

HALF-YEAR REPORT 2016 BIOTEST AG



KEY FIGURES

BIOTEST GROUP		H1 2016	H1 2015	Change in %
Revenue	€ million	306.1	287.7	6.4
thereof:				
Germany	€ million	54.5	61.5	-11.4
Rest of world	€ million	251.6	226.2	11.2
thereof:				
Therapy	€ million	203.3	196.3	3.6
Plasma & Services	€ million	99.1	87.0	13.9
Other Segments	€ million	3.7	4.4	-15.9
EBITDA	€ million	30.7	17.6	74.4
Operating profit (EBIT)	€ million	18.2	2.3	691.3
<i>EBIT in % of revenue</i>	%	5.9	0.8	–
Earnings before taxes	€ million	13.9	2.1	561.9
Earnings after taxes	€ million	7.7	-2.2	450.0
Financing				
Cash flow from operating activities	€ million	49.6	31.2	59.0
Depreciation and amortisation	€ million	12.5	15.3	-18.3
		30 June 2016	31 December 2015	
Equity	€ million	416.7	412.3	1.1
<i>Equity ratio</i>	%	42.4	42.8	–
Employees (full-time equivalents)	amount	2,340	2,271	3.0

CONTENTS

3	INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 2016	12	CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS AS OF 30 JUNE 2016
3	Group Principles	12	Consolidated statement of income
3	Business model of the Group	12	Consolidated statement of comprehensive income
3	Group strategy	13	Consolidated statement of financial position
3	Research and development (general)	14	Consolidated cash flow statement
4	Economic report	14	Consolidated statement of changes in equity
4	Business and general framework	15	Selected note disclosures
4	Industry-specific framework	19	FINANCIAL CALENDAR
5	Business performance	19	ACKNOWLEDGEMENTS
8	Presentation of results of operations, financial position and cash flows		
10	Supplementary report		
10	Outlook, risk and opportunities report		
10	Outlook		
11	Risk report		
11	Opportunities report		

INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 2016

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. 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.

B. PERSONNEL

As of 30 June 2016 Biotest employed a staff of 2,340 full-time equivalents. Compared to 2,271 full-time equivalents this represents an increase of 3.0% at the end of 2015.

II. GROUP STRATEGY

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

In order to continue participating in future global market growth the Biotest Group is expanding its production capacity at its headquarters at Dreieich. As part of the Biotest Next Level project the product portfolio will be expanded, profitability increased and production capacity more than doubled.

III. RESEARCH AND DEVELOPMENT (GENERAL)

Research and development are 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 concentrated on plasma proteins. Biotest is also actively aiming at the goal of developing products together with partners in the area of monoclonal antibodies. After completion of the current studies, Biotest will pursue further activities only together with a partner. This is intended to reduce development risks and development costs.

A detailed schedule of the progress made in the research and development projects carried out in the first half of 2016 is shown in the "Research and development" section of the Business Report.

B. ECONOMIC REPORT

I. BUSINESS AND GENERAL FRAMEWORK

The economic situation in Germany is still developing very robustly. Adjusted for seasonal factors, economic activity increased by 0.7% in the first three months of 2016.¹ The stable price level, rising employment and increasing income of private households enabled a further increase in private consumer spending. Government spending on supplies for refugees arriving in Germany primarily from the crisis areas in the Middle East had a supporting effect on the economy.² After the positive start into 2016, however, the growth of the German economy is assumed to have slowed somewhat in the second quarter. For 2016 as a whole, the German federal government expects gross domestic product to increase by 1.7%.³

In Europe, the economic recovery continued likewise in the first half of 2016. In its spring forecast, the European Commission anticipates a growth of 1.6% for 2016 and 1.8% for 2017.⁴ However, the first economic researchers are already warning of weaker economic growth in 2016 and 2017 due to the referendum in Great Britain to leave the European Union.⁵

Global conditions are continuing to deteriorate. The International Monetary Fund recently lowered its growth forecast for 2016 by 0.2 percentage points to 3.2%.⁶ Uncertainty for the global economy has increased overall, according to the IMF experts. The biggest risks are further financial market turbulences, permanently low oil prices, a sharp decline in the Chinese economy and non-economic shocks such as geopolitical conflicts, terrorism, refugee migrations and global epidemics. The economists see the low oil price as an obstacle for the global economy, because the positive effects for import countries cannot compensate for the negative impact on export countries.⁷

¹ BMWI (2016), *The economic situation in Germany in May 2016*, Berlin, p. 1

² BMWI (2016), *The economic situation in Germany in May 2016*, Berlin, p. 1

³ BMWI (2016), *The economic situation in Germany in May 2016*, Berlin, p. 1

⁴ European Commission (2016), *European Economic Forecast. Spring 2016, Institutional Paper 25*, p. 1

⁵ Macroeconomic Policy Institute (IMK) (2016), *Report 115, June 2016*

⁶ International Monetary Fund (IMF), *World Economic Outlook, April 2016*

⁷ International Monetary Fund (IMF), *World Economic Outlook, April 2016*

In the United States, expansion slowed in the first half of 2016. The forecast for the total year was lowered from 2.6% to 2.4%.⁸ For 2017, the economists of the IMF even expect a contraction of 0.1%. Among the emerging markets, prospects for Russia and Brazil have deteriorated significantly. Only China is viewed more positively. The strong domestic demand and robust growth of the service sector will compensate for the decline in industrial production more significantly than expected.

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, it cannot be excluded that the operating business will be impacted, particularly by local crises.

II. INDUSTRY-SPECIFIC FRAMEWORK

Immunoglobulins and albumins, the best-selling products of the Biotest Group, show stable growth. This is true for the established markets such as the USA and Europe as well as for the 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 around 6–7% annually.⁹ To meet this heightened demand, the industry is increasingly collecting source plasma. For example, plasma collections in the USA rose by 8% in 2015.¹⁰ The industry is increasing the plasma collection volume in preparation for the additional fractionation capacities.

EU prices for intravenous immunoglobulins (IVIG) are still significantly lower than in the United States.¹¹ Although price levels in both regions are stable, exchange rate developments lead to an increasing price gap, with EU preparations currently costing around 40% less than comparable US preparations. The German market developed positively in the first quarter of 2016

⁸ International Monetary Fund (IMF), *World Economic Outlook, April 2016*

⁹ Goldman Sachs: Morgan Stanley: *Plasma Market Tracker No. 54* (6 April 2016)

¹⁰ PPTA (2016)

¹¹ Goldman Sachs: *IPPC 2016: Plasma product market healthy* (29 March 2016)

in terms of quantities, while average prices were slightly below previous year's level.¹² With the market growth for intravenous immunoglobulins (IVIg) in Germany, sales of the Biotest preparation Intratect® increased slightly in the public prescription market in the first quarter of 2016 compared to the same period of the previous year, while quantities in the hospital sector were cut back to lower prices. Overall, the Intratect® price level on the German market was increased slightly.

The growth of the global albumin market is estimated at 4% per year until 2020.¹³ The demand for human albumin is slightly higher than the supply, which is generally increasing prices in many countries.¹⁴ 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 for plasmatic factor VIII products is expected to grow by 2% p.a. until 2020.¹⁵ 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, where it is often only the drug with the lowest price that is authorised for distribution in the respective country.

¹² IMS Health Germany, as of March 2016, Insight Health, as of March 2016

¹³ Biotest Market Research based on MRB (2015)

¹⁴ Goldman Sachs: IPPC 2016: Plasma product market healthy (29 March 2016)

¹⁵ Biotest Market Research based on MRB (2015)

III. BUSINESS PERFORMANCE

A. AT A GLANCE

In the first half of 2016 the Biotest Group recorded revenue of € 306.1 million, representing an increase of 6.4% compared to the same period of the previous year (€ 287.7 million).

The markets of North America as well as Middle East and Africa made the most significant contribution to the revenue growth. However, the company achieved the highest growth rates year on year in the Central and South America region.

EBIT at Group level increased in the first half of 2016 to € 18.2 million (same period of the previous year: € 2.3 million). The EBIT margin amounted to 5.9% after 0.8% in the same period of the previous year. While Biotest recorded an EBIT of € -11.2 million last year in the Therapy segment, operating income was positive in the first six months of 2016 at € 0.4 million. EBIT in the Plasma & Services segment rose by 25.5% to € 18.7 million (same period of the previous year: € 14.9 million). EBIT in Other Segments reached € -0.9 million after € -1.4 million in the same period of the previous year.

The cooperation agreement concluded in January 2016 with Kedrion Biopharma Inc., USA, will have a positive effect on business performance in 2016. Kedrion Biopharma Inc. will take over the exclusive distribution of Bivigam® in the USA until the end of 2022 and is guaranteeing Biotest minimum purchase quantities. Biotest expects the cooperation to improve profits by USD 4 to 5 million in the 2016 financial year.

In the first half of 2016, Biotest conducted a detailed analysis of the phase II study with IgM Concentrate and announced the data at the ISICEM Congress in Brussels. The data showed that the relative mortality rate of a subgroup of patients was reduced by more than 50%.

In March 2016, the results of the ZEUS (Zutectra Early Use) study were published. The early use of Zutectra® was started in Germany shortly thereafter. In other European markets, negotiations with payers on reimbursement are ongoing.

In the first half of 2016, impressive results were published for Pentaglobin® in the treatment of donor-specific antibodies following lung transplantations. In addition, a retrospective analysis by the Hellenic Sepsis Study Group (HSSG) revealed that Pentaglobin® shows a significant survival advantage in the case of severe infections caused by multidrugresistant bacteria.

In the second quarter of 2016, Biotest also announced the opening of the fourth Hungarian plasma collection centre in Győr and the opening of a new plasma collection centre in Brookings, South Dakota, USA. Biotest therefore has a total of twelve plasma collection stations in Europe and nineteen stations in the USA, thus securing a long-term supply of plasma.

B. RESEARCH AND DEVELOPMENT

Research and development costs decreased by 35.2% in the first six months of the 2016 financial year to € 26.0 million (same period of the previous year: € 40.1 million). This reflects the reduction of activities in the area of monoclonal antibodies. The Biotest Group's development projects are detailed in the 2015 Annual Report in the "Research and Development" section starting on page 16 of the Group management report.

Biotest also made significant progress in a number of projects in the first half of 2016.

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 of the 47 patients in total has been completed. In the extension arm of the study investigating the combination with pomalidomide and dexamethasone all 17 patients were enrolled, and recruitment has thus been completed. The treatment of patients is still ongoing in both treatment arms. The results of the study to date have shown very good tolerability and efficacy.

In the phase I/IIa study (no. 989), in which patients with triple-negative 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. 35 patients in the study have already been treated with indatuximab ravtansine (BT-062).

Indication area Clinical Immunology

BT-063: The first part of the IIa study (no. 990) of the treatment of patients diagnosed with systemic lupus erythematosus (SLE) was completed in the second quarter. The patients received either BT-063 or a placebo over a treatment period of three months. The data from the interim analysis of part 1 of the study are expected in the third quarter of 2016. Those data will serve as a basis for the planning of the second part of the study.

IgG Next Generation: The immunoglobulin G product IgG Next Generation is being developed to treat primary immune deficiencies, secondary antibody deficiency syndromes and several autoimmune diseases. A brand new production process was developed for this project with significantly higher yields and enhanced product properties. In the long term, IgG Next Generation will supersede the two existing products Intratect® and Bivigam® as a global product and the "master product" for the new Biotest Next Level manufacturing facility. In the second quarter, two pre-approval studies for IgG Next Generation were submitted to the authorities for approval in several countries: Firstly a phase III study (no. 991) on the treatment of patients with primary immune deficiencies (PID) and secondly a phase III study (no. 992) on the treatment of immune thrombocytopenia (ITP).

Civacir®: In the phase III study with Civacir®, the patient treatment and follow-up phase has been completed. No new reinfections were observed and the positive data previously reported were confirmed. However, after market research conducted last year, Biotest now expects the market prospects to be significantly reduced as a result of the newly introduced, highly effective virostatics, which lower the reinfection rate to less than 10%. In addition, they are now also evaluated for use shortly after liver transplantation. After completion, the results of the phase III study will be presented to the international expert audience. It is planned to take the next steps in the development of Civacir® together with a partner only.

Tregalizumab (BT-061): Biotest is currently using pre-clinical modelling systems to examine which alternative indications of tregalizumab (BT-061) could have potential.

Indication area Intensive Care Medicine

IgM Concentrate: In the indication area Intensive Care Medicine, the phase II study with patients with severe community acquired pneumonia (sCAP) was completed with good results in 2015. An extraordinary relative reduction in mortality rates in a subgroup of patients (patients with a significant elevation in inflammatory markers) of over 50% was shown. The relevant international health authorities are currently being consulted as part of the preparation for the phase III study in sCAP.

Pentaglobin®: In the first half of 2016, impressive results were published for Pentaglobin® in the treatment of donor-specific antibodies following lung transplantations. In a study by the Medizinische Hochschule Hannover (Hanover Medical School), a relative reduction in the mortality rate of over 70% was achieved for patients treated with Pentaglobin®. In addition,

a retrospective analysis by the Hellenic Sepsis Study Group (HSSG) demonstrated that Pentaglobin® shows a significant survival advantage in the case of severe infections caused by multiresistant bacteria. In infections with proven antibiotic resistance, complementary treatment with Pentaglobin® lowered the relative mortality rate by 33%. Biotest believes that Pentaglobin® offers considerable future potential in terms of use against antibiotic-resistant bacteria.

Fibrinogen: Recruitment for the first part of the clinical phase I/II study (no. 984) of the fibrinogen product under development was completed in 2015. This part of the study looked at 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 severe haemorrhage or when undergoing operations. The Paul Ehrlich Institute recently approved the expansion of this study to a phase III study with the existing treatment plan and a higher number of patients. On the basis of the results of this study, the marketing authorisation of the drug for congenital fibrinogen deficiency can be applied for. Coordination is currently under way with the relevant international health authorities for a phase III study concept for acquired fibrinogen deficiency.

C. 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. It was launched on the Saudi Arabian and Libyan markets in May 2016. Marketing authorisations in Brazil and other countries are also expected in 2016.

In April 2016, the shelf-life extension of Intratect® from 24 to 36 months was approved Europe-wide. In the first quarter of 2016, Biotest received marketing authorisation for Intratect® 50 g/l (5%) in Brazil. Intratect® 50 g/l (5%) was sold to Libya for the first time in May 2016. Initial sales of the product were also achieved in Slovenia. After the launch in the first quarter of 2016, first sales in Indonesia were recorded. In June 2016, Intratect® 100 g/l (10%) was introduced in Portugal for the first time.

In December 2015, the European Commission granted approval for the early use of the hepatitis B hyperimmunoglobulin Zutectra® after liver transplantation. While so far treatment with Zutectra® could not begin until six months after a liver transplantation, from now on Zutectra® can be used as early as one week after the transplantation. In Germany, the early

use of Zutectra® after liver transplantations has already begun. In other European markets, negotiations with payers on reimbursement are ongoing. Market launches and reimbursement in other European countries are still expected in 2016. In France, sales of Zutectra® continue to grow. Further Zutectra® marketing authorisations in countries outside Europe (Brazil, the Gulf States and Saudi Arabia) are expected in 2016.

A comprehensive review of the current literature underlines that the prophylactic use of Cytotect® has a positive effect both on patients' overall survival after transplantation and on the health and functionality of the transplanted organs. The experiences of experts and the literature consulted indicate that patients can benefit from a combination of Cytotect® with CMV-specific antivirals in the treatment of a CMV disease and associated complications, such as pneumonitis or the development of resistance against common antiviral drugs.¹⁶ Based on these results, Biotest is planning to begin extensive retrospective data analysis on the use of Cytotect® after heart and lung transplantations soon. In addition, Cytotect® has obtained marketing authorisation in the Netherlands.

Indication area Intensive Care Medicine

The start of marketing in Switzerland for the Biotest products Albiomin® 5% and 20% is planned for the second half of 2016.

Pentaglobin® was successfully introduced in Brazil in the first quarter of 2016.

Indication area Haematology

The plasmatic factor VIII product Haemoctin® is continuing to record stable growth on the German market. Other key markets include North Africa, Turkey and Asia. The first study to compare the inhibitor development risk between plasmatic and recombinant factor VIII products in previously untreated haemophilia A patients (SIPPET) shows a considerable advantage for the plasmatic products containing von Willebrand factor, like Haemoctin®. The SIPPET study is the largest haemophilia study to date and could increase demand for Haemoctin® over the medium to long term.

Plasma & Services

In the first half of 2016, Biotest opened two new plasma collection centres, namely in Brookings, South Dakota, USA, and in Győr, Hungary. Biotest therefore has a total of twelve plasma collection stations in Europe and nineteen stations in the USA, thus securing a long-term supply of plasma.

¹⁶ *Transplantation*. 2016 Mar; 100 Suppl 3: pp. 1–18

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

A. RESULTS OF OPERATIONS

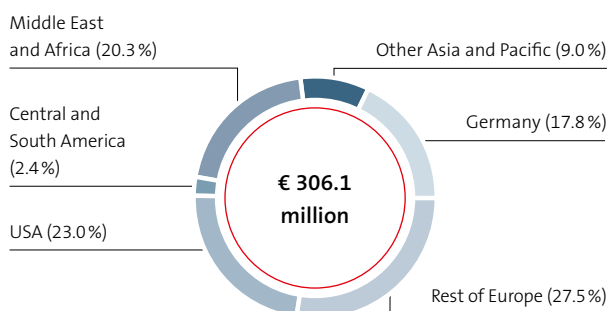
In the first half of 2016 the Biotest Group generated revenue of € 306.1 million, representing an increase of 6.4% compared to the same period of the previous year. Revenue was increased both in the Therapy segment (+ 3.6%) and in the Plasma & Services segment (+ 13.9%).

SALES BY SEGMENT

in € million	H1 2016	H1 2015	Change in %
Therapy	203.3	196.3	3.6
Plasma & Services	99.1	87.0	13.9
Other Segments	3.7	4.4	-15.9
Biotest Group	306.1	287.7	6.4

In its domestic market Germany the Biotest Group generated revenue of € 54.5 million. This is a decrease of 11.4% compared to the same period of the previous year, in which singularly large amounts of plasma were sold in Germany. However, the development was offset by stronger international business. Biotest generated growth in all foreign markets, most significantly in Central and South America (+ 39.6%) and in the Other Asia and Pacific region (+ 36.8%). Development in the USA was similarly positive with growth of 11.1%. In the region Middle East and Africa, sales increased by 13.3% to € 62.3 million. Overall, the breakdown of Group sales shifted towards the international market in the first half of the year. In the period from January to June 2016, Biotest Group generated 82.2% of its sales outside Germany (previous year: 78.6%).

SALES BY REGION FIRST HALF OF 2016



The cost of sales increased moderately to € 211.7 million in the first six months of 2016 after € 195.0 million in the same period of the previous year. The increase is attributable chiefly to the excess quantity produced. Marketing and distribution costs decreased in absolute terms and as a percentage of sales from € 34.1 million (percentage of sales: 11.9%) in the previous year to € 30.1 million (percentage of sales: 9.8%). The lower marketing and distribution costs are attributable in particular to the new cooperation agreement with Kedrion Biopharma Inc.

Administrative expenses increased to € 20.2 million. Their percentage share of sales was up on the previous year's 5.9% at 6.6%.

Research and development costs decreased from € 40.1 million in the same period of the previous year to € 26.0 million. R&D expenditure's share in sales was 8.5% in the first half of the year (same period of the previous year: 13.9%). The higher research and development costs in the same period of the previous year resulted in particular from the increased production of clinical trial material and the expenses for the pre-production of tregalizumab (BT-061).

ESSENTIAL P&L POSITIONS OF THE BIOTEST GROUP*

in € million	H1 2016	% of sales	H1 2015	% of sales
Cost of sales	-211.7	69.2	-195.0	67.8
Marketing and distribution costs	-30.1	9.8	-34.1	11.9
Administrative expenses	-20.2	6.6	-16.9	5.9
Research and development costs	-26.0	8.5	-40.1	13.9
Other operating income and expenses	0.1	0.0	0.7	0.2
Financial result	-4.3	1.4	-0.2	0.1

* Costs/expenses are denoted with a negative sign

Due to the reduced expenses, operating profit (EBIT) increased considerably from € 2.3 million to € 18.2 million. Last year, several factors reduced EBIT: in particular higher R&D expenses in the Therapy segment and unabsorbed costs due to the reduced production of Bivigam®.

EBIT in the Therapy segment increased to € 0.4 million in the first half of 2016 (same period of the previous year: € - 11.2 million). Operating earnings in the Plasma & Services segment increased by 25.5 % to € 18.7 million. This success is due to the considerable growth in plasma sales in the USA. EBIT in Other Segments was € - 0.9 million after € - 1.4 million in the same period of the previous year.

In the first half of 2016, the financial result amounted to € - 4.3 million (same period of the previous year: € - 0.2 million). In the same period of the previous year, the weaker development of the US dollar generated foreign exchange gains, which was the case to only a minor extent in the first half of 2016. This resulted in earnings before taxes (EBT) of € 13.9 million for the Biotest Group compared to € 2.1 million in the same period of the previous year. Earnings after taxes (EAT) amounted to € 7.7 million (same period of the previous year: € - 2.2 million). Earnings per share thus increased from € - 0.05 to € + 0.19 in the period under review.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	H1 2016	H1 2015	Change in %
EBIT	18.2	2.3	+ 691.3
EBT	13.9	2.1	+ 561.9
EAT	7.7	- 2.2	+ 450.0
Earnings per share in €	0.19	- 0.05	+ 480.0

B. FINANCIAL POSITION

As of 30 June 2016 the total assets of the Group increased from € 962.7 million as of 31 December 2015 to € 981.9 million.

On the asset side, non-current assets rose significantly from € 375.9 million as of 31 December 2015 to € 427.8 million as of 30 June 2016. This was attributable to an increase in property, plant and equipment, which resulted mainly from the Biotest Next Level capacity expansion project at Dreieich. Property, plant and equipment increased by 15.9 % to € 367.8 million as of 30 June 2016 (31 December 2015: € 317.2 million).

Current assets decreased compared to the end of 2015 and totalled € 554.1 million (31 December 2015: € 586.8 million). This is mainly due to the decline in other financial assets, which amounted to € 51.8 million on the reporting date

(31 December 2015: € 120.8 million). In contrast, cash and cash equivalents doubled to € 114.4 million (31 December 2015: € 53.8 million), which is due to the scheduled expiration of securities. As planned, these resources are now available for further capital expenditure in the Biotest Next Level project.

As of 30 June 2016 86.2 % of total assets were financed by equity or non-current debt, thereby reflecting the Biotest Group's healthy and sustainable financing structure.

On the liabilities side, equity increased slightly compared to 31 December 2015 to € 416.7 million (31 December 2015: € 412.3 million). The equity ratio reached 42.4 % on the reporting date. Total debt increased slightly to € 565.2 million (31 December 2015: € 550.4 million), with current liabilities and therein trade payables increasing in particular. The latter totalled € 57.8 million (31 December 2015: € 53.1 million). Other liabilities increased to € 34.0 million (31 December 2015: € 31.8 million).

C. CASH FLOW

The positive cash flow from operating activities amounted to € 49.6 million in the first half of 2016. This is an increase of 59.0 % compared to the same period of the previous year. In addition to the positive operating profit, the reduction in working capital caused by lower receivables and inventories also made a positive contribution to this development.

Cash flow from investing activities amounted to € 7.9 million in the period under review after € - 113.4 million in the same period of the previous year. In particular, this item included inflows from other financial assets as a result of the expiration of securities mentioned above and from financial assets in the amount of € 70.0 million (same period of the previous year: outflow of € 85.7 million). Adjusted for this item, cash flow from investing activities amounted to € - 62.1 million after € - 27.7 million in the same period of the previous year. Cash flow from financing activities amounted to € 3.1 million in the first six months of 2016 after € - 1.2 million in the same period of the previous year.

D. SUMMARY ASSESSMENT OF THE BUSINESS SITUATION OF THE COMPANY

The Biotest Group continued on its path of sales growth in the period from January to June 2016. Sales increased by 6.4 % compared to the same period of the previous year. Operating cash flow totalled € 49.6 million. The Biotest Group therefore has the overall resources to drive forward the operating business and the research and development work as planned.

Additional profit potential is offered by already achieved or future market entries of plasma protein products into other lucrative regions as well as potential further developments in the area of monoclonal antibodies in cooperation with partners 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 form a solid foundation for planned future growth of the Biotest Group.

C. SUPPLEMENTARY REPORT

On 14 July 2016, the Landgericht Darmstadt (District Court Darmstadt) sentenced a former Biotest representative for Russia to 5 years and 9 months in prison. In the opinion of the court, the former employee is guilty of aiding and abetting embezzlement and tax evasion between 2007 and 2011. Her husband was sentenced to 4 years and 6 months in prison. The verdict is not yet final. An appeal before the Bundesgerichtshof (German Federal Court of Justice) is possible. The company dismissed the former employee in 2013.

The company will wait for the written court opinion in order to examine any financial consequences for the company on this basis.

On 3 August 2016 the Finanzamt Offenbach am Main (tax office Offenbach am Main) served to Biotest AG altered tax assessments for corporate tax, solidarity tax and trade tax for the years 2005 until 2008. The alterations are based on the investigations by the tax authorities and the public prosecutor in connection with the Russia business of Biotest AG. This leads to liabilities for tax and interest totalling to approx. € 20 million.

The company will have the tax assessments evaluated by their tax consultants. According to our first appraisal this approach by the financial authorities is conflicting with recently published decisions by the Bundesfinanzhof (Federal Fiscal Court) on the tax deduction of operating expenses.

D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. OUTLOOK

A. EXPECTED DEVELOPMENTS IN THE MARKET ENVIRONMENT

According to current studies, global demand for immunoglobulins (IgG) will continue to increase by 7% annually over the coming years.¹⁷ Although the prices of these preparations remained largely constant in 2015, some regions and distribution channels are currently characterised by rising price pressure.¹⁸ This is due partly to additional fractionation capacities arising at the various plasma firms around the world and gradually coming to market. Additional supply is also expected in 2016, which could have a further negative effect on prices. The price pressure is expected to make itself felt only temporarily. Due to the positive market growth, demand will catch up again, so equilibrium is expected in the medium term.¹⁹

The Biotest Group expects the global market volume for plasmatic clotting factors to increase by around 2% p. a. until 2020.²⁰ The start of sales of Albiomin® 20% in China also offers new medium-term sales potential in a market that is expected to see average annual growth of 10% between now and 2020.²¹ Further sales are forecasted up to 2018 in all product groups as part of new or extensions to existing marketing authorisations.

There could arise significant future sales potential for the Biotest Group in the area of monoclonal antibodies. Preparations to treat multiple myeloma (Biotest indatuximab ravtansine (BT-062) development project) generated worldwide sales of approx. USD 8 billion in 2015. Furthermore, the treatment of various solid tumours with indatuximab ravtansine (BT-062) offers additional sales potential following marketing authorisation for corresponding indications, which we can realise only together with a partner.

¹⁷ Biotest Market Research based on MRB (2015)

¹⁸ IMS Health (2015), Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS

¹⁹ Goldman Sachs (18 May 2015): Global: Medical Technology: Medical Supplies: Industry structure to support demand, pricing; Buy CSL, GRLS

²⁰ Biotest Market Research based on MRB (2015)

²¹ MRB (2015)

B. EXPECTED PERFORMANCE OF THE BIOTEST GROUP

Revenue and earnings

The Board of Management expects an increase in sales in the low single-digit percentage range for 2016.

Profitability will be influenced by various factors in 2016. The continuing rise in quality and safety requirements will necessitate additional costs of € 3 to 5 million in this area.

Costs relating to the Biotest Next Level expansion project that is now under way are estimated at € 10 to 15 million for 2016, resp. € 40 to 45 million including development costs. The costs for research and development in the field of monoclonal antibodies are estimated at € 12 million. Additional costs of € 10 to 12 million also result from unabsorbed costs due to insufficient capacity utilisation.

Despite these factors, Biotest increased the EBIT forecast for 2016 by more than 10% on 23 March 2016. The company now expects an EBIT in the range of € 33 to 35 million. In November 2015, Biotest issued an EBIT forecast of € 30 million.

As a result, the Board of Management expects a return on capital employed (RoCE) of approx. 4% and a continuing positive cash flow from operating activities despite of the expected increase in working capital without consideration for potential additional tax payment as described in the supplementary report.

Cash flow

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 finance the expansion of capacity at Dreieich. Furthermore, the increase in current assets required for the sales growth must be financed. For the 2016 financial year capital expenditure of up to € 160 million is planned for the Biotest Group, 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 Biotest Pharmaceuticals Corp. (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 meet the increase in investments as well as the increase in sales and the associated working capital.

II. RISK REPORT

The Biotest Group's risk situation has not changed materially from the presentation set out in the 2015 Annual Report (pages 27 to 33) except the facts outlined hereafter.

The immunoglobulin manufacturing plant of Biotest Pharmaceuticals Corp. in Boca Raton, Florida, USA, received a warning letter from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2014. The warning letter expressed concerns regarding several deficiencies observed during a 2014 inspection related to the facility's compliance with current good manufacturing practice (CGMP). In the first quarter of 2016, the FDA performed a follow-up inspection and noted again several observations. The company is currently working closely with the FDA to address all their concerns, and is preparing for a meeting scheduled with the FDA in August 2016 to further discuss the situation. Up to now the issues noted have not caused any interruption with the manufacturing at the facility and the FDA has continued to approve manufactured batches for sale. Currently there are several batches under evaluation by FDA because of a technical deviation within the manufacturing process with the decision for release pending. In the past comparable material was released by FDA. If there won't be a release by FDA, a depreciation of up to € 10 million will be necessary in 2016.

III. OPPORTUNITIES REPORT

The Biotest Group's opportunities situation has not changed materially from the presentation set out in the 2015 Annual Report (pages 33 to 34) with the exception of the aforementioned cooperation agreement with Kedrion Biopharma.

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 June 2016

in € million	Q2 2016	Q2 2015	H1 2016	H1 2015
Revenue	159.0	145.2	306.1	287.7
Cost of sales	-110.6	-96.9	-211.7	-195.0
Gross profit	48.4	48.3	94.4	92.7
Other operating income	0.7	1.0	1.4	2.1
Marketing and distribution costs	-15.6	-16.2	-30.1	-34.1
Administrative expenses	-10.9	-8.7	-20.2	-16.9
Research and development costs	-12.3	-21.5	-26.0	-40.1
Other operating expenses	-0.7	-0.7	-1.3	-1.4
Operating profit	9.6	2.2	18.2	2.3
Financial result	-0.4	-4.3	-4.3	-0.2
Earnings before taxes	9.2	-2.1	13.9	2.1
Income taxes	-3.3	-1.5	-6.2	-4.3
Earnings after taxes	5.9	-3.6	7.7	-2.2
Attributable to:				
Equity holders of the parent	5.9	-3.6	7.7	-2.2
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €	0.14	-0.09	0.19	-0.05

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 June 2016

in € million	H1 2016	H1 2015
Consolidated profit for the period	7.7	-2.2
Exchange difference on translation of foreign operations	-2.1	14.3
Income tax effect	0.0	0.0
Other comprehensive income, net of tax, to be reclassified to profit or loss in subsequent periods	-2.1	14.3
Other comprehensive income, net of tax, not to be reclassified to profit or loss in subsequent periods	0.0	0.0
Other comprehensive income, net of tax	-2.1	14.3
Total comprehensive income, net of tax	5.6	12.1
Attributable to:		
Equity holders of the parent	5.6	12.1
Non-controlling interests	0.0	0.0

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 June 2016

in € million	30 June 2016	31 December 2015
ASSETS		
Non-current assets		
Intangible assets	43.7	44.7
Property, plant and equipment	367.8	317.2
Investments in associates	2.2	3.5
Other assets	0.7	1.0
Other financial assets	0.9	0.8
Deferred tax assets	12.5	8.7
Total non-current assets	427.8	375.9
Current assets		
Inventories	203.2	218.7
Trade receivables	172.6	173.9
Current income tax assets	0.8	5.8
Other assets	11.3	13.8
Other financial assets	51.8	120.8
Cash and cash equivalents	114.4	53.8
Total current assets	554.1	586.8
Total assets	981.9	962.7
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	149.5	235.3
Share of profit or loss attributable to equity holders of the parent	7.7	-82.5
Equity attributable to equity holders of the parent	416.6	412.2
Non-controlling interests	0.1	0.1
Total equity	416.7	412.3
Liabilities		
Provision for pensions and similar obligations	73.7	72.6
Other provisions	6.8	6.6
Financial liabilities	334.6	335.5
Other liabilities	2.5	2.2
Deferred tax liabilities	12.0	7.7
Total non-current liabilities	429.6	424.6
Other provisions	25.2	27.5
Current income tax liabilities	3.6	4.3
Financial liabilities	15.0	9.1
Trade payables	57.8	53.1
Other liabilities	34.0	31.8
Total current liabilities	135.6	125.8
Total liabilities	565.2	550.4
Total equity and liabilities	981.9	962.7

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 June 2016

in € million	H1 2016	H1 2015
Operating cash flow before changes in working capital	32.4	18.6
Cash flow from changes in working capital	21.0	26.1
Interest and taxes paid	-3.8	-13.5
Cash flow from operating activities	49.6	31.2
Cash flow from investing activities	7.9	-113.4
Cash flow from financing activities	3.1	-1.2
Cash changes in cash and cash equivalents	60.6	-83.4
Exchange rate-related changes in cash and cash equivalents	0.0	0.8
Cash and cash equivalents on 1 January	53.8	179.4
Cash and cash equivalents on 30 June	114.4	96.8
thereof cash flow from investing activities from changes in other financial assets	70.0	-85.7
Cash flow from investing activities adjusted for financial investments in the scope of short-term financial disposition	-62.1	-27.7

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 June 2016

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
As of 1 January 2015	33.8	225.6	19.4	201.3	480.1	0.1	480.2
Gains/losses recognised directly in equity	–	–	14.3	–	14.3	–	14.3
Profit for the period	–	–	–	-2.2	-2.2	–	-2.2
Total comprehensive income	0.0	0.0	14.3	-2.2	12.1	0.0	12.1
Dividend payments	–	–	–	-8.3	-8.3	–	-8.3
Balance on 30 June 2015	33.8	225.6	33.7	190.8	483.9	0.1	484.0
As of 1 January 2016	39.6	219.8	37.0	115.8	412.2	0.1	412.3
Gains/losses recognised directly in equity	–	–	-2.1	–	-2.1	–	-2.1
Profit for the period	–	–	–	7.7	7.7	–	7.7
Total comprehensive income	0.0	0.0	-2.1	7.7	5.6	0.0	5.6
Dividend payments	–	–	–	-1.2	-1.2	–	-1.2
Balance on 30 June 2016	39.6	219.8	34.9	122.3	416.6	0.1	416.7

SELECTED NOTE DISCLOSURES

METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 30 June 2016 have been prepared in accordance with the International Financial Reporting Standards (IFRS) as required to be applied in the European Union. Accordingly, these interim consolidated financial statements as of 30 June 2016 have been prepared in accordance with IAS 34 Interim Financial Reporting and are presented in a condensed form compared with the consolidated financial statements. The IFRS comprise the International Financial Reporting Standards (IFRS) and International Accounting Standards (IAS) as well as the interpretations of the International Financial Reporting Interpretations Committee (IFRIC) and the interpretations of the Standing Interpretation Committee (SIC). The accounts of the Biotest Group are prepared in accordance with IFRS which are mandatory for financial years beginning on 1 January 2016.

These interim consolidated financial statements were approved for publication by the Board of Management on 11 August 2016.

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

in € million	H1 2016	H1 2015
Operating profit (EBIT)	18.2	2.3
Financial result	-4.3	-0.2
Earnings before taxes (EBT)	13.9	2.1
Income taxes	-6.2	-4.3
Earnings after taxes (EAT)	7.7	-2.2

NET DEBT

in € million	30 June 2016	31 December 2015
Financial liabilities to financial institutions	345.9	340.8
Liabilities from finance leases	3.7	3.8
Financial liabilities	349.6	344.6
Cash and cash equivalents	114.4	53.8
Financial investments in other current financial assets*	50.0	119.9
Liquid assets and financial assets as part of the short-term financial disposition	164.4	173.7
Net debt	185.2	170.9

* Current financial investments of surplus cash and cash equivalents are included in other current financial assets.

SEGMENT REPORTING

of the Biotest Group for the period from 1 January to 30 June 2016

in € million	Revenue			EBIT		
	H1 2016	H1 2015	Change in %	H1 2016	H1 2015	Change in %
Therapy	203.3	196.3	3.6	0.4	-11.2	103.6
Plasma & Services	99.1	87.0	13.9	18.7	14.9	25.5
Other Segments	3.7	4.4	-15.9	-0.9	-1.4	35.7
Biotest Group	306.1	287.7	6.4	18.2	2.3	691.3

in € million	Revenue with third parties based on customer's geographical location		
	H1 2016	H1 2015	Change in %
Germany	54.5	61.5	-11.4
Rest of Europe	84.1	82.5	1.9
USA	70.3	63.3	11.1
Central and South America	7.4	5.3	39.6
Middle East and Africa	62.3	55.0	13.3
Other Asia and Pacific	27.5	20.1	36.8
Biotest Group	306.1	287.7	6.4

QUARTER-TO-QUARTER COMPARISON

by business segments

in € million	Revenue				
	Q2 2016	Q1 2016	Q4 2015	Q3 2015	Q2 2015
Therapy	103.0	100.3	123.4	91.7	98.0
Plasma & Services	54.3	44.8	46.5	36.2	44.8
Other Segments	1.7	2.0	1.8	2.3	2.4
Biotest Group	159.0	147.1	171.7	130.2	145.2

in € million	EBIT				
	Q2 2016	Q1 2016	Q4 2015	Q3 2015	Q2 2015
Therapy	-0.1	0.5	2.8	-88.8	-4.8
Plasma & Services	10.3	8.4	7.5	5.2	7.8
Other Segments	-0.6	-0.3	-0.1	-0.7	-0.8
Biotest Group	9.6	8.6	10.2	-84.3	2.2
Earnings before taxes	9.2	4.7	10.9	-87.3	-2.1

OTHER NOTE DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2015	Capital expenditure	Net disposals	Depreciation and amortisation	Currency translation differences	Carrying amount as of 30 June 2016
Intangible assets	44.7	0.6	-0.1	-0.8	-0.7	43.7
Property, plant & equipment	317.2	63.6	-0.4	-11.7	-0.9	367.8
Total	361.9	64.2	-0.5	-12.5	-1.6	411.5

Employees

by operating functions

Full-time equivalents	30 June 2016	31 December 2015	Change in %
Marketing and distribution	204	213	-4.2
Administration	250	265	-5.7
Production	1,709	1,612	6.0
Research and development	177	181	-2.2
Biotest Group	2,340	2,271	3.0

Financial instruments as of 30 June 2016

in € million	Carrying amount	Fair value
Assets		
Trade receivables	172.6	172.6
Other assets		
Other receivables	11.0	11.0
Derivatives not designated as hedging instruments	1.0	1.0
Other financial assets	52.7	52.7
Equity and liabilities		
Trade payables	57.8	57.8
Financial liabilities	349.6	366.3
Other liabilities	34.8	34.8
Derivatives not designated as hedging instruments	1.7	1.7

FAIR VALUE HIERARCHY

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 closeness to the market of the data used to calculate fair value. 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 measurement at fair value) 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.

The fair values of trade receivables and trade payables, other receivables and liabilities are assumed to be equal to their carrying amounts due to their short maturities.

For the other financial assets 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 classification takes place in hierarchy level 2.

Derivative financial assets are marked to market on the basis of quoted exchange rates and yield curve structures obtainable on the market. Fair value classification takes place in hierarchy level 2.

The fair values of 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.

In determining fair value, counterparty risk was taken into account via an add-on approach. The currency basis spread was also taken into account.

BUSINESS RELATIONSHIPS WITH RELATED PARTIES

The Biotest Group has reportable relationships with the associate BioDarou P.J.S. Co., Tehran, Iran, and its subsidiary Plasma Gostar Pars P.J.S, Tehran, Iran.

These two companies purchased goods and services totalling € 6.7 million from Biotest in the first six months. As of 30 June 2016, Biotest had receivables from BioDarou P.J.S. Co. and Plasma Gostar Pars P.J.S. totalling € 10.1 million. In addition, there were liabilities to BioDarou P.J.S. Co. on the reporting date from payments in advance on future goods deliveries amounting to € 1.7 million.

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

Apart from these business relationships, no material transactions were conducted with related parties during the reporting period.

EVENTS AFTER THE REPORTING DATE

On 14 July 2016, the Landgericht Darmstadt (District Court Darmstadt) sentenced a former Biotest representative for Russia to 5 years and 9 months in prison. In the opinion of the court, the former employee is guilty of aiding and abetting embezzlement and tax evasion between 2007 and 2011. Her husband was sentenced to 4 years and 6 months in prison. The verdict is not yet final. An appeal before the Bundesgerichtshof (German Federal Court of Justice) is possible. The company dismissed the former employee in 2013.

The company will wait for the written court opinion in order to examine any financial consequences for the company on this basis.

Two more plasmapheresis centres were opened, namely in Clemson, South Carolina, USA, on 27 July 2016 and in Szeged, Hungary, on 29 July 2016.

On 3 August 2016, the Finanzamt Offenbach am Main (tax office Offenbach am Main) served to Biotest AG altered tax assessments for corporate tax, solidarity tax and trade tax for the years 2005 until 2008. The alterations are based on the investigations by the tax authorities and the public prosecutor in connection with the Russia business of Biotest AG. This leads to liabilities for tax and interest totalling to approx. € 20 million.

The company will have the tax assessments evaluated by their tax consultants. According to our first appraisal this approach by the financial authorities is conflicting with recently published decisions by the Bundesfinanzhof (Federal Fiscal Court) on the tax deduction of operating expenses.

ASSURANCE BY THE LEGAL REPRESENTATIVES

Declaration in accordance with section 37y no. 1 of the German Securities Trading Act (WpHG) in conjunction with sections 297 (2) sentence 3 and 315 (1) sentence 6 of the German Commercial Code (HGB)

To the best of our knowledge, and in accordance with the applicable reporting principles for interim financial reporting, the interim consolidated financial statements give a true and fair view of the financial position, cash flow and result of operations of the Group, and the interim 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 for the remaining months of the financial year.

Dreieich, 11 August 2016
Biotest Aktiengesellschaft
Board of Management



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

FINANCIAL CALENDAR

ACKNOWLEDGEMENTS

10 NOVEMBER 2016

Quarterly Statement
as of 30 September 2016

10 NOVEMBER 2016

Analyst conference

30 MARCH 2017

Annual Report 2016

30 MARCH 2017

Financial statements
press conference 2016

11 MAY 2017

Quarterly Statement as of
31 March 2017

11 MAY 2017

Annual Shareholders' Meeting

14 AUGUST 2017

Half-Year Report 2017

14 NOVEMBER 2017

Quarterly Statement
as of 30 September 2017

14 NOVEMBER 2017

Analyst conference

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This 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 forward-looking statements are only valid at the time of publication of this report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

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