January	3.8	2.3
Interest income	0.1	0.1
Expenses recognised in the consolidated statement of income	0.1	0.1
Return on plan assets (excluding amounts included in net interest expense)	-0.1	-0.1
Revaluations recognised directly in the consolidated statement of comprehensive		
income		-0.1
Employer contributions	0.2	1.5
Fair value of plan assets as of 31 December	4.0	3.8

The following benefits are expected to be paid in subsequent years based on the existing pension obligations:

in € million	2015	2014
In the next 12 months	3.4	3.4
Between 2 and 5 years	14.5	14.4
Between 5 and 10 years	21.5	20.0
After 10 years	79.9	79.9
Total expected payments	119.3	117.7

The weighted average term of the defined benefit plans is 13.2 years (previous year: 13.4 years) as of 31 December 2015.

Plan assets were invested in the following asset classes as of the reporting date:

in € million	2015	2014
Reinsurance	0.9	1.0
Cash and cash equivalents	2.8	2.5
Fund units	0.3	0.3
	4.0	3.8

The calculation is based on the following actuarial assumptions:

in %	2015	2014
Discount rate as of 31 December	1.8-2.6	1.4-2.1
Expected return on plan assets	2.6	2.1
Rate of increase for wages and salaries	3.4	3.4
Rate of increase for pensions	1.8	2.0
Labour turnover rate	0.0-7.3	0.0-6.9

Actuarial assumptions are based on empirical values with the exception of the discount rate. The rate of increase for pensions was adjusted to 1.8% due to the persisting low interest rate situation and the emerging price increases (consumer price index).

Under IAS 19.145 the effect of any changes to parameters for the underlying assumptions used to calculate the pension obligations must be disclosed in the sensitivity analysis. Only changes that are realistically expected to occur in the following financial year are to be considered.

The actuarial rate of interest, salary trend, pension trend and life expectancy are regarded as material assumptions. These parameters are shown in the following overview together with information on the parameter changes and their impact on the net present value calculation as of 31 December 2015.

Parameters	Parameter change	Impact on the pension obligation in € million
Rate of interest	Increase by 50 basis points	-4.7
Rate of interest	Decrease by 50 basis points	5.2
Salary trend	Increase by 50 basis points	1.1
Salary trend	Decrease by 50 basis points	-1.1
Pension trend	Increase by 100 basis points	6.6
Pension trend	Decrease by 100 basis points	-5.6
Life expectancy	Increase by one year	2.9

€ 8.2 million (previous year: € 7.7 million) was recognised as expense for defined contribution plans in financial year.

Expenses for defined contribution plans are broken down as follows:

in € million	2015	2014
Defined contribution plans of the company	1.4	1.0
Employer contributions to statutory pension insurance scheme	6.8	6.7
	8.2	7.7

#### 12 OTHER PROVISIONS

in € million	Staff-related provisions	Litigation risks	Provisions for sales agreements	Miscel- laneous provisions	Total	thereof current
Balance as of 31 December 2014	10.0	2.3	6.4	11.1	29.8	23.5
Additions	8.1	2.9	5.0	7.0	23.0	
Utilisation	7.3	1.1	5.9	2.3	16.6	
Releases	1.8	_	0.5	0.4	2.7	
Book transfers	0.4	-0.1		-0.3		
Effect of foreign currency translation differences	0.2		0.2	0.3	0.7	
Accrued interest	-0.1				-0.1	
Balance as of 31 December 2015	9.5	4.0	5.2	15.4	34.1	27.5

The staff-related provisions consist primarily of provisions for profit-sharing, the Long Term Incentive Programme, anniversaries, severance pay and contributions to the employer's liability insurance association. The provisions under the Long Term Incentive Programme are explained in detail in Section F1.

The provisions for litigation risk are explained again in detail in Section F12.

The provisions for sales agreements include provisions for outstanding bonuses, discounts and credit notes.

Miscellaneous provisions include provisions for guarantees and similar items

Additions to provisions in the 2015 financial year mainly comprise additions of  $\leqslant$  6.2 million (previous year:  $\leqslant$  5.0 million) for employee profit-sharing,  $\leqslant$  0.3 million (previous year:  $\leqslant$  1.3 million) for the Long Term Incentive Programme and  $\leqslant$  2.9 million (previous year:  $\leqslant$  1.3 million) for litigation risk.

Reversals of other provisions mainly comprise  $\in$  1.3 million (previous year:  $\in$  0.4 million) relating to the Long Term Incentive Programme and  $\in$  0.4 million (previous year:  $\in$  0.6 million) relating to employee profit sharing.

#### **13 FINANCIAL LIABILITIES**

in € million	2015	2014
Non-current liabilities		
Promissory notes	218.9	213.6
Unsecured non-subordinated loans	112.9	109.8
Unsecured subordinated loans		1.3
Unsecured other loans		1.1
Long-term portion of liabilities from finance leases	3.7	
	335.5	325.8
Current liabilities		
Promissory notes	0.3	0.5
Unsecured non-subordinated loans	4.3	1.3
Unsecured subordinated loans	1.3	2.5
Unsecured other loans	3.1	1.8
Short-term portion of liabilities from finance leases	0.1	
	9.1	6.1

The promissory notes issued in the amount of € 210 million in October 2013 and comprising the following tranches formed the financing core at the reporting date:

Promissory notes	Currency	Term	Interest rate
Tranche 1	EUR	5 years	Fixed interest rate
Tranche 2	EUR	5 years	Variable interest rate
Tranche 3	USD	5 years	Variable interest rate
Tranche 4	EUR	7 years	Fixed interest rate
Tranche 5	EUR	7 years	Variable interest rate
Tranche 6	EUR	10 years	Fixed interest rate

Loans granted by the Reconstruction Loan Corporation (Kreditanstalt für Wiederaufbau, KfW) totalling € 118.5 million (previous year: € 115.6 million) were a further component of the financing arrangements.

The subsidy amount of  $\in$  0.8 resulting from the energy efficiency loans was disclosed under other liabilities in the previous year and is amortised over the useful life of the assets. As of 31 December 2015, the subsidy amount was still  $\in$  0.7 million.

In the previous year, the Biotest Group also received a commitment from the Reconstruction Loan Corporation (Kreditanstalt für Wiederaufbau, KfW) for four innovation loans totalling  $\leqslant$  20 million.  $\leqslant$  7.4 million had been drawn from these loans as of the 31 December 2015 reporting date. Proof of the related development costs must be provided for these drawings.

€ 99.3 million (previous year: € 118.2 million) of the committed bilateral credit lines remain unused as of 31 December 2015.

Information on the hedging of exchange-rate and interest risks is given in Section F4 Financial risk management.

The pricing and repayment terms and the maturity profile of financial liabilities are set out below:

<b>2015</b> (in € million)	Total	Time to maturity < 1 year	Time to maturity 1 to 5 years	Time to maturity > 5 years
Promissory notes		(Tyean	1 to 3 years	7 5 years
Euro – fixed at 2.3 to 3.8 %	104.8	0.3	84.5	20.0
Euro – variable at 1.0%	68.5		68.5	
USD – variable at 1.2 %	45.9		45.9	_
Other loans				
USD – fixed at 1.2 to 5.8 %	2.9	2.9	_	_
Euro – fixed at 4.0 to 6.0 %	0.2	0.2	_	_
Unsecured subordinated loans				
Euro – fixed at 3.6%	1.3	1.3	<u> </u>	_
Unsecured non-subordinated loans				
Euro – fixed at 0.6 to 3.8 %	117.2	4.3	58.2	54.7
Liabilities from finance leases				
Euro – fixed at 2.5 %	3.8	0.1	0.7	3.0
	344.6	9.1	257.8	77.7

The pricing and repayment terms and the maturity profile of the previous year's financial liabilities are set out below:

<b>2014</b> (in € million)	Total	Time to maturity < 1 year	Time to maturity 1 to 5 years	Time to maturity > 5 years
Promissory notes				
Euro – fixed at 2.3 to 3.8%	104.2	0.3	28.5	75.4
Euro – variable at 1.2%	68.6	0.1	24.5	44.0
USD – variable at 1.4%	41.3	0.1	41.2	_
Other loans				
USD – fixed at 1.2 to 1.7%	2.7	1.6	1.1	_
Euro – fixed at 6.0 %	0.2	0.2	_	_
Unsecured subordinated loans				
Euro – fixed at 3.6%	3.8	2.5	1.3	
Unsecured non-subordinated loans				
Euro – fixed at 0.9 to 3.8%	111.1	1.3	45.0	64.8
	331.9	6.1	141.6	184.2

The liabilities from finance leases are settled as follows:

in € million	2015			2014		
	Payment	Interest	Principal repayments	Payment	Interest	Principal repayments
Due in < 1 year	0.2	0.1	0.1	_	_	_
Due in 1 to 5 years	1.0	0.3	0.7			-
Due in > 5 years	3.5	0.5	3.0			-
	4.7	0.9	3.8	_	_	

The total future minimum lease payments as of the reporting date of  $\in$  4.7 million (previous year:  $\in$  0.0 million) equates to a present value of  $\in$  3.8 million (previous year:  $\in$  0.0 million).

The Biotest Group has not entered into any lease agreements that could result in contingent rent payments.

No collateral was pledged nor were financial indicators agreed for any of the loans existing as of the reporting date.

Net debt amounted to € 170.9 million (previous year: € 92.8 million) as of the reporting date and was derived as follows:

Net debt	173.7	239.1
Other non-current financial assets		5.0
Other current financial assets	119.9	54.7
Cash and cash equivalents	53.8	179.4
	344.6	331.9
Liabilities from finance leases	3.8	
Financial liabilities to financial institutions	340.8	331.9
in € million	2015	2014

Surplus liquidity, which was invested for three to 12 months at matching maturities with the investment plan, is shown under other current financial assets.

#### 14 OTHER LIABILITIES

in € million	2015	2014
Commissions payable	21.8	24.8
Liabilities from derivative financial instruments	2.2	2.6
Social security liabilities	2.1	1.4
Value added tax	1.9	2.3
Deferred income	1.8	0.8
Payments received in advance from associated companies	1.7	-
Deferred liabilities	1.5	1.3
Payments received in advance	0.4	1.3
Wage tax liabilities	0.2	0.3
Other liabilities	0.4	0.4
	34.0	35.2

Other liabilities with a residual maturity of over one year amount to € 2.2 million (previous year: € 2.5 million) as of the reporting date.

#### F. MISCELLANEOUS NOTES

#### 1 LONG TERM INCENTIVE PROGRAMME

Biotest AG pursues a business policy focused on the interests of shareholders and based on a shareholder value principle that promotes long-term growth in the value of the Biotest Group. Therefore, in 2006 the Company introduced a Long Term Incentive Programme (LTIP), renewable annually subject to the approval from the Supervisory Board.

In 2009 a decision was made with the consent of the Supervisory Board to renew the Long Term Incentive Programme in 2009 with the LTIP 2009. The LTIP established in 2009 was increased by a tranche in each of the subsequent years (2010 to 2015). An additional personal investment by eligible participants was required for the 2009 LTIP. As with the previous LTIPs, the personal investment from the first tranche of 2009 may be applied to all later tranches.

The amounts reported for the 2013, 2014 and 2015 tranches relate to all employees eligible to participate in the programme.

#### LONG TERM INCENTIVE PROGRAMME 2009/ TRANCHE 2013, 2014, 2015 (LTIP 2013, 2014, 2015)

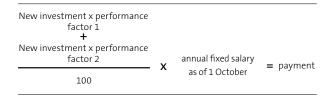
Participation in the programme requires a personal investment by the participant in the form of a purchase of preference shares of Biotest AG. The personal investment consists of the summation of new preference shares to be acquired under the LTIP ("new investment") and a number of additional preference shares to be contributed dependent on the new investment ("additional investment").

To take part in the individual tranches of the LTIP 2009, each eligible participant is required to contribute an additional investment of 50% of the number of newly acquired preference shares. Eligible participants may contribute preference shares acquired and/or contributed under earlier tranches of the LTIP 2009 as a new investment and/or additional investment for the respective tranche of the LTIP 2009. Only the new investment is used to calculate the incentive payment.

The entire personal investment in preference shares is to be held in a custody account until the incentive payment is disbursed. For legal reasons based on the laws of the USA, participants from the subsidiary Biotest Pharmaceuticals Corporation are not required to make a personal investment. Accordingly, incentive payments are 15 % lower than those of eligible Biotest AG participants.

On expiry of the programme, each beneficiary will receive an incentive payment in cash after the Annual Shareholders' Meeting for the relevant financial year; this cash payment will depend on the level of new investment, the fixed salary as of 1 October of the respective start year of the tranche and the achievement of two performance targets. Performance targets are assigned factors by which the new investment is multiplied.

The amount of the incentive payment is calculated using the following formula:



Performance factor values are based on the extent to which the Company has achieved its set performance targets.

Performance Target 1 is identical in all tranches and refers to the performance of the share price against a relevant benchmark. In this case, the performance of Biotest AG preference shares is compared against the performance of stocks listed on the SDAX index.

Performance Factor 1	Position in relation to the benchmark (SDAX stocks)		
Maximum 0.05	Equal to or better than the third quartile and a minimum 15% absolute price increase over the benchmark		
0.04	Equal to or better than the third quartile		
0.02	Equal to the median		
0.01	Equal to first quartile or minimum 25% absolute price increase		
0.00	Worse than the first quartile and less than a 25 % absolute price increase		

The key criterion for Performance Factor 1 is that the Group must achieve earnings before interest and tax (EBIT) of at least € 15.0 million in the financial year in which the respective tranche expires. If EBIT is less than € 15.0 million, the factor applied is 0 in any event.

Performance Factor 2 refers to the average EBIT margin achieved at the Group level in the years during the term of the respective tranche. This is calculated by adding the annual EBIT margin for all three years and then dividing it by three.

Performance Factor 2 is also linked to another key criterion. This factor applies only when the price of Biotest preference shares has outperformed the first quartile of SDAX stocks during the period or rose by at least 25 % in absolute terms. It is calculated in the same way as Performance Factor 1.

Performance Factor 2	Average EBIT margin 2013–2015 (LTIP 2013)	Average EBIT margin 2014–2016 (LTIP 2014)	Average EBIT margin 2015 – 2017 (LTIP 2015)
Maximum 0.05	Better than 13.4%	Better than 14.4%	Better than 12.0%
0.04	Equal to 13.4%	Equal to 13.5 %	Equal to 11.0 %
0.02	Equal to 11.9%	Equal to 12.25%	Equal to 9.13 %
0.01	Equal to 10.9%	Equal to 11.95%	Equal to 8.73 %
0.00	Less than 10.15%	Less than 11.60%	Less than 8.39%

For targets achieved that lie between the values shown above, the factor is determined through linear interpolation.

If both performance criteria are met, on expiry of the performance period a minimum of 1% and a maximum of 10% of the annual fixed salary as of 1 October of the respective start year of the tranche is paid for a new investment of 100 shares.

Participation in the respective tranches of the LTIP 2009, including by members of the Board of Management, is as follows:

	LTIP 2013	LTIP 2014	LTIP 2015
Number of participants	97	106	115
New investment in preference shares	23,005	25,475	25,290
Number of preference shares virtually allocated			
to BPC employees	4,725	5,550	6,100

The valuation was performed by external experts (Towers Watson, Frankfurt/Main) using the Monte Carlo simulation. In assessing both market and non-market conditions in accordance with IFRS 2 "Share-based Remuneration", conditions affecting the incentive payment but not observable in the market are viewed separately from observable market conditions. Market conditions are determined through a fair value assessment.

All market parameters that are not directly observable are determined by means of statistical estimates. Historical market data is used to estimate volatilities. The applicable risk-free market interest rate is determined based on parameters using the Svensson method as published by the Deutsche Bundesbank. To calculate the number of persons who are likely to drop out of the programme during its term, a 4% turnover rate for eligible employees was assumed. Non-market conditions are taken into account by adding Performance Factor 2, which is calculated on the basis of budget forecasts.

The performance factors per 100 preference shares and  $\le$  100 of fixed salary are as follows:

	LTIP 2013	LTIP 2014	LTIP 2015
Fair value on date granted	2.689	2.080	1.124
Fair value on reporting date		1.000	1.000
Total of performance factors in the financial year	<u> </u>	1.000	1.000
Total of performance factors in the previous year	4.28	2.502	

The distribution of the total expense of each tranche over its term results in the following provisions and expenses for the financial year:

in € million	LTIP 2013	LTIP 2014	LTIP 2015
Provision as of reporting date		0.3	0.1
Expense for the financial year	-1.3		0.1

In the 2015 financial year, five employees with a new or virtual investment of 3,288 preference shares left the Biotest Group. This resulted in income of  $\leqslant$  0.1 million.

#### LONG TERM INCENTIVE PROGRAMME 2009/ TRANCHE 2012 (LTIP 2012)

The 2012 tranche of the Long Term Incentive Programme was described in detail in the consolidated financial statements as of 31 December 2012.

A payment of € 2.4 million was made in the 2015 financial year in respect of the Tranche 2012.

#### FURTHER GENERAL INFORMATION ABOUT THE LTIP

Entitlement to an incentive payment ceases for the programme and all tranches if employment within the Biotest Group ends for any reason (other than retirement, early retirement, partial retirement, occupational disability or invalidity).

Participants will receive a pro rata incentive payment in the event of a change of control in which at least 30% of the voting rights are transferred to a shareholder who did not previously hold these voting rights, of a delisting from the stock market or of a merger or change in the legal status of the parent company, or of the exit of the company by which the participant is employed from the parent group.

#### **2 FINANCIAL INSTRUMENTS**

#### 2.1 CLASSIFICATION OF FINANCIAL INSTRUMENTS

The Biotest Group classifies financial instruments in accordance with their accounting treatment. They are differentiated on the basis of their measurement. Accordingly, financial assets and financial liabilities are divided into assets and liabilities recognised at amortised cost and asset and liabilities recognised at fair value. Cash and cash equivalents as well as derivatives constitute a separate class.

One class may contain several different financial position items. The Biotest Group classifies financial instruments as follows:

Class of financial instruments	Financial position items	Measure- ment category
Cash and cash equivalents	Cash and cash equivalents	None
	Trade receivables	LaR
Assets recognised	Other financial assets	LaR
at amortised cost	Other assets	LaR
Assets recognised at fair value	Other financial assets	FAFVtPL
	Financial liabilities	FLAC
Liabilities recognised	Trade payables	FLAC
at amortised cost	Other liabilities	FLAC
Liabilities recognised at amortised cost	Liabilities from finance leases	None
	Other financial assets	FAHfT
Derivatives	Other liabilities	FLHfT

The measurement categories under IAS 39 are abbreviated as follows: Loans and receivables (LaR), investments held to maturity (HtM), financial assets at fair value through profit and loss (FAFVtPL), financial assets held for trading (FAHfT), financial liabilities held for trading (FLHfT) and financial liabilities at amortised cost (FLAC).

As in the previous year, financial instruments were not reclassified in the 2015 financial year.

# 2.2 RECONCILIATION OF STATEMENT OF FINANCIAL POSITION ITEMS TO MEASUREMENT CATEGORIES AS WELL AS THEIR VALUATION BASIS AND FAIR VALUES

in € million			Measureme	Measurement			
Financial position items	Measurement category under IAS 39	Carrying amount as of 31 December 2015	Amortised cost of purchase	Cost of purchase	Fair value recognised directly in equity	Fair value recognised through profit or loss	basis in the statement of financial position under IAS 17
Assets							
Trade receivables	LaR	173.9	173.9			_	
Other assets							
Original financial assets	LaR	14.8	14.8				
Other financial assets							
Promissory notes/other financial assets	LaR	120.6	120.6			_	_
Derivatives not designated as hedging instruments	FLHfT	0.4				0.4	_
Receivables from associated companies	LaR	0.5		_		_	_
Bond funds	FAFVtPL	0.1				0.1	
Equity and liabilities					·		
Trade payables	FLAC	53.1	53.1				
Financial liabilities							
Unsecured liabilities to banks	FLAC	337.7	337.7	_		_	
Other unsecured loans	FLAC	3.1	3.1			_	
Liabilities from finance leases	none	3.8					3.8
Other liabilities	- <del></del>						
Original financial liabilities	FLAC	31.1	31.1		_	_	
Derivatives not designated as hedging instruments	FLHfT	2.2				2.2	

Cash and cash equivalents with a carrying amount of  $\leqslant$  53.8 million (previous year:  $\leqslant$  179.4 million) are not included in the above table, as these financial instruments are not assigned to a IAS 39 measurement category.

			Measuremer	nt basis in the sta under	Measure- ment basis in the			
	Measure- Carrying ment amount as of Fair value as of 31 category 31 December December 2015 under IAS 39 2014	Amortised cost of purchase	Cost of purchase	Fair value recognised directly in equity	Fair value recognised through profit or loss	statement of financial position under IAS 17	Fair value as of 31 December 2014	
173.9	LaR	181.6	181.6					118.5
14.8	LaR	12.8	12.8					12.8
120.7	LaR	59.7	59.7					59.7
0.4	FLHfT							
0.5	LaR	1.0	-	_	-	_	_	1.0
0.1	FAFVtPL	0.2				0.2		0.2
53.1	FLAC	55.5	55.5					55.5
343.7	FLAC	329.0	329.0		_	_		337.9
3.1	FLAC	2.9	2.9					3.1
3.8	none							
31.1	FLAC	31.7	31.7					31.7
2.2	FLHfT	2.6				2.6		2.6

#### 2.3 AGGREGATION OF THE MEASUREMENT CATEGORIES INCLUDING THEIR MEASUREMENT BASIS AND FAIR VALUES

in € million			Measurement	basis in the stat under IA	Measure-			
Categories	Measure- ment category under IAS 39	Carrying amount as of 31 December 2015	Amortised cost of purchase	Cost of purchase	Fair value recognised directly in equity	Fair value recognised through profit or loss	ment basis in the statement of financial position under IAS 17	Fair value as of 31 December 2015
Loans and receivables	LaR	309.8	309.8	_	_	_	_	309.9
Financial assets at fair value through profit and loss	FAFVtPL	0.1			_	0.1		0.1
Financial assets held for trading	FLHfT	0.4				0.4		0.4
Financial liabilities recognised at amortised cost	FLAC	425.0	425.0					431.0
Financial liabilities held for trading	FLHfT	2.2				2.2		2.2
in € million			Measurement	basis in the stat				
Categories	Measure- ment category under IAS 39	Carrying amount as of 31 December 2014	Amortised cost of purchase	Cost of purchase	Fair value recognised directly in equity	Fair value recognised through profit or loss	ment basis in the statement of financial position un- der IAS 17	Fair value as of 31 December 2014
Loans and receivables	LaR	255.1	255.1					255.3
Financial assets at fair value through profit and loss	FAFVtPL	0.2				0.2		0.2
Financial liabilities recognised at amortised cost	FLAC	419.1	419.1					428.2
Financial liabilities held for trading	FLHfT	2.6			_	2.6		2.6

#### 2.4 NET GAIN OR LOSS BY MEASUREMENT CATEGORY

The net gain or loss for the 2015 financial year by measurement category is as follows:

in € million		From subs	sequent measurer	ment			
Categories	From interest	At fair value	Currency translation	Impairment	From disposal	Net gain or loss 2015	
Loans and receivables	0.4		5.3	-1.5	_	4.2	
Financial investments held to maturity					_		
Financial assets recognised at fair value				_	_		
Financial assets held for trading		0.7				0.7	
Financial liabilities held for trading		-1.9				-1.9	
Financial liabilities recognised at amortised cost			-2.5			-9.0	
Total	-6.1	-1.2	2.8	-1.5		-6.0	

The net gain or loss for the previous financial year by measurement category is as follows:

in € million		From subs	sequent measurer	ment		
Categories	From interest	At fair value	Currency translation	Impairment	From disposal	Net gain or loss 2014
Categories	-0.2	3.6	0.6	-0.1		3.9
Loans and receivables						
Financial investments held to maturity				_		
Financial assets recognised at fair value				_		
Financial assets held for trading		-2.5		_		-2.5
Financial liabilities held for trading		-0.8	-0.2			-6.6
Financial liabilities recognised at amortised cost	-5.8	0.3	0.4	-0.1	_	-5.2
Total						

All components of the net gain or loss are recorded under other financial expenses or other financial income, except for allowances for bad debts, which are disclosed under other operating expenses.

A loss of  $\in$  1.2 million (previous year: loss of  $\in$  2.5 million) comprising both interest rate and currency effects is included in the result from the subsequent measurement of financial instruments falling under the valuation category assets and liabilities held for trading.

#### 2.5 CASH FLOW BY TIME BAND

The tables below show the contractually agreed, undiscounted interest payments and principal repayments relating to original financial liabilities and derivative financial instruments with positive and negative fair values. The second table contains comparative values for cash flows in specific periods based on the previous financial year.

in € million		Casl	n flows in 20	16	Cash flows in 2017		
Financial position items	Carrying amount as of 31 December 2015	Fixed interest	Variable interest	Principal repay- ments	Fixed interest	Variable interest	Principal repay- ments
Original financial liabilities:							
Liabilities to financial institutions	-337.6	-5.4	-0.8	-5.9	-5.2	-0.9	-13.6
Liabilities from finance leases	-3.8	-0.1	_	-0.1	-0.1		-0.2
Other interest-bearing liabilities	-3.2	_	-0.1	-3.2	_	_	
Trade payables	-53.1	_	_	-53.1	_	_	
Other liabilities	-31.8			-31.1			
Derivative financial liabilities:							
Currency derivatives not designated as a hedging instrument	-0.7	_		-0.7	_		_
Interest rate derivatives not designated as a hedging instrument		-0.5			-0.5		
Derivative financial assets:							
Currency derivatives not designated as a hedging instrument	0.4			0.4			
in € million		Cashflow in 2015			Cashflow in 2016		
Financial position items	Carrying amount as of 31 December 2014	Fixed interest	Variable interest	Principal repay- ments	Fixed interest	Variable interest	Principal repay- ments
Original financial liabilities:							
Liabilities to financial institutions	-329.0	-4.3	-1.8	-4.3	-4.4	-1.8	-4.9
Other interest-bearing liabilities	-2.9	_		-1.8	_		-1.2
Trade payables	-55.5	_		-55.5	_		
Other liabilities	-32.5			-31.7			_
Derivative financial liabilities:							
Interest rate derivatives not designated as a hedging instrument	-0.8			-0.8			

All instruments held in the portfolio as of the reporting date for which payments were already contractually agreed are included. Forecast figures for future new liabilities are not included. Foreign currency amounts are translated at the exchange rate of the reporting date. Variable interest payments

on financial instruments are calculated using the last fixed interest rate prior to 31 December 2015. Financial liabilities repayable at any time are always assigned to the earliest time band.

Cas	n flows in 20:	18	Casl	n flows in 20:	19	Casl	h flows in 202	20	Cash	flows after 2	020
Fixed interest	Variable interest	Principal repay- ments									
-5.2	-1.0	-114.0	-3.7	-0.7	-14.7	-3.2	-0.7	-114.7	-3.4		-74.7
-0.1		-0.2	-0.1		-0.2	-0.1		-0.2	-0.5		-2.9
											-
	·	·									
-0.5			-0.2			-0.1		<u> </u>			
Cas	hflow in 201	.7	Cas	hflow in 201	8	Cas	shflow in 201	9	Cash	shflow after 2019	
Fixed interest	Variable interest	Principal repay- ments									
-4.3	-1.8	-13.8	-4.2	-1.8	-108.0	-3.4		-13.8	-5.8	-0.7	-185.6

#### 3 DETERMINATION OF FAIR VALUE

Trade receivables and other accounts receivable mainly have times to maturity of less than a year. Carrying amounts as of the reporting date therefore are approximately equal to fair values. Impaired trade receivables are to be assigned solely to Level 3 with regard to the assessment of default/credit risk, as the input factors are based primarily on an internal evaluation of the respective receivables. These are partially attributable to the ageing cluster of the receivable, origin of the debtor ("country risk") and a combination of the factors. These are derived from historical experience. The evaluation is also partially based on individual factors such as the knowledge that the customer concerned is insolvent. The allowance for bad debts ratio amounts to up to 100 % depending on the cluster.

For other non-current receivables and investments held to maturity with times to maturity of more than one year, fair values are equivalent to present values of payments relating to the assets taking into account current interest rate parameters reflecting market- and partner-specific changes in terms and expectations.

For financial assets disclosed under other financial assets that are measured at fair value no market prices are directly observable. These items are measured on the basis of observable market information at the time of issue and standard yield curves. Fair value is assigned to hierarchy level 2.

Trade payables as well as other liabilities regularly have times to maturity of less than one year. Therefore, in this case as well, carrying amounts correspond approximately to fair values.

The fair values of liabilities to banks and other financial liabilities are measured as the present values of payments relating to the debt based on the respective applicable yield curve as well as the analysed credit spread curve for each currency. Fair value is assigned to hierarchy level 2.

The Biotest Group holds no major investments categorised as available for sale in its portfolio as of 31 December 2015.

In the case of derivative financial assets or liabilities (interest rate caps, interest rate swaps and currency transactions) the mark-to-market measurement performed is based on quoted exchange rates and yield curve structures obtainable on the market. Fair value is assigned to hierarchy level 2.

The fair value of the bond funds is assigned to hierarchy level 1.

#### **4 FINANCIAL RISK MANAGEMENT**

In the course of its ordinary operations and due to existing international trade relationships, Biotest is exposed to currency and interest rate risks.

To hedge currency positions, Biotest uses derivative financial instruments to minimise risks inherent in exchange rate fluctuations. In addition, Biotest also used interest rate hedging instruments during the financial year. Derivative financial instruments are generally subject to changes in market prices.

Biotest is not in full compliance with the formal requirements of IAS 39 for hedge accounting. Consequently, all gains and losses arising from market valuation of derivative financial instruments used to hedge interest rate and currency risks are recognised through profit or loss.

Financial instruments are recognised at the time that the corresponding contracts are concluded. They are initially recognised at cost of purchase and then measured at their respective market values as of the reporting date. Financial instruments are derecognised once contractual obligations have been fulfilled by both parties or upon the closing out of the instrument.

The market values of derivative financial instruments are disclosed in the statement of financial position under other financial assets or other liabilities. € 0.4 million (previous year: € 0.0 million) is disclosed under other financial assets and € 2.2 million (previous year: € 2.6 million) under other liabilities as of 31 December 2015.

#### **CREDIT RISK**

A credit risk is the financial risk that a contractual partner will not meet his payment obligations. Default risk is countered through the continuous management of receivables. The customer's credit rating is assessed and subsequently credit terms and other conditions are defined. In addition, portions of domestic receivables and selected foreign receivables are sold to factoring companies or banks.

Countries that account for more than 10% of total receivables are Iran and Saudi Arabia. Allowances for bad debts of  $\in$  0.9 million (previous year: none) were recognised on receivables from customers in these countries.

Credit insurance has been obtained from various companies for certain customers in selected countries. A deductible of up to 10% was agreed in the existing credit insurance policy.

Specific bad debt charges are made for potential default risks in connection with original financial instruments.

To present the maximum default risk of original financial assets, the corresponding carrying amount is used as an equivalent for the maximum default risk:

in € million	2015	2014
Trade receivables	173.9	181.6
Other assets	14.8	12.8
Other financial assets	121.2	60.9

#### MARKET RISK

Market price risk results from changes in market prices. These lead to fluctuations in fair values or future cash flows from financial instruments. Market risk comprises foreign exchange risk, interest rate risk and other price-related risk.

#### **CURRENCY RISK**

The Biotest Group operates internationally and is therefore exposed to foreign currency risk based on changes in the exchange rates of various foreign currencies, mainly the US dollar. Foreign currency risks arise from expected future transactions,

recognised assets and liabilities and net investments in foreign operations. Basically the Biotest Group protects itself against identifiable future currency risk whenever it anticipates such exposure. In addition, risks in the statement of financial position are hedged selectively. The Biotest Group makes use of opportunities to offset currency risk naturally and to use currency futures to manage currency risk.

The Biotest Group holds the following positions in foreign currencies that are material to the Group:

Foreign currency risk	US	D	GBP		
in € million	2015	2014	2015	2014	
Cash reserves	6.8	9.8	0.6	0.3	
Trade receivables	77.4	76.4	2.1	2.2	
Other original financial assets	4.9	4.5	0.1	0.1	
Other derivative financial assets	0.3	_	_	_	
Trade payables	-24.7	-16.9	-0.2	-0.2	
Liabilities to financial institutions	-48.9	-44.0			
Other original financial liabilities		12.3			
Other derivative financial liabilities	-0.7	-0.4			
Net position	7.4	17.1	2.5	2.4	

Foreign currency risk	н	JF	RUB		
in € million	2015	2014	2015	2014	
Cash reserves	1.1	0.4	_	0.6	
Trade receivables	1.3	2.4	1.6	2.1	
Other original financial assets	0.5	0.7	0.1	_	
Other derivative financial assets		=	0.1		
Trade payables	-1.3	-0.2		_	
Liabilities to financial institutions	_	_	_	_	
Other original financial liabilities	-0.5	-0.4	_	_	
Other derivative financial liabilities				-0.4	
Net position	1.1	2.9	1.8	2.3	

The following currency futures for the sale of USD and RUB were held as of the reporting date:

in € million	Nominal	amount	Market values		
	2015	2014	2015	2014	
Currency futures	69.6	17.7	-0.3	-0.8	

See Section B3 for information about principal exchange rates during the reporting period.

#### INTEREST RATE RISK

The Biotest Group's interest rate risk arises from non-current financial liabilities. Variable-rate loans also expose the Group to interest-related cash flow risks. Fixed-rate loans give rise to an interest-related risk from changes in fair value.

The Biotest Group is exposed to interest rate risk resulting from existing loans (see also section E13 Financial liabilities). To minimise a portion of interest-related cash flow risks, interest rate swaps were used that convert a variable interest rate into a fixed one. Such interest rate swaps hedge the interest-related cash flow risk.

The following interest rate hedges were in place during the 2015 financial year:

in € million	Nominal	amount	Market values		
	<b>2015</b> 2014		2015	2014	
Interest rate swaps	30.0	30.0	-1.5	-1.8	

The interest rate hedging transactions have a term of up to 10 September 2018 and 23 September 2020, respectively and bear a fixed interest rate of 1.45% and 1.8175%, respectively. These interest rate hedging transactions were also outstanding as of the reporting date of the previous year.

The nominal amount is the sum of all purchase and sale amounts for derivative financial transactions. The market values result from the measurement of open positions at market prices without taking into account the opposite change in value of the underlying transactions. They correspond to the income or expense that would result if the derivative contracts were closed out as of the reporting date.

#### LIQUIDITY RISKS

Liquidity risk is the risk that a company will be unable to meet its financial commitments to a sufficient extent. A shortage of financial capital may result in an increase in financing costs.

The Biotest Group manages its liquidity by maintaining sufficient liquid funds and credit lines with banks in addition to cash flows from business operations.

The Biotest Group had access to the following contractually established credit lines as of 31 December 2015:

in € million	2015	2014
Loans drawn down	340.8	331.9
Credit lines not used	111.9	138.2

The individual corporate divisions supply the central Treasury with the necessary information for creating a liquidity profile. All financial assets, financial liabilities and anticipated payment flows from planned transactions are included.

A maturity overview illustrating how cash flows from liabilities as of 31 December 2015 impact the Group's liquidity position is provided in Section F2.5.

The available liquidity, short- and long-term credit lines and the option of generating cash flows by securitising receivables give the Biotest Group sufficient flexibility in covering its funding needs. Due to the diversification of funding sources and liquid funds, the Biotest Group is not exposed to a concentration of risk in terms of liquidity.

#### 5 SENSITIVITY ANALYSIS PURSUANT TO IFRS 7.40

The Biotest Group is exposed to market risk comprising foreign currency risk and interest rate risk.

By using sensitivity analyses, the effects of any changes in the relevant risk variables on profit or loss and equity as of the reporting date are determined for each type of risk.

#### **CURRENCY RISK**

A sensitivity analysis is performed for specific currencies that pose a significant risk to the Biotest Group for the purposes of analysing foreign currency risk. The following major currencies are analysed: USD and GBP.

If the euro had appreciated by 10% against all currencies as of 31 December 2015, the financial result would have been € 8.3 million higher (previous year: € 1.4 million higher).

If the euro had depreciated by 10% against all currencies as of 31 December 2015, the financial result would have been € 8.5 million lower (previous year: € 1.3 million lower).

The hypothetical impact on profit or loss of € 8.3 million or € 8.5 million results from the following currency sensitivities:

in € million	Appreciation of the EUR by 10%	Depreciation of the EUR by 10%
EUR to USD	8.3	-8.6
EUR to GBP		0.1
	8.3	-8.5

It should be noted that the sensitivity analysis required by IFRS 7 only takes into account exchange rate risk on financial assets and liabilities but not translation risk. If translation risk had been taken into account, the effect would have been different.

#### INTEREST RATE RISK

For interest rate risk, a sensitivity analysis serves to illustrate the effects of changes in market interest rates on interest income and expenses, other income components and, where applicable, equity.

Changes in the market interest rates of original financial instruments with fixed interest rates only influence income if recognised at fair value. Financial instruments with fixed interest rates measured at amortised cost therefore are not exposed to interest rate risk as defined by IFRS 7.

Changes in the market interest rates of interest rate derivatives (interest rate swaps, interest rate/currency swaps and interest rate caps) that do not form part of a hedging relationship under IAS 39 impact other financial income (measurement result from the adjustment of financial assets to fair value) and are therefore incorporated in income-related sensitivity calculations.

Currency derivatives and changes in their value due to interest rate changes were not taken into account in calculating interest rate sensitivities.

The sensitivity analysis is based on the net effect of interest-bearing liabilities, bank balances and current financial assets. If the market interest rate level as of 31 December 2015 had been 100 basis points higher, the fair values of the financial instruments would have been € 0.9 million (previous year: € 1.3 million) higher. The hypothetical impact on profit or loss of € 1.5 million (previous year: € 2.0 million) arises from the potential effects from interest rate derivatives of € 0.9 million (previous year: € 1.3 million) and original financial liabilities of € 0.6 million (previous year: € 0.7 million).

Given the low reference interest rates as of the reporting date, no sensibility analysis for downward changes in market interest rates was conducted on de minimis grounds.

If the market interest rate level as of 31 December 2015 had been 100 basis points higher or 0 basis points lower, equity would have remained unchanged. For changes in equity due to actuarial gains and losses from pension plans, please refer to Section E11.

#### MARKET RISK

The figures for the sensitivity analysis prepared in accordance with IFRS 7.40b include both fair value risk and cash flow risk. Since these values were determined simultaneously using computer models, no specific differentiated statements can be made with regard to the individual values.

#### OTHER PRICE-RELATED RISK

As part of the presentation of market risk, IFRS 7 also requires information about how hypothetical changes in risk variables affect the prices of financial instruments. Possible risk variables are, in particular, stock market prices or indices.

Other price-related risk has no material impact on the prices of financial instruments held by the Biotest Group.

#### **6 CAPITAL MANAGEMENT**

The primary objective in managing capital is to ensure an attractive overall rating for investors and to maintain adequate capital ratios in order to guarantee the strategic business development of the Biotest Group.

The equity of the Biotest Group that is the focus of capital structure optimisation efforts is the equity disclosed on the statement of financial position which is attributable to the owners of Biotest AG as the parent company. After the share split, which was entered into the commercial register on 22 June 2015, the share capital consists of 19,785,726 ordinary voting shares and 19,785,726 non-voting preference shares. Non-controlling interests play only a minor role in capital management due to the low volume.

Strategic capital management analyses are based on longterm forecast calculations, which are used to determine the corresponding future values and indicators. In the short term, budget forecasts for the following year serve as the basis for financial indicators.

As part of its strategy, the Biotest Group seeks to maintain an equity ratio of at least 40%. The equity ratio of the Biotest Group was 42.8% as of 31 December 2015 (previous year: 46.5%). In addition, both long-term and quarterly special financial ratios are used for analysis and management purposes. One of the key indicators here is the leverage factor, calculated as the ratio of net debt to EBITDA.

No fundamental changes were made to the objectives or processes for managing capital in the 2015 financial year. An adequate organisational structure and defined work flows and monitoring processes were implemented for the necessary controlling of the Biotest Next Level project and related required financial resources.

The Biotest Group has various options at its disposal for achieving its capital management objectives. These include capital increases through the issue of new shares with or without pre-emptive rights, dividend policies and the repurchase of shares. Efforts to optimise capital structure are also supported through debt reduction measures and active management of working capital.

In June 2013 Biotest AG carried out a capital increase. The maximum possible number of 1,461,909 new preference shares were acquired at a price of € 52 per share by existing shareholders through exercising their subscription rights or placed with institutional investors. New no-par value bearer

preference shares conveying a pro-rata interest in the share capital of € 2.56 per share were issued generating gross issue proceeds of € 76 million.

In the 2013 financial year Biotest AG privately placed promissory notes with an equivalent value of € 210 million on the capital markets. EUR tranches with a maturity of 5, 7 and 10 years and an US tranche with a maturity of 5 years were underwritten. The tranches with a maturity of 5 and 7 years have fixed and variable interest rates. The tranche with a maturity of 10 years has a fixed rate coupon.

In the 2014 financial year, the Biotest Group took up loans totalling € 100.5 million under the Reconstruction Loan Corporation (Kreditanstalt für Wiederaufbau, KfW) energy efficiency programme. These have a term of 10 years with a grace period of two years and bear interest at a fixed rate.

In the current financial year the Biotest Group took up fixed-rate loans totalling € 7.4 million with a term of 10 years under the KfW innovation programme.

The proceeds from the promissory note, capital increase and loans taken up under the energy efficiency programme are being used in particular for the expansion of the facilities at Dreieich and also for general financing of the company.

## 7 CONTINGENT ASSETS AND CONTINGENT LIABILITIES

A contingent asset is a potential asset that arises from past events and whose existence is confirmed by the occurrence or non-occurrence of one or more uncertain future events that are not fully under the control of the Company.

Contingent liabilities are potential commitments resulting from past events. Their existence must be confirmed by the occurrence or non-occurrence of one or more future events that are not within the full control of the Company. However, contingent liabilities may also stem from current commitments resulting from past events that are not recorded because either the outflow of resources plus losses in economic benefit is not probable or the amount of the commitment cannot be estimated with sufficient reliability.

The Biotest Group has contingent liabilities under guarantees in the amount of € 14.5 million (previous year: € 16.9 million). These relate mainly to guarantees for the delivery of goods and the performance of services, in which the probability of a claim against the Biotest Group is considered low.

In Italy, there is a risk that the Italian health authorities will request reimbursement from the launch of Zutectra® in 2010 with respect to additional revenue generated by Zutectra® in 2011 and 2012 in the retail market. Biotest considers this claim to be unjustified given that the overall market for hepatitis B immunoglobulins in 2011 and 2012 remained more or less at the same as in 2010 and the Italian public health system experienced no disadvantages but only advantages through the launch of Zutectra®. In January 2014, Biotest was successful in its action at first instance against the reimbursement claim. For this reason, a provision for the claim was not recognised in the consolidated financial statements as was the case in the previous year. The risk is estimated to be in the low single-digit millions.

#### 8 OTHER FINANCIAL COMMITMENTS

in € million	in 2016	2017 to 2020	as of 2021	Total
Obligations under long-term service agreements	20.9	41.8		62.7
Purchase commitments for property, plant and equipment	100.3	40.7		141.0
Future payments under rental and operating lease contracts	6.3	13.6	11.4	31.3
Other financial obligations	0.9			0.9
	128.4	96.1	11.4	235.9

Payments for approved investments in fixed assets will be made within one year.

Obligations under long-term service agreements mainly relate to purchase commitments under two toll manufacturing agreements for the period from 2016 to 2018 totalling € 43.5 million (previous year: € 54.2 million).

The Biotest Group rents or leases operating equipment as a lessee. Operating leases include vehicle and office equipment with a base rental term of two to five years. In the 2015 financial year, expenses under rental and operating lease agreements amounted to € 6.5 million (previous year: € 4.8 million).

Some rental, lease and operating lease agreements in connection with plasma stations run by Plasma Service Europe GmbH include clauses allowing price adjustments based on the German consumer price index.

#### 9 RELATED PARTIES

The Biotest Group maintains reportable relationships with the associate BioDarou P.J.S. Co., Tehran, Iran, and its subsidiary Plasma Gostar Pars P.J.S., Tehran, Iran, with the members of the Board of Management and the Supervisory Board and related parties as well as with shareholders with significant influence over Biotest AG.

#### A) ASSOCIATES

BioDarou P.J.S. Co. acquired no goods or services from Biotest Group companies in the financial year (previous year: none). The receivables from associated companies amounted to € 1.2 million on the reporting date (previous year: € 1.0 million). There were also liabilities to BioDarou P.J.S. Co. from payments in advance for future goods deliveries of € 1.7 million as of the reporting date (previous year: € 0.0 million).

#### B) OTHER RELATED PARTIES

Dr Cathrin Schleussner notified the Biotest Group that, as of 19 December 2007, her voting rights in the Company totalled 50.03%. These voting rights are held via OGEL GmbH, Frankfurt/Main, Germany. OGEL GmbH is controlled by Dr Cathrin Schleussner.

The family members of Dr Cathrin Schleussner are also considered related parties within the meaning of IAS 24. As in the previous year, expenses incurred by related parties of the Schleussner family were low in 2015.

As a related company of the Biotest Group, Kreissparkasse Biberach maintains employee custody accounts for the Long Term Incentive Programme.

Plasma Gostar Pars P.J.S. acquired goods and services from Biotest Group companies totalling  $\leqslant$  12.6 million during the year (previous year:  $\leqslant$  16.3 million). The resulting receivables from the subsidiary of the associate amounted to  $\leqslant$  9.9 million as of the reporting date (previous year:  $\leqslant$  8.7 million).

## C) SUPERVISORY BOARD AND BOARD OF MANAGEMENT

#### **Board members**

As of 31 December 2015, the members of the Supervisory Board and the Board of Management also served on statutory supervisory boards and comparable controlling bodies of commercial enterprises as follows:

#### **Supervisory Board**

#### Dr Alessandro Banchi,

Milan, Italy

Former speaker of the Management Board for Boehringer Ingelheim, Ingelheim am Rhein, Germany Chairman of the Supervisory Board of Biotest AG Non-executive Board Director of Enel S.p.A., Rome, Italy

#### Dr Cathrin Schleussner,

Neu-Isenburg, Germany

Managing director of OGEL GmbH, Frankfurt am Main, Germany

Deputy chairperson of the Supervisory Board of Biotest AG

#### Dr Christoph Schröder,

Berlin, Germany

Managing director of OMOS Equity Partners GmbH, Berlin, Germany

#### Thomas Jakob,

Ulm, Germany

Businessman

Deputy chairman of the Board of Management of Kreissparkasse Biberach, Biberach, Germany

Member of the Administrative Board of Aktiengesellschaft für Umsatzfinanzierung S.A., Senningerberg, Luxembourg

#### Kerstin Birkhahn,

Langen, Germany

Engineer

Employee representative

#### Jürgen Heilmann,

Dreieich, Germany

Administrative staff member

Employee representative

#### **Supervisory Board remuneration**

Members of the Supervisory Board were paid a total of € 219 thousand in the current year (previous year: € 257 thousand), of which € 219 thousand (previous year: € 177 thousand) is attributable to fixed remuneration components and € 0 thousand (previous year: € 80 thousand) to variable remuneration components.

In addition to the listed Supervisory Board remuneration, additional amounts paid in financial years 2015 and 2014 to employee representatives on the Supervisory Board under their employment agreements were also expensed. These amounts were based on collective bargaining agreements and/or company pay rates for non-pay-scale employees.

A detailed description of the Supervisory Board remuneration and the individual amounts are set out in the Remuneration Report in the Management Report of this Annual Report.

#### **Board of Management**

#### Dr Bernhard Ehmer,

Heidelberg, Germany

Chairman of the Board of Management

#### Dr Michael Ramroth,

Mörfelden-Walldorf, Germany

Member of the Board of Management

#### Dr Georg Floß,

Marburg, Germany

Member of the Board of Management

#### Remuneration of the Board of Management

Total remuneration of current members of the Board of Management amounted to € 1,898 thousand for the 2015 financial year (previous year: € 1,480 thousand). The Board of Management remuneration is broken down into non-performance-based components of € 1,276 thousand (previous year: € 893 thousand) and performance-based components of € 622 thousand (previous year: € 588 thousand).

Participation of members of the Board of Management in the Long Term Incentive Programme is included in the performance-based component at the fair value of the LTIP tranche set up in the respective financial year on the date granted.

Participation of members of the Board of Management in the Long Term Incentive Programme is as follows:

Personal invest- ment in preference shares (in number of shares)	Fair value of options as of 31 December	Total costs of the stock option plan in the financial year
1,800	55	
1,800	46	-126
1,800	40	-109
5,400	141	
1,800	162	37
1,800	655	182
1,800	436	122
5,400	1,253	341
	1,800 1,800 1,800 1,800 1,800 1,800	Investment in preference shares (in number of shares)

The 2012 tranche of the Long Term Incentive Programme was disbursed in financial year 2015; Dr Michael Ramroth received € 316 thousand and Dr Georg Floß € 130 thousand.

Pension entitlements for current members of the Board of Management total € 5,138 thousand (previous year: € 4,625 thousand). Assets in the amount of € 1,186 thousand (previous year: € 1,177 thousand) were transferred to Biotest Vorsorge Trust e.V. for insolvency protection of the pension entitlements as of 31 December 2015.

A supplementary agreement to the Board of Management employment contract of all active Board of Management members contains a severance pay clause that becomes effective in the event of the early termination of such contract as a result of a clearly defined change of control. The severance payment includes the fixed remuneration up to the end of the term and is limited to a maximum of three times the annual fixed salary. Pro-rata variable remuneration components that are calculated on the basis of the average for the previous two financial years plus compensation for the value in use of the Company vehicle provided are also paid. In addition to these claims, the severance payment also includes up to twice the annual fixed salary. In total, however, the severance payment amount must not exceed triple the annual fixed salary.

There shall be no entitlement if the Board of Management employment contract is terminated for good cause, illness or incapacity to work or if the Board of Management member at the time of the termination has already completed the age of 60 or receives monetary or non-monetary benefits in connection with the change of control.

No other one-off or recurring commitments exist in the event of termination of a Board of Management assignment.

Provisions of € 6,683 thousand (previous year: € 7,437 thousand) were recognised for pension commitments to former members of the Board of Management and their dependants. There were no loans outstanding to members of the Company's management bodies as of the reporting date.

Pension payments of € 541 thousand (previous year: € 426 thousand) were made to former members of the Board of Management in the 2015 financial year. In the 2015 financial year, former members of the Board of Management were also paid € 487 thousand as part of profit-sharing and the LTIP 2012.

As of 31 December 2015, provisions for former members of the Board of Management as part of LTIP have been established in the amount of  $\le$  40 thousand.

A detailed description of the Board of Management remuneration and the individual amounts are set out in the Remuneration Report in the Management Report of this Annual Report.

#### **10 PARTICIPATING INTERESTS**

The following is a list of the companies in which Biotest AG holds a direct or indirect participating interest pursuant to  $\ensuremath{\mathsf{HGB}}$ Section 313 (2). All amounts were calculated for the purposes of the consolidated financial statements in accordance with IASB rules.

Company name	Company headquarters	Equity in € million	Share of equity in %	Earnings after taxes in € million	
Biotest Pharma GmbH**	Dreieich, Germany	124.6	100.00	-0.2	
Biotest Grundstücksverwaltungs GmbH*	Dreieich, Germany	7.7	98.00	0.8	
Biotest France SAS	Paris, France	0.2	100.00	-0.2	
Biotest (UK) Ltd.	Birmingham, UK	3.5	100.00	0.4	
Biotest Italia S.r.l.	Milan, Italy	11.1	100.00	0.8	
Biotest Austria GmbH	Vienna, Austria	3.0	100.00	0.5	
Biotest (Schweiz) AG	Rupperswil, Switzerland	2.1	100.00	0.4	
Biotest Hungaria Kft.	Budapest, Hungary	3.5	100.00	0.1	
Biotest Farmacêutica Ltda.	São Paulo, Brazil	0.2	100.00	-0.3	
Biotest Hellas MEPE	Athens, Greece		100.00	0.0	
Biotest Medical S.L.U.	Barcelona, Spain	0.6	100.00	0.1	
Plasmadienst Tirol GmbH*	Innsbruck, Austria	0.3	100.00	0.0	
Plasma Service Europe GmbH*/***	Dreieich, Germany	3.9	100.00	0.0	
Biotest Pharmaceuticals Corporation*	Boca Raton, USA	76.7	100.00	-91.1	
Biotest US Corporation	Boca Raton, USA	194.0	100.00	0.0	
Plazmaszolgálat Kft.*	Budapest, Hungary	2.4	100.00	0.7	
BioDarou P.J.S. Co.*	Tehran, Iran	7.0	49.00	3.6	
Biotest Pharmaceuticals Ilac Pazarlama Anonim Sirketi****	Istanbul, Turkey	0.0	100.00	0.0	

Indirect interest
 After assumption profit according to German Commercial Code (Handelsgesetzbuch HGB) by Biotest AG
 After assumption profit according to German Commercial Code (Handelsgesetzbuch HGB) by Biotest Pharma GmbH
 Non-consolidated company

## 11 EXEMPTION OPTION UNDER SECTION 264 (3) GERMAN COMMERCIAL CODE (HANDELSGESETZBUCH HGB)

The exemption option under Section 264 (3) German Commercial Code (Handelsgesetzbuch HGB) is utilised for the separate financial statements of Biotest Pharma GmbH and Plasma Service Europe GmbH, both Dreieich, Germany, for the 2015 financial year to the extent that no separate company management report is compiled and no annual financial statements are published.

## 12 PENDING AND IMMINENT LEGAL PROCEEDINGS

Provisions of € 4.0 million (previous year: € 2.2 million) were recognised for pending and imminent legal proceedings as of the reporting date.

The provision for litigation risk mainly includes the expected defence costs arising in connection with the public prosecutor's investigations into Biotest AG's business in Russia and other Eastern European countries.

The investigation proceedings of the Frankfurt am Main public prosecutor's office for suspicion of bribery, breach of trust and tax evasion in May 2012 in connection with Biotest's business in Russia and other Eastern European countries are ongoing. The persons concerned and Biotest AG consider the allegations to be unfounded. With regard to the investigation initiated by the Frankfurt am Main public prosecutor's office in late 2011 concerning Biotest's business in Russia, the criminal proceedings against the former head of Biotest's representative office in Moscow and her husband are ongoing. In connection with this investigation, the fiscal authorities have examined the business expenses claimed by Biotest in the period 2005−2008. This could potentially lead to charges for taxes and interest of up to € 16 million,

although the legality of any such payments would naturally be carefully reviewed. In the event that the public prosecutor's allegations prove to be founded or an agreement is reached with the investigating authorities to avoid yearlong legal action, this could result in penalties being imposed on the Company in the form of fines or similar, which would adversely impact the Group results.

#### 13 EVENTS AFTER THE REPORTING DATE

On 19 January 2016, Biotest announced that the US subsidiary BPC, Boca Raton, USA, and Kedrion Biopharma Inc., Fort Lee, USA, entered into a seven-year cooperation agreement for the distribution of Bivigam® in the USA. Kedrion is an established manufacturer and distributor on the US market with a well-developed marketing and distribution organisation and will exclusively take over the distribution of Bivigam® in the USA from BPC.

The agreement stipulates mandatory minimum purchase quantities for both parties that increase over time. On non-fulfilment of the associated supply obligations by BPC or of the purchase obligations by Kedrion Biopharma Inc., the contract provides for appropriate compensation payments. Biotest AG has provided Kedrion Biopharma Inc. with a guarantee for the fulfilment of BPC's contractual obligations.

#### 14 CORPORATE GOVERNANCE

The Board of Management and the Supervisory Board of Biotest AG have issued the Declaration of Compliance required under Section 161 of the German Stock Corporation Act (AktG) and have made it permanently available to shareholders on the Company's website.

Dreieich, 9 March 2016

Dr Bernhard Ehmer Chairman of the Board of Management

Dr Michael Ramroth Member of the Board of Management Dr Georg Floß Member of the Board of Management DECLARATION OF THE BOARD OF MANAGEMENT IN ACCORDANCE WITH SECTION 37Y NO. 1 OF THE GERMAN SECURITIES TRADING ACT (WPHG) IN CONJUNCTION WITH SECTION 297 (2) SENTENCE 4 AND SECTION 315 (1) SENTENCE 6 OF THE GERMAN COMMERCIAL CODE (HGB)

"To the best of our knowledge, and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the Group, and the Group management report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group."

Dreieich, 15 March 2016

Biotest Aktiengesellschaft

Management Board

Dr Bernhard Ehmer Chairman of the Board of Management Dr Michael Ramroth Member of the Board of Management

M. Kamoh

Dr Georg Floß Member of the Board of Management

#### **AUDIT OPINION**

We have audited the consolidated financial statements prepared by Biotest Aktiengesellschaft, Dreieich, comprising the statement of financial position, the income statement, the statement of comprehensive income, the cash flow statement, the statement of changes in equity, and the notes to the consolidated financial statements, together with the group management report for the fiscal year from 1 January to 31 December 2015. The preparation of the consolidated financial statements and the group management report in accordance with IFRSs [International Financial Reporting Standards] as adopted by the EU, and the additional requirements of German commercial law pursuant to Sec. 315a (1) HGB ["Handelsgesetzbuch": German Commercial Code] is the responsibility of the Company's management. Our responsibility is to express an opinion on the consolidated financial statements and the group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with Sec. 317 HGB ["Handelsgesetzbuch": German Commercial Code] and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with [German] principles of proper accounting and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the group management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Sec. 315a (1) HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with [German] principles of proper accounting. The group management report is consistent with the consolidated financial statements and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks relating to future development.

Eschborn/Frankfurt am Main, 9 March 2016

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

Kretschmer Kaefer

Wirtschaftsprüfer Wirtschaftsprüfer [German Public Auditor] [German Public Auditor]

#### 2015 SUPERVISORY BOARD REPORT

The fiscal year 2015 was a very difficult year for the Biotest group. Not only was Biotest confronted with the challenges of the healthcare markets worldwide but also with the not significant result of the clinical phase II study of the product tregalizumab (BT-061), the monoclonal antibody against rheumatoid arthritis. As a consequence AbbVie terminated the cooperation agreement. Even bigger losses had to be recorded at the end of the third quarter. Declining sales of Bivigam®, the immunoglobulin produced and marketed in the US, led to substantial write-offs and to an impairment test of the bookvalue of the manufacturing plant of Biotest Pharmaceuticals Corp., BPC, in Boca Raton, Florida, USA. Here, too, an extraordinary write-down was necessary because not only the degree of utilized capacity of the plant became questionable by the reduced Bivigam® sales. In addition, the market prospects for the development product Civacir® had deteriorated significantly which should have been produced in the plant in Boca Raton. During the last financial year all those issues formed a substantial part of the fulfillment of the duties of the Supervisory Board according to statutory law, the articles of association and rules of procedure, including the continuous monitoring of the management activities of the Board of Management. Besides the regular advising of the Board of Management with regard to the management of the Company, the Supervisory Board focussed on the joint discussion of the consequences of such extraordinary developments. The Board of Management informed the Supervisory Board in a prompt and comprehensive manner, both orally and in writing. The discussion on those extraordinary topics and on the setting of a new strategic direction as a consequence thereof was taking place together with the regular information relating to planning and business performance, to compliance, to risk situation and to risk management. Furthermore, the Supervisory Board was informed on a monthly basis and in writing by the Board of Management of the business situation and any deviations from current and planned business developments. The Chairman of the Supervisory Board and the Chairman of the Audit Committee automatically received all Internal Audit reports.

The members of the Supervisory Board had the opportunity to critically examine the reports submitted and the proposed resolutions of the Board of Management and to make their own suggestions. In particular, all business transactions which had led to the losses in 2015 were discussed in detail by the Supervisory Board. In addition, the Supervisory Board reviewed the reports and information given by the Board of Management for plausibility and discussed necessary consequences. In general, the Supervisory Board was well informed about all decisions of fundamental importance to the Company, including those decisions where the approval of the Supervisory Board is not necessary.

During the 2015 financial year, the Supervisory Board held five regular meetings. All members of the Supervisory Board attended all meetings during all topics of the agenda. One resolution was approved by way of circulation and one meeting (strategy meeting) was attended solely by the shareholders' representatives. In addition, the Chairman of the Board of Management regularly informed the Chairman of the Supervisory Board outside the Supervisory Board meetings of current business developments and intentions and transactions that were of particular importance for the Company. The Board of Management informed the Chairman of the Supervisory Board about the extra-ordinary write-offs which were necessary at the end of the third quarter in a personal meeting while the other Supervisory Board members had been informed in a telephone conference. The Supervisory Board was involved at an early stage in any other matters which were fundamental for the Company. The Board of Management properly submitted written documentation on business transactions requiring approval by the Supervisory Board. No conflicts of interest involving members of the Board of Management and Supervisory Board, which must be immediately disclosed to the Supervisory Board and reported to the Annual Shareholders' Meeting, arose during the reporting year 2015.

#### MAIN FOCUS OF SUPERVISORY BOARD DELIBERATIONS

In addition to the extraordinary topics already mentioned in the beginning subjects regularly discussed by the Supervisory Board during all its meetings included, among others, planning of the Company, the Company's current business performance, the strategy, the Biotest Next Level project and the current developments in Biotest Pharmaceuticals Corporation (BPC), in particular the stage of discussions with the Food and Drug Administration (FDA) regarding Bivigam®.

The Supervisory Board obtained information on the status of investigations in Russia, Italy and Germany due to potential economic crimes and criminal offences relating to taxes from the Board of Management on an on-going basis. Any arising questions were discussed directly and comprehensively. Thus, the Supervisory Board always received the most current information. In this context, it was discussed with, among others, the Board of Management and the advisers, that to date there exists no evidence for the specified offences and that there was no evidence to doubt that the Board of Management acted diligently when handling the subject. It was again agreed that the Board of Management and the Supervisory Board will continue to cooperate closely in this matter in the future.

At the meeting held on 17 March 2015, the Group results until the end of February 2015 and the further forecast for the 2015 financial year were discussed. The Supervisory Board was informed in detail about the status of investigations in Russia and Italy. Furthermore, it has been resolved to reorganise the committees (see also under "Committees" below) and it has been decided to update the rules of procedure for the Board of Management, the Supervisory Board and the committees. The Board of Management informed the Supervisory Board on the 2014 single entity and consolidated financial statements and explained the balance sheet and the profit and loss account of Biotest AG. The auditor and the Chairman of the Audit Committee reported in this regard. Furthermore, the agenda for the 2015 Annual Shareholders' Meeting was adopted and the continuation of the Long Term Incentive Programme for the 2015 tranche approved. The Supervisory Board informed on the degree of achievement by the members of the Board of Management of the agreed targets, agreed on the targets for 2015 and discussed (in the absence of members of the Board of Management) the upcoming extension of the management contracts with Dr Floß and Dr Ramroth. The Board of Management presented the Environmental, Health and Security Report to the Supervisory Board.

At the meeting held on 7 May 2015 the Board of Management presented to the Supervisory Board the results of the Group until the end of April 2015. The Rules of Procedure for the Supervisory Board and for the new Governance Committee and the newly designated Personnel and Compensation Committee were resolved. The current status of the preparation of the upcoming Annual Shareholders' Meeting and the IT security issues were discussed.

The meeting on 10 July 2015 has been held in form of a strategy workshop (strategy meeting) with the representatives of shareholders in the Supervisory Board and members of the Board of Management. The Board of Management explained the representatives of shareholders in the Supervisory Board, among others, the current business strategy and business development of the Group. The data from the current study regarding tregalizumab (BT-061) has been presented and the consequences of the not significant result of the clinical phase II study and the subsequent termination of the development co-operation by AbbVie had been discussed. Also the results of the CIGMA 982 study regarding IgM Concentrate and the conduct of further development tests on this basis were discussed. Furthermore, the new results of the study on the examination of the effects of Civacir® on the hepatitis C virus were presented. The Board of Management informed the Supervisory Board on the current status of the investigations in Germany and Italy. Furthermore, the change of the Chief Executive Officer (CEO) of BPC as well as the business plan for the financial years 2015 until 2024 were discussed.

In the Supervisory Board meeting on 15 September 2015 the Chairman of the Supervisory Board informed about the results of the Strategy Meeting. The Board of Management presented to the Supervisory Board the Group results until end of August 2015 and explained the forecast for the (remaining) year 2015. At the request of the Supervisory Board, the Board of Management presented the effects of the developments in 2015 financial year on the milestones of the budget planning for 2016. As part of the risk management system, the Board of Management presented a list of material risks. The Board of Management informed about the compliance activities in 2015 and the current status of investigations in Russia and Italy. Dr Schleussner reported on the last meeting of the Governance Committee. The Supervisory Board decided to limit the membership in the committees (with the exception of certain shareholders) to two terms of office with a term of five years, respectively, and to offer to the members the possibility to participate at least once a year in a training on the tasks of a supervisory board. At the end, the Rules of Procedure for the Board of Management were resolved. Finally, the necessity of compliance with gender quotas by the Company was discussed. Biotest has complied with the legally required target quota for female members of the supervisory board of 30 % since 2004. The proposal of the Supervisory Board to determine a fixed gender quota target for the Board of Management until 30 June 2017 has not been implemented since the employment contracts of all members of the Board of Management of Biotest AG have the terms going beyond the year 2017. The Board of Management presented its quota targets for the proportion of women of 17% and 38%, respectively, for the two highest management levels below the Board of Management in the year 2017.

In the meeting held on 26/27 October 2015 the Board of Management presented to the Supervisory Board the Group results until the end of September 2015 and explained in detail the reasons for the impairment test and the write-offs at the end of the third quarter, the resulting strategic adjustments and the actions needed to improve the profitability of BPC in the US. Also, the business planning for the year 2016 has been discussed. Finally, the Board of Management discussed in detail the development of profitability of the Company and possible cooperation with various cooperation partners and the current status of the respective negotiations. Finally, the key parameters of the budget for 2016 were presented and the issues relevant for the financing of the Group in the years 2016 until 2023 were discussed.

In the meeting on 3 December 2015 the Group results until end of October 2015 and the preliminary sale numbers for November 2015 were discussed. The Board of Management informed the Supervisory Board about the possible cooperation on fostering the business development. The budget for 2016 and the business planning 2016/2017 were discussed. The Chairman of the Audit Committee, Dr Schröder, provided an overview of the activities of the Audit Committee. As part of the following discussion, the Supervisory Board made it clear that no breach of compliance rules will be tolerated within the company. Furthermore, general and strategic risks in relation to compliance were discussed. In addition, it has been reported on the environmental, health and security issues. In addition, the Board of Management reported to the Supervisory Board on the current developments in investigations of economic crimes and criminal offences relating to taxes in Russia and Italy. Dr Schleussner presented the results of the last meeting of the Governance Committee. The Chairman of the Supervisory Board informed that his term will end with the General Shareholders' Assembly in May 2017 and that according to the Rules of Procedure of the Supervisory Board he will not be available for reelection.

By way of circulation, the Supervisory Board on 30 December 2015 unanimously approved the conclusion of an agreement between BPC and Kedrion Biopharma Inc. regarding the sale and distribution of Bivigam® by Kedrion in the USA.

#### COMMITTEES

The Supervisory Board was assisted in its work by the committees formed by it. In March 2015 the Supervisory board rearranged the committees and their tasks.

The Audit Committee remained unchanged. The Presiding Committee has been replaced by a new Governance Committee, consisting of Dr Schleussner as Chairwoman and Dr Banchi and Dr Schröder as further members. The Personnel Committee has been renamed to the Personnel and Compensation Committee without personnel changes.

In 2015, the Audit Committee held two meetings with the Board of Management. At the meeting on 16 March 2015 the Board of Management presented to the Committee the single and consolidated financial statements for the 2014 financial year as well as the findings of the auditor. Then the Board of Management explained the results of the audit regarding the management of business partners by the auditor and the measures already taken or resolved on this basis. Furthermore, the proposal regarding the execution of a share split and a share buy-back programme as well as a conclusion of a domination and profit and loss transfer agreement by Biotest AG with Biotest Pharma GmbH as transferring company were discussed. At the meeting held on 2 December 2015, the Board of Management explained the underperformance of the market and production numbers for Bivigam® and why the market prospects for Civacir® had been assessed much lower than before. In consequence, the reduced production planning led to an impairment test of the bookvalue of the manufacturing facility in Boca Raton, Florida, resulting in the write-down of the bookvalue. The procedure regarding impairment test for assets of the Biotest Group was presented in detail and the scope and strategy regarding the upcoming audits were explained and subsequently discussed by the Audit Committee with the Board of Management. The current status of investigations in Russia and Italy and the status quo of compliance management at Biotest were discussed. Finally, the summary of the internal audits in 2015 has been dealt with and the Audit Committee agreed on the Audit Plan for 2016.

The Presiding Committee held one meeting with the Board of Management in 2015. At this meeting, which took place on 16 March 2015, the planned restructuring/renaming of the committees of the Supervisory Board and the planned update of the Rules of Procedure of the Supervisory Board and its committees were discussed. The Committee has then been informed on the current status of the ongoing investigations in Russia and Italy. The proposals regarding the execution of a share split and a share buy-back programme as well as conclusion of a domination and profit and loss transfer agreement by Biotest AG with Biotest Pharma GmbH as transferring company were discussed.

The new Governance Committee held two meetings with the Board of Management. At the first meeting on 15 September 2015 the necessity of the compliance with gender quota within the company has been discussed. The planned new version of the Rules of Procedure for the Board of Management to be presented to the Supervisory Board was discussed. Furthermore, the adjustment of the risk management system regarding mid- and long-term risks was discussed. Furthermore, the Committee dealt with the changes of the Corporate Governance Code, among others with respect to the number and term of the term of office of members of the supervisory board and the measures necessary to effectively implement those changes. Finally, the overview of the activities of the Supervisory Board in the last twelve months was discussed. In the last meeting in the year on 2 December 2015 the overview of the decisions of the Supervisory Board was again discussed and finalised. Finally, the size of the Supervisory Board starting from the year 2017 and the qualification of its future members were discussed.

The Personnel or, as the case may be in the course of the year the Personnel and Compensation Committee, held two meetings in 2015. In the first meeting on 17 March 2015 the Committee discussed the realisation of the targets by the Board of Management members for the 2014 financial year. The new targets for the Board of Management for the 2015 financial year were agreed. Then the new tranche of the Long Term Incentive Programme for the years 2015 until 2017 was discussed. Finally, the Committee prepared a proposal for the extension of service contracts for the members of the Board of Management, Dr Floß and Dr Ramroth. In its last meeting during the year, on 2 December 2015, the head of the Human Resource Department presented to the Committee and the Board of Management the key issues in the personnel area in 2015 and the upcoming tasks in this area in the year 2016. The current remuneration model was discussed and it was decided that no changes are necessary. The targets for the Board of Management in 2016 were discussed and finally agreed.

#### **CORPORATE GOVERNANCE**

In 2015, the Supervisory Board continually monitored the further development of corporate governance standards within the Company. The Board of Management and Supervisory Board reported on corporate governance in accordance with Section 3.10 of the German Corporate Governance Code in the Corporate Governance Report which was published along with the declaration of conformity with the recommendations of the government commission on the German Corporate Governance Code in accordance with Section 161 of the German Stock Corporation Act (AktG). In March 2016, the Board of Management and the Supervisory Board of Biotest AG issued a declaration of conformity with the recommendations of the government commission on the German Corporate Governance Code in accordance with Section 161 AktG.

## CHANGES TO THE BOARD OF MANAGEMENT AND THE SUPERVISORY BOARD

The appointment as members of the Board of Management and the management contracts of the members of the Board of Management, Dr Floß and Dr Ramroth, were extended. Dr Ramroth has been reappointed as member of the Board of Management from 1 January 2016 until 31 December 2020 and received a respectively adjusted service contract. The same applies to Dr Floß whose new term of office lasts from 9 January 2016 until 8 January 2021. The Supervisory Board would like to thank Dr Ramroth and Dr Floß for the successful cooperation so far built on mutual trust and is looking forward to further cooperation. There were no other changes to the Board of Management and the Supervisory Board.

#### SINGLE ENTITY AND CONSOLIDATED FINANCIAL STATEMENTS

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Eschborn/Frankfurt am Main, audited the single entity financial statements of Biotest AG and the consolidated financial statements as of 31 December 2015 together with the management report and Group management report and issued an unqualified opinion.

The above mentioned documents, the auditor's report and the Board of Management's proposal on the appropriation of net profit were submitted to all members of the Supervisory Board in a timely manner. They were discussed in detail at the meeting of the Audit Committee on 14 March 2016 as well as at the meeting of the Supervisory Board on 15 March 2016. In both meetings, the auditor reported on the main results of the audit and were on hand to answer questions and provide additional information.

After reviewing and discussing the single entity and consolidated financial statements, the management report and Group management report and the Board of Management's proposal on the appropriation of the net profit, the Supervisory Board raised no objections and approved the auditor's report. The Supervisory Board approved the single entity and consolidated financial statements for the 2015 financial year as prepared by the Board of Management. The annual financial statements are thereby adopted. The Supervisory Board approved the Board of Management's proposal on the appropriation of net profit.

The Supervisory Board would like to thank the Board of Management and all employees for their commitment and hard work in the 2015 financial year which has been difficult for the Biotest Group.

Dreieich, 15 March 2016

The Supervisory Board

Dr Alessandro Banchi

(Chairman

#### CORPORATE GOVERNANCE REPORT

JOINT REPORT OF THE BOARD OF MANAGEMENT AND THE SUPERVISORY BOARD OF BIOTEST AG IN ACCORDANCE WITH SUBPARAGRAPH 3.10 OF THE GERMAN CORPORATE GOVERNANCE CODE (GCGC)

#### Corporate governance principles

The management and control practices of Biotest AG are aimed at securing the Company's long-term success. The Board of Management and Supervisory Board work closely together and base their actions on internationally recognised standards of good corporate governance. The Company's management and control practices meet all applicable legal requirements and the recommendations ("prescribed" targets) of the GCGC, except where expressly indicated in the Declaration of Compliance. The recommendations and suggestions, which have been amended and expanded many times over recent years, represent a high standard in our view, including at the international level.

#### Notes regarding the GCGC

The government commission on the German Corporate Governance Code adopted amendments to the Code in its plenary session on 5 May 2015. The following information applies to both the old version of 24 June 2014 and the updated version of the Code of 5 May 2015.

#### **DECLARATION OF COMPLIANCE**

Declaration of the Board of Management and the Supervisory Board of Biotest AG on the recommendations of the GCGC in accordance with Section 161 of the German Stock Corporation Act (Aktiengesetz – AktG)

Since the last Declaration of Compliance dated 17 March 2015, which referred to the GCGC as amended on 13 May 2013 and 24 Juni 2014, Biotest AG has complied with all recommendations of the GCGC as amended on 24 June 2014 and 5 May 2015 with the following exceptions:

• Biotest AG continues not to follow the recommendation in Section 3.8 (3) of the GCGC to set a deductible on D&O insurance for the members of the Supervisory Board in the amount prescribed in Section 93 (2) clause 3 of the AktG for members of the Board of Management. The reasons given in the last Declaration of Compliance remain valid. A deductible equivalent to the deductible for members of the Board of Management, would be out of proportion to the current remuneration levels for Supervisory Board duties. Biotest AG has set in its view an appropriate deductible for its Supervisory Board members.

- The recommendation set forth in Section 4.2.3 (2) of the GCGC requires that an upper limit be set for the remuneration amount in total and variable remuneration components for the Board of Management. The contracts entered into with Board of Management members do not contain any explicit upper limit amounts for the remuneration in total. However, a limit is specified for the maximum amount of each and every remuneration component. The Supervisory Board is of the opinion that it is not necessary, to additionally set an explicit upper limit amount for the remuneration in total.
- The recommendation set forth in Section 4.2.3 (3) requires the Supervisory Board to determine the targeted level of benefits also based on the length of time served on the Board of Management and to take into account the annual expense for the Company derived from this. The Board of Management members are included in the company pension scheme of Biotest AG. They each have been given an individual commitment. The corresponding benefits are not derived from a pre-defined level of benefits so that the recommendation set forth in Section 4.2.3 (3) is currently not complied with. The Supervisory Board does not intend at the present time to change what it considers to be an appropriate pension system for the Board of Management members of Biotest AG.
- Biotest AG did not follow the recommendation set forth in Section 5.3.3 of the GCGC to form an own Supervisory Board Nomination Committee. The tasks of the Nomination Commitee are carried out by the Governance Commitee of the Supervisory Board of Biotest AG.
- Section 5.4.1 (2) and (3) of the GCGC requires that the Supervisory Board set specific targets with regard to its composition that take into account the international activities of the company, potential conflicts of interest, the number of independent Supervisory Board members within the meaning of Section 5.4.2 of the GCGC, a defined age limit for Supervisory Board members and a regular limit of length of membership and, of diversity in light of the Company's specific situation. The Supervisory Board must take these targets into account when making recommendations to the selection committees. The targets and the status of their implementation are to be published in the Corporate Governance Report. Biotest AG

has not followed the recommendations. The reasons which were presented in the last Declarations of Compliance are still valid. In line with the Law on Equal Participation of Women and Men in Private-Sector and Public-Sector Management Positions dated 14 April 2015, Biotest AG has complied with the target quota for female members of the supervisory board of 30% since 2004.

The Supervisory Board of Biotest AG has already set a specific target for the maximum age of its members. The Company's international activities are covered by the Chairman of the Supervisory Board, who is an Italian citizen. Biotest AG does not follow the recommendation that a target be established for the number of independent Supervisory Board members. The right of OGEL GmbH to appoint a member to the Supervisory Board is laid down in the Articles of Association. A Supervisory Board member has a business relationship with Kreissparkasse Bieberach as a major shareholder. An internal analysis found that the setting of specific targets for the composition of the Supervisory Board is not necessary under the existing specific circumstances and shareholder structure.

With non-compliance with the recommendation of Section 5.4.1 (2) of the GCGC, accordingly, the relevant statements cannot be made in the Corporate Governance Report. Therefore, an exception is also declared in respect of Section 5.4.1 (3) of the GCGC.

• Under Section 5.4.6 (2) of the GCGC, performance-based remuneration is to be paid to Supervisory Board members based on the sustained performance of the company. This is generally understood as a multi-year basis for calculating performance-based remuneration. Biotest AG does not comply with this recommendation. Pursuant to Section 16 (1) (b) of the

Articles of Association the Supervisory Board members receive an annual variable remuneration for each past financial year based on the amount of the dividend paid. Biotest AG is of the opinion that the currently determined variable remuneration of the Supervisory Board is appropriate with regard to the calculation basis and amount. In the event that the Company comes to the conclusion in its regularly scheduled review of the remuneration system that the performance-based remuneration should be adjusted, the recommendation set forth in Section 5.4.6 (2) of the GCGC will be incorporated into its analysis.

• An amendment to Section 6.3 and since 5 May 2015, Section 6.2, respectively, of the GCGC requires that shares or related financial instruments held by the Board of Management and the Supervisory Board members now are disclosed separately in the Corporate Governance Report by the Board of Management and the Supervisory Board, if it directly or indirectly holds more than 1% of the shares issued. Dr Schleussner, Deputy Chairwoman of the Supervisory Board, controls OGEL GmbH, which, to the knowledge of the Company, holds approx. 50.03 % of the issued ordinary shares of the Company. She therefore indirectly holds 50.03 % of the ordinary shares of Biotest AG. Information regarding this can be found in the Group Management Report under "Explanatory notes in accordance with Section 315 (4) of the German Commercial Code (Handelsgesetzbuch - HGB)". The combined total of the shares held by other members of the Supervisory Board as well as by Board of Management members is below 1% of the ordinary shares issued by the Company. The Company does not consider it necessary to repeat the information contained in the Group Management Report in the Corporate Governance Report. It does not follow the recommendation in this respect.

Dreieich, 15 March 2016

For the Board of Management

For the Supervisory Board

Dr Bernhard Ehmer

Dr Michael Ramroth

Dr Georg Floß

Dr Alessandro Banchi

#### CORPORATE GOVERNANCE IN THE FINANCIAL YEAR

The Annual Shareholders' meeting of Biotest AG was held on 7 May 2015 in Frankfurt am Main. 77.54% of the voting capital (ordinary share capital) was represented. All resolutions submitted (appropriation of net profit, approval of the actions of the members of the Board of Management and Supervisory Board, election of the annual auditors, approval of a domination and profit and loss transfer agreement, capital increase from capital reserve and reclassification of the share capital (share split) and corresponding amendments of the articles of association, authorization to acquire and to use treasury shares and to exclude the right to offer and to subscribe) were approved by a clear majority.

# DIRECTORS' DEALINGS (NOTICE ON TRANSACTIONS BY EXECUTIVES PURSUANT TO SECTION 15A OF THE GERMAN SECURITIES TRADING ACT (WERTPAPIERHANDELSGESETZ – WPHG))

The following reportable share purchase and sale transactions were executed by members of executive bodies and other senior executives of Biotest AG in the 2015 financial year:

Date	Person obligated to report	Role	Transaction type and place of execution	Financial instrument	ISIN	Number	Price in €	Transaction amount in €
29.04.2015	Dr Michael Ramroth	CFO	Purchase/Xetra	Preference shares	DE0005227235	500	80.00	40,000.00
18.05.2015	OGEL GmbH	Legal person closely related to a member of an executive body	Purchase/ Off-market	Ordinary shares	DE0005227201	4,000	73.71	294,846.80
19.05.2015	OGEL GmbH	Legal person closely related to a member of an executive body	Purchase/ Off-market	Ordinary shares	DE0005227201	4,000	75.12	300,492.40
13.08.2015	Dr Michael Ramroth	CFO	Purchase / Xetra	Preference shares	DE0005227235	1,000	23.90	23,900.00
17.08.2015	OGEL GmbH	Legal person closely related to a member of an executive body	Purchase/ Off-market	Ordinary shares	DE0005227201	2,000	23.16	46,327.60
06.11.2015	Dr Michael Ramroth	CFO	Purchase/Xetra	Preference shares	DE0005227235	1,200	14.00	16,800.00
10.11.2015	OGEL GmbH	Legal person closely related to a member of an executive body	Purchase/ Off-market	Ordinary shares	DE0005227201	5,000	14.90	74,482.00
16.11.2015	OGEL GmbH	Legal person closely related to a member of an executive body	Purchase/ Off-market	Ordinary shares	DE0005227201	5,000	15.16	75,805.00

#### GLOSSARY / TECHNICAL TERMS

#### Α

#### ALBUMIN (OR HUMAN ALBUMIN)

Protein produced in the liver that serves to maintain plasma volume and acts as a transport vehicle for many physiological and pharmacological substances.

#### **ANTIBODIES**

Proteins in the blood plasma produced by special cells of the immune system as a defence reaction against various disease pathogens.

#### ANTIBODY DEFICIENCY SYNDROME

The body's inability to react to an antigen stimulus with sufficient antibody production. A distinction is made between primary (congenital) and secondary (acquired) antibody deficiency syndromes.

#### **AUTOIMMUNE DISEASE**

Activity of the immune system directed against tissues and cells of one's own body.

#### В

#### BLADDER CANCER

General term for malignant tumours that spread from the bladder.

#### C

#### **CLOTTING FACTORS**

Proteins responsible for blood coagulation. The 13 different clotting factors are designated with the Roman numerals I to XIII.

#### CYTOMEGALOVIRUS (CMV)

Usually harmless infection caused by cytomegalovirus (CMV). If it occurs during pregnancy, it can cause severe damage to the unborn child. One of the most common virus infections in organ transplantation, which can lead to loss of the transplant. As the viruses stay permanently in the body after an infection, there can be serious consequences in case of reactivations or new infections in the event of a suppressed immune system.

#### D

#### DEXAMETHASONE

A drug used, among other things, in combination with lenalidomide to treat multiple myeloma and in the treatment of various tumours. Dexamethasone has an anti-inflammatory action and a dampening effect on the immune system.

#### DOSE ESCALATION

Increase in the dosage of a drug.

#### F

#### **FIBRINOGEN**

Protein produced in the liver that plays a central part in blood clotting. During clotting, it is converted to fibrin, which acts like a glue in the blood for sealing wounds. A fibrinogen deficiency is one possible cause of blood clotting disorders.

#### FOOD AND DRUG ADMINISTRATION (FDA)

US-American agency responsible for monitoring foods and licensing drugs.

#### FRACTIONATION (PLASMA FRACTIONATION)

Process for obtaining proteins from human plasma.

#### Н

#### HAEMATOLOGY

Branch of medicine that involves blood and diseases of the blood.

#### HAFMOPHILIA

A blood clotting disorder resulting from defective or missing coagulation factors VIII or IX (type A or B haemophilia).

#### **HEPATITIS**

Inflammation of liver, which can be attributed to various causes, especially virus infections and autoimmune diseases. It leads to death or damage of liver cells and to impairment or even cessation of the liver's metabolic functions. Liver transplantation is often necessary.

#### HER 2

The HER 2 protein is a receptor molecule located on the surface of body cells. The protein is classified as a member of a family of certain epidermal growth factor receptors. The number of receptors on the cell surface is determined by the HER 2 gene.

#### HYDROXYETHYL STARCH (HES)

Substance synthesised from waxy maize starch or potato starch, used as a substitute for human albumin.

#### i

#### IMMUNE SYSTEM

Totality of all factors responsible for recognising and defending against infectious agents in the body and which exercise control over self-destructive processes.

#### IMMUNOGLOBULIN M (IGM)

Largest antibody molecule in the plasma. In conjunction with the complement system (a system of plasma proteins that is activated as part of the immune response), it destroys bacteria and neutralises bacterial toxin.

#### **IMMUNOGLOBULINS**

Synonymous with antibodies. They recognise and bind disease pathogens, facilitating their destruction by cells of the immune system.

#### **IMMUNOLOGY**

The study of immune defences and immune regulation that enables the body to fight disease pathogens.

#### **IMMUNOSUPPRESSIVE**

A process that suppresses immunological processes. This is relevant if adverse reactions, such as in the case of autoimmune diseases or after tissue and organ transplantations, are to be inhibited.

#### INDICATION

The therapeutic use for which a substance or medication can be developed and authorised.

#### INTENSIVE CARE MEDICINE

Medical specialty that deals with the diagnosis and treatment of life-threatening conditions.

#### INTRAVENOUS (I.V.)

Administration of a medication through an injection into a vein.

#### Ĺ

#### LENALIDOMIDE

Lenalidomide is a drug substance of the group of immune modulators. Drug used in combination with dexamethasone especially for the treatment of multiple myeloma, to inhibit the division of certain tumour cells, among other things. Lenalidomide is structurally related to Thalidomide and Pomalidomide.

#### LIVER INSUFFICIENCY

Also called liver failure, meaning that the liver ceases to function.

#### M

#### **METHOTREXATE**

Drug used to treat rheumatoid arthritis and other autoimmune diseases (for example, psoriasis, multiple sclerosis) and various tumours.

#### MONOCLONAL ANTIBODIES (MAB)

Antibodies whose production can be traced back to a single cell and which each specifically recognise and bind only a certain antigen.

#### MULTIPLE MYELOMA

Hematological disease; malignant plasma cell growth in the bone marrow.

#### 0

#### **OESTROGEN**

Most important female sex hormone, one of the steroid hormones. When oestrogen preparations are taken, side effects may occur in the form of autoimmune reactions such as systemic lupus erythematosus (SLE).

#### P

#### PAUL EHRLICH INSTITUTE (PEI)

German Federal Institute for Vaccines and Biomedicines (higher federal authority). The PEI is responsible, among other things, for the approval of clinical trials, the authorisation of vaccines and preparations derived from human plasma and for the release for sale of production batches.

#### **PHARMACODYNAMICS**

The sum of all processes caused by the action of a drug, from the description of the activity profile and dose response relationship to the mechanism of action.

#### **PHARMACOKINETICS**

The sum of all processes that a medication undergoes in the body, from release of the medication and its absorption into the bloodstream to its distribution in the body, biochemical conversion and breakdown, and elimination of the substance.

#### **PHARMACOVIGILANCE**

Systematic monitoring of a drug's safety to identify undesirable effects and take appropriate risk minimisation measures.

#### PIVOTAL STUDY

Key study that provides significant proof of the efficacy of a drug. This is a phase III study in most cases.

#### **PLACEBO**

A dummy medication. Medically inactive substance that is used to meet a subjective need for drug therapy. In many clinical studies, a control group is treated with placebo. The results are compared with those of the participants who have received the trial drug.

#### **PLASMAPHERESIS**

Obtaining of blood from donated blood. The cellular components are returned to the donor. This leaves blood plasma, a clear yellowish fluid, which contains the blood's soluble protein components.

#### PLASMA PROTEINS

#### PLASMA PROTEIN THERAPEUTICS ASSOCIATION (PPTA)

Association of the world's leading manufacturers of plasma proteins.

#### PRIONS

Proteins that can occur in both normal and pathogenic structures in the human and animal body.

#### PRIMARY IMMUNE DEFICIENCY (PID)

Congenital defect in the immune system that results in a deficiency of antibodies.

#### PROGESTERONE (CORPUS LUTEUM HORMONE)

Forms the female sex hormones together with oestrogen. Progesterone prepares the uterus for pregnancy and maintains the pregnancy.

#### **PSORIASIS**

Scaly patches. Chronic skin disease.

#### R

#### RECOMBINANT

Produced with the aid of genetically modified micro-organisms or cell lines.

#### RHEUMATOID ARTHRITIS

Chronic inflammatory disease of the joints.

#### S

#### sCAP (SEVERE COMMUNITY ACQUIRED PNEUMONIA)

Spread of the inflammation from the lung to the body often results in complications such as sepsis, septic shock or organ failure.

#### SEROCONVERSION

Development of specific antibodies against antigens of a foreign body due to infection or vaccination or a change in antibody class in the course of an infection from IgM (early antibodies) to IgG (later antibodies).

#### **SERUM PROTEINS**

Name given to proteins contained in blood serum.

#### SUBCUTANEOUS (S.C.)

In anatomical terms, the layer of tissue beneath the skin. This consists mainly of connective tissue and fat. A subcutaneous injection is given under the skin.

#### SUBSTITUTION THERAPY

Medicinal use of a substance that is not produced sufficiently by the body itself.

#### SYSTEMIC LUPUS ERYTHEMATOSUS (SLE)

Autoimmune disease that often starts with a fever. Patients usually have rheumatoid-like joint pains. Areas of erythema (redness due to dilated blood vessels) develop on the skin. Other organs can also be affected by this disease.



#### **VARICELLA ZOSTER VIRUS**

A virus belonging to the herpesvirus family. The first infection usually leads to chickenpox. Reactivation, for instance if the immune system is weakened, can lead to shingles.

#### GLOSSARY / FINANCIAL TERMS

#### Α

#### **ASSOCIATE**

A Group company that is not fully consolidated (participating interest < 50%) and is significantly influenced by the parent company.

#### C

#### **CASH FLOW**

Actual movement of cash into or out of the company in a period (inflows and outflows). An indicator of a company's internal financing ability.

#### **CONTRIBUTION MARGIN**

A category used in cost accounting. Difference between revenue and variable costs.

#### **CURRENCY OPTION**

Transaction that hedges the risk of fluctuations in exchange rates. The buyer of a currency option acquires the right, but not the obligation, to purchase or sell a currency at a specific rate on a specified date.

#### D

#### D&O INSURANCE

Directors' and officers' insurance (also: executive body and manager liability insurance). Financial loss liability insurance that a company obtains for its executive bodies (Board of Management and Supervisory Board) and senior managers.

#### **DEFERRED TAXES**

Income taxes payable or receivable in the future, which do not constitute actual receivables or payables at the time the financial statements are prepared.

#### DERIVATIVE

Financial instrument, the price of which is based on market-related factors. Used among other things to hedge against fluctuations in value.

#### **DIRECTORS' DEALINGS**

Transaction in securities issued by a listed company executed by the company's management or related companies or persons.

#### Ε

#### FAT

Earnings after taxes.

#### EBIT

Earnings before interest and taxes.

#### EBT

Earnings before taxes.

#### F

#### FACTORING

Financial service. The factor acquires a company's accounts receivables due from the company's debtors.

#### FAIR VALUE

A rational and unbiased estimate of the potential market price of an asset or liability.

## FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT AND LOSS (FAFVtPL)

A financial instrument category as defined in IFRS 7.

#### FORWARD FOREIGN EXCHANGE TRANSACTION

Binding agreement to exchange one currency for another on a specific date at a specified rate.

#### Н

#### **HEDGE ACCOUNTING**

Accounting technique. Creates hedging relationships between the underlying transaction and the derivative financial instruments used for hedging purposes.

#### HELD TO MATURITY (HtM)

A financial instrument category as defined in IFRS 7.

L

#### LOANS AND RECEIVABLES (LaR)

A financial instrument category as defined in IFRS 7.

#### LONG TERM INCENTIVE PROGRAMME

 $\ \ \, \text{A variable, success-based remuneration system}.$ 

#### Ν

#### **NET PRESENT VALUE**

Key business indicator for dynamic capital budgeting, in which payments that occur at any point in time are made comparable by discounting such payments back in time to the start of the investment. The net present value is the sum of the present values of all payments (inflows and outflows) resulting from the investment.

0

#### ORDINARY SHARE

A share that confers voting rights and is the counterpart to the preference share.

#### Р

#### PREFERENCE SHARE

Share without voting rights, but which entitles the holder to a preferred and generally higher dividend. The counterpart to a preference share is the ordinary share.

#### PROMISSORY NOTE

Form of (long-term) debt financing for companies, in which a borrower is granted a loan by different creditors through the provision of capital.

R

#### RETURN ON CAPITAL EMPLOYED (RoCE)

A measure of the return that a company realises on its capital.

S

#### SENSITIVITY ANALYSIS

Used to determine the impact of specific factors on certain performance indicators.

#### SWAP

Exchange of receivables and liabilities in the same or a foreign currency with the aim of obtaining a financing, interest rate or yield advantage.

W

#### WEIGHTED AVERAGE COST OF CAPITAL (WACC)

The weighted average cost of capital approach denotes an approach that forms part of the discounted cash flow methods used for valuing companies. This method is also often called the free cash flow method. It is mostly used to determine the minimum rate of return for investment projects.

#### WORKING CAPITAL

Short-term tied-up capital.

#### FINANCIAL CALENDAR

#### **ACKNOWLEDGEMENTS**

#### 12 MAY 2016

Three-month report for 2016

#### 12 MAY 2016

Annual Shareholders' Meeting

#### 11 AUGUST 2016

Half-year report for 2016

#### 10 NOVEMBER 2016

Nine-month report for 2016

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The annual report contains forward-looking statements on overall economic development as well as on the state of business, results of operation, cash flows and financial position of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and are thus subject to risks and elements of uncertainty that could result in significant deviation of actual developments from expected developments. The forwardlooking statements are only valid at the time of publication of this annual report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

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