

## HALF-YEAR REPORT 2015 BIOTEST AG



### **KEY FIGURES**

BIOTEST GROUP		H1 2015	H1 2014	Change in %
Revenue	€ million	287.7	264.1	8.9
thereof:				
Germany	€ million	61.5	51.6	19.2
Rest of world	€ million	226.2	212.5	6.4
thereof:				
Therapy	€ million	196.3	202.6	-3.1
Plasma & Services	€ million	87.0	57.3	51.8
Other Segments	€ million	4.4	4.2	4.8
EBITDA		17.6	42.5	-58.6
Operating profit (EBIT)	€ million	2.3	26.5	-91.3
EBIT in% of revenue		0.8	10.0	
Earnings before taxes	€ million	2.1	21.7	-90.3
Earnings after taxes	€ million	-2.2	13.8	
Financing				
Cash flow from operating activities	€ million	31.2	-34.6	190.2
Depreciation and amortisation	€ million	15.3	16.0	-4.4
		30 June 2015	31 December 2014	
Equity	€ million	484.0	480.2	0.8
Equity ratio		46.0	46.5	
Employees (full-time equivalents)	amount	2,218	2,158	2.8

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#### INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 2015

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

#### B. PERSONNEL

The Biotest Group had a workforce of 2,218 full-time equivalents as of 30 June 2015. This represents an increase of 2.8% compared with 31 December 2014 (2,158 full-time equivalents).

The Supervisory Board has extended the contracts of Dr Michael Ramroth until 31 December 2020 and Dr Georg Floß until 8 January 2021.

#### II. GROUP STRATEGY

The core element of Biotest's strategy is a clear focus on marketing and the further development of biological products in the three defined indication areas. In addition to continuously advancing its own research and development pipeline, the Company is striving to obtain marketing authorisation and intensify its marketing activities in order to further internationalise its business and diversify its portfolio. In addition to the successful expansion of the product portfolio in European markets, the focus is on the US, Asia and South America.

The Biotest Group is expanding its production capacity at its headquarters at Dreieich in order to continue to participate in future global market growth. Production capacity will be doubled by 2018/19 as part of the "Biotest Next Level" project. The aim of this project is to further strengthen the Company's competitiveness on the global markets, to expand its product range and to lay the foundations for continued growth.

#### III. RESEARCH AND DEVELOPMENT (GENERAL)

Research and development are the foundations for future growth under the corporate strategy. In this area the further development of existing products as well as the new development of products opens up significant potential. Great importance is attached to both research and development in the area of plasma proteins and the development of monoclonal antibodies.

#### **B. ECONOMIC REPORT**

#### I. BUSINESS AND GENERAL FRAMEWORK

According to the latest "World Economic Outlook" published by the International Monetary Fund (IMF), the global economy is still growing at a slow pace. For this reason, the IMF is warning of a longer, sustained global growth crisis. While developed economies saw a slight acceleration in growth rates, the upward trend is slowing in the emerging markets. In its July forecast, the IMF made a slight downward revision to its estimate of global economic growth compared with the spring forecast published in April 2015. Global economic output is now expected to increase by 3.3% rather than 3.5% in the current year. Meanwhile, the experts are continuing to forecast growth of 3.8% in 2016.

The European Commission is currently forecasting economic growth of 1.8% for the EU and 1.5% for the euro zone in 2015.<sup>3</sup> An increase of 2.1% (EU) and 1.9% (euro zone) is forecasted for the coming year. The European Commission believes that the quantitative easing measures will be reflected in improved lending conditions, among other things, while fiscal policy in Europe is at least neutral.

Leading German economic research institutes are anticipating an increase in German gross domestic product of 2.1% in 2015. According to the statisticians, the pace is expected to slow only slightly in the coming year.<sup>4</sup>

The US Federal Reserve Bank (Fed) has again lowered its forecast for the US for the current year. In June, it announced that it expected growth between 1.8% and 2.0%, compared with the range of between 2.3% and 2.7% that was published in March 2015.<sup>5</sup>

In principle, the Biotest Group is only marginally dependent on economic cycles due to the high level of unmet medical needs 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 enjoying stable growth in established markets such as the US and Europe as well as in other regions of the world. For example, industry experts expect the market for intravenous immunoglobulin (IVIG) products to see global increase in demand within a long-term range of 6–8%.6 The prices of these preparations are coming under increasing pressure throughout the world due to growing fractionation capacities.

EU prices for intravenous immunoglobulins (IVIG) are still significantly lower than those in the United States. Although price levels in both regions are stable, exchange rate developments mean that the price gap has increased, with EU preparations currently costing around 40% less than their US equivalents. The German market developed positively in 2014 in terms of quantities, while average prices remained at the prior-year level. With the IVIG market growth in Germany, the Biotest preparation Intratect® was able to record revenue gains and maintain its market share at a stable level with largely constant prices. This development continued in Germany in the first quarter of 2015. The average prices of all IVIG products on the hospital market remained stable. In a growing overall market, i.e. sales via hospitals and practising physicians, Intratect's market share remained unchanged.

<sup>1</sup> International Monetary Fund (IMF), World Economic Outlook, April 2015

<sup>2</sup> International Monetary Fund (IMF), World Economic Outlook UPDATE, July 2015

<sup>3</sup> European Commission, press release, 5 May 2015

<sup>4</sup> Joint diagnosis project group, joint diagnosis, Spring 2015, 16 April 2015

<sup>5</sup> Board of the Governors of the Federal Reserve System, minutes of the federal open market committee, 17 June 2015

<sup>6</sup> Goldman Sachs: Global: Medical Technology: Medical Supplies, 18 May 2015

<sup>7</sup> UBS Investment Research, Plasma Pharmaceuticals: Mar-15 Plasma Price & Supply Survey: Non-IVIG price gains a feature, 21 May 2015

<sup>8</sup> IMS Health Germany, as of December 2014

Demand for plasma factor VIII products is also continuing to grow. This development is primarily being caused by factor VIII therapies becoming increasingly established in other regions. There were signs of a moderate upward trend in Europe. <sup>10</sup> The global market is expected to grow by 4% p.a. until 2020. <sup>11</sup> An increase of 2% p.a. is forecasted for plasmatic factor VIII products and around 6% p.a. for the recombinant factor VIII products segment. The recombinant segment will benefit considerably from the introduction of new factor VIII products; however, this could intensify competition and thereby significantly increase price pressure in the market.

#### III. BUSINESS PERFORMANCE

#### A. AT A GLANCE

The Biotest Group recorded significant year-on-year sales growth in the first half of 2015. The Group recorded revenue of € 287.7 million in the period from January to June 2015, an increase of 8.9% compared with the same period of the previous year (€ 264.1 million).

Substantial revenue growth was achieved in the US, Germany and the "Other Asia and Pacific" reporting region in particular. In the US, in addition to the increased marketing of Bivigam® the sales of plasma increased. Biotest operates plasma collection centres for long-term cooperation partners who are active in other market segments.

The Biotest Group is continuing to invest considerable funds in the development of new products and the further development of its existing products. Operating income (EBIT) decreased from € 26.5 million to € 2.3 million due to these increased research and development costs, costs incurred for the capacity expansion already in progress, unabsorbed costs at the US subsidiary Biotest Pharmaceuticals Corporation (BPC), as well as continued price pressure in individual product areas and regions. The expected moderate earnings performance was seen at the start of the year and was reflected in the forecast for 2015 that was issued in March this year.

The research and development work can create significant value for the future. Two study results were presented at the 50<sup>th</sup> International Liver Congress (EASL 2015) in Vienna in April. The Civacir® study has showed very positive interim results. The product is intended for prophylaxis of hepatitis C reinfection after liver transplantation. With the ZEUS study (Zutectra Early USe), Biotest successfully demonstrated the effective use of Zutectra® in the early phase following liver transplantation as a result of chronic hepatitis B infection. This application will contribute significantly to ensuring a safer, quicker and more cost-effective patient care and improved user-friendliness for patients.

The phase IIb study (TREAT 2b) of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis did not meet the primary endpoint. In June, AbbVie exercised its right to opt out of the global licence, development and commercialisation agreement. All rights granted in connection with the agreement were returned to Biotest at no cost.

The completed phase II study of IgM Concentrate, which was published in late June, showed encouraging results for life-threatening pneumonia in terms of reducing the time spent on ventilation as well as mortality rates. Additional analyses of the study data and discussions and evaluations of the results with recognized experts are currently taking place in preparation for the next phase of the clinical development.

The first results of the current phase I/II study (no. 983) of indatuximab ravtansine (BT-062) with the new combination product pomalidomide are expected to be available at the end of the year; patient recruitment is complete.

#### **B. RESEARCH AND DEVELOPMENT**

In the first half of 2015, research and development costs increased by 16,6% to  $\leqslant$  40.1 million (same period of the previous year:  $\leqslant$  34.4 million). The Biotest Group's development projects are detailed in the 2014 Annual Report in the "Research and Development" section starting on page 14 of the Group management report.

While the first results of the phase IIb study of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis were disappointing, Biotest made further progress in all of its other current studies and development work.

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. After 12 weeks of treatment with tregalizumab (BT-061) in combination with methotrexate, no statistically significant improvement in defined rheumatic illness criteria, known cumulatively as the ACR 20 score (primary endpoint), could be shown in comparison with the placebo. Patient safety in the TREAT 2b study was frequently monitored by the independent Data Safety Monitoring Board (DSMB). No safety concerns for tregalizumab (BT-061) were noted in the study.

Treatment of patients in the phase I/II study (no. 975) of indatuximab ravtansine (BT-062) for monotherapy of multiple myeloma, a malignant disease of the bone marrow, was concluded.

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 who had already undergone intensive prior treatment is ongoing. All patients were enrolled in the extension arm of the study investigating the combination with pomalidomide and dexamethasone, and recruitment has been completed.

In the phase I/II 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 has taken place and the maximum tolerated dose (MTD) has been defined. Recruitment for the second part of the study has started.

The phase IIa study (no. 990) of BT-063 for the treatment of patients diagnosed with systemic lupus erythematosus (SLE) was submitted to the authorities of several countries for approval in the first half of the year.

In April 2015, Biotest presented the positive interim results of the pivotal phase III study (no. 988) of Civacir® at the 50<sup>th</sup> International Liver Conference in Vienna, Austria. The product is intended for prophylaxis of hepatitis C reinfection after liver transplantation. The study results presented show a reinfection in one patient in the treatment group with the highest Civacir® dosage (corresponding to a 4% reinfection rate), whereas reinfection still occurred in 32% of the patients in the control group despite prior treatment with new virostatic drugs. Recruitment is expected to be completed in the third quarter of 2015. The presentation of the final data is scheduled for early 2016.

The planned 20 patients have already been enrolled and treated in the first part of the clinical phase I/II study (no. 984) of the fibrinogen product that is under development. Fibrinogen is being tested in patients with a congenital fibrinogen deficiency in order to evaluate its pharmacokinetic properties tolerability and safety.

The completed phase II study (no. 982) of the IgM-high content 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 ventilation as well as mortality rates. Additional analyses of the study data are currently being performed in preparation for the next phase of clinical development. The randomised, double-blind, placebocontrolled 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 product Zutectra® has been approved in the EU since 2009 for the indication of prevention of hepatitis B virus (HBV) reinfection in patients six months after liver transplantation due to HBV-induced liver failure. With the phase III study "ZEUS" (Zutectra Early USe, no. 987), Biotest has now successfully demonstrated the effective use of Zutectra® in the early phase following liver transplantation. This application will make a major contribution to ensuring safer, quicker and more cost-effective patient care and improved user-friendliness for patients, as it can already be used and taught in hospitals. Biotest's aim is to use the study data to obtain marketing authorisation for the use of Zutectra® in the first week after transplantation. The study data has been submitted to the European Medicines Agency (EMA) and marketing authorisation is expected to be granted in late 2015.

Pentaglobin® has now been on the market for 30 years and is used for the treatment of severe bacterial infections in combination with antibiotics. In the last two years, various studies have been conducted into the efficacy of Pentaglobin® on antibiotic resistant bacteria. These bacteria are one of the biggest challenges for the health systems of the future. "In vitro" and "in vivo" testing has led to convincing results.

#### C. MARKETING AND DISTRIBUTION

Fovepta®, a hyperimmune globulin 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. The first sales in the country have now been recorded and sales growth is expected by the end of the year. Deliveries to Vietnam, Algeria and Jordan are also planned for the end of 2015.

Hepatect® and Zutectra® were also introduced in new markets. Zutectra® was launched in Israel, Singapore and Peru, and it will also be introduced in Romania by the end of the year. The product is set to be launched in Saudi Arabia and Iraq in the coming year, with further Asian countries to follow.

Hepatect® CP is not expected to see rising sales as intravenous Hepatect® CP is increasingly being replaced in practice by subcutaneous Zutectra®.

The plasmatic product Haemoctin® is continuing to record stable growth on the German market.

Current publications are reporting on the use of the product Cytotect® in heart and lung transplantations. This data could lead to Cytotect® being used to protect transplanted organs from cytomegalovirus reinfection to a greater extent in the future.

The Biotest product Albiomin® 20% received marketing authorisation in both Sweden and Norway in the first half of the year. Albiomin® 5% and 20% were also approved by the Gulf Central Committee for Drug Registration, meaning that they now have central marketing authorisation for the Gulf region.

## IV. PRESENTATION OF RESULTS OF OPERATIONS, FINANCIAL POSITION AND FINANCIAL STATUS

#### A. RESULTS OF OPERATIONS

In the first half of 2015, the Biotest Group generated sales of  $\[ \in \]$  287.7 million. This represents an increase of 8.9% compared with the same period of 2014, in which sales of  $\[ \in \]$  264.1 million were generated. While the Plasma & Services segment recorded significant sales growth (+51.8%), sales in the Therapy segment were down slightly year-on-year ( $\[ \in \]$  3.1%).

SALES BY SEGMENT

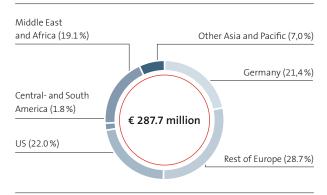
in € million	H1 2015	H1 2014	Change in %
Therapy	196.3	202.6	-3.1
Plasma & Services	87.0	57.3	51.8
Other Segments	4.4	4.2	4.8
Biotest Group	287.7	264.1	8.9

The Biotest Group's sales growth in the first half of 2015 was primarily generated in the US, in the Group's domestic market of Germany, and in the Asia and Pacific region. The US recorded growth of 65.7%. Sales development in North America was driven by the market relaunch of Bivigam® and increased sales of specialty and normal plasma.

The positive performance in Central and South America in the first quarter was followed by a further improvement in the second quarter, meaning that Biotest generated significant overall revenue growth of 17.8% in this region in the first half of the year. Sales in the rest of Europe (excluding Germany) declined by 13.6%. This was attributable to the continued price pressure in individual product areas and regions.

As this was accompanied by a positive trend in Germany, the breakdown of Group sales has shifted slightly towards the domestic market. In the period from January to June 2015, the Biotest Group generated 78.6% of its sales outside Germany (previous year: 80.5%).

#### SALES BY REGION



The cost of sales clearly increased to € 195.0 million in the first six months of 2015 after € 154.1 million in the same period of the previous year. This was attributable to unabsorbed costs resulting from reduced production of Bivigam® due to high inventories – as well as the resulting lower availability of intermediates – at the Boca Raton site in the US. The lack of intermediates from the US lead to lower utilisation of the Albumin production capacity at Dreieich.

The cost of sales ratio rose significantly from 58.3% in the same period of the previous year to 67.8%. In contrast marketing and distribution costs grew to a lower extent than sales, increasing by just 3.3% year-on-year from  $\le 33.0$  million (percentage of sales: 12.5%) to  $\le 34.1$  million (percentage of sales: 11.9%).

Administrative expenses remained constant at € 16.9 million despite the increase in the number of employees. Accordingly their percentage share of sales of 5.9 % was down on the previous year (6.4%).

Research and development costs rose mainly as a result of successful patient recruitment for clinical trials and the corresponding growth in the production of clinical trial material. In particular, this includes expenses for the pre-production of tregalizumab (BT-061) for the phase III study that was originally planned. Research and development costs increased by 16.6% year-on-year, amounting to 40.1 million in the first half of 2015 (previous year: 40.1 million) and accounting for 13.9% of sales (previous year: 13.0%).

Other operating expenses stayed at € 1.4 million and were below the previous year level of € 2.1 million.

Operating profit (EBIT) decreased significantly from € 26.5 million in the previous year to € 2.3 million as a result of the higher level of expenses in particular and the increase in the cost of sales.

This development was attributable to the Therapy segment, where higher research and development costs, the unabsorbed costs described above and continued price pressure in individual product areas and regions resulted in significantly negative EBIT. The planned, successful progress of the "Biotest Next Level" expansion project, which will double production capacities at the Group's headquarters in Dreieich, negatively impacted earnings by € 2.6 million. EBIT in the Therapy segment declined to € −11.2 million as a result (previous year: € +20.6 million). By contrast, EBIT in the Plasma & Services segment almost doubled, increasing by 98.7% year-on-year from € 7.5 million to € 14.9 million. This success is primarily due to the growth in sales of plasma to long-standing cooperation partners.

The financial result amounted to  $\in$  -0.2 million (previous year:  $\in$  -4.8 million). The valuation of a US dollar loan to the US subsidiary BPC at the reporting date had a particularly positive impact.

#### ESSENTIAL P&L POSITIONS OF THE BIOTEST GROUP\*

in € million	H1 2015	% of sales	H1 2014	% of sales
Production costs	-195.0	67.8	-154.1	58.3
Distribution costs		11.9		12.5
Administrative expenses		5.9		6.4
Research and development costs		13.9		13.0
Other operating income and expenses	0.7	0.2	0.8	0.3
Financial result	-0.2	0.1	-4.8	1.8

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

This resulted in earnings before taxes (EBT) of € 2.1 million for the Biotest Group compared with € 21.7 million in the previous year. Earnings after taxes (EAT) were negative at € -2.2 million (previous year: € +13.8 million). The high tax rate is due to the non-recognition of potential tax assets for losses at the US subsidiary.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	H1 2015	H1 2014	Change in %
EBIT	2.3	26.5	-91.3
EBT	2.1	21.7	-90.3
EAT	-2.2	13.8	
Earnings per share in €	-0.17	1.05	

#### **B. FINANCIAL POSITION**

The total assets of the Group increased from € 1,032.6 million as of 31 December 2014 to € 1,052.2 million as of 30 June 2015.

On the asset side, non-current assets rose significantly from € 353.3 million as of 31 December 2014 to € 402.7 million as of 30 June 2015. This was attributable to a further increase in property, plant and equipment – particularly as a result of the capacity expansion project – and the higher level of other non-current financial investments related in particular to the investment of current surplus liquidity.

All in all, current assets decreased compared with year-end 2014. The investment of surplus liquidity and payments for capital expenditure in the amount of  $\leqslant$  27.7 million resulted in a decline of cash and cash equivalents from  $\leqslant$  179.4 million to  $\leqslant$  96.8 million. This includes cash outflows for investments as part of short-term and medium-term financial planning. Despite the sales growth in the first half of the year, trade receivables were reduced from  $\leqslant$  181.6 million to  $\leqslant$  168.9 million.

88% of total assets were financed by non-current equity and debt as of 30 June 2015, thereby reflecting the Biotest Group's healthy and sustainable financing structure.

On the liabilities side, equity increased further to € 484.0 million (31 December 2014: € 480.2 million) as a result of currency effects. As a consequence, despite the higher level of total assets, the equity ratio remained largely unchanged at a very solid 46.0% following 46.5% as of 31 December 2014. Total debt increased to € 568.2 million (31 December 2014: € 552.4 million). This was due to the growth in non-current liabilities in particular and, within this item, non-current financial liabilities, which increased from € 325.8 million to € 338.3 million due to additional borrowings. Trade payables remained essentially unchanged at € 55.0 million after € 55.5 million at year-end 2014. Other current liabilities increased to € 41.4 million (31 December 2014: € 32.7 million).

#### C. FINANCIAL STATUS

Cash flow from operating activities amounted to a positive  $\in$  31.2 million in the first half of 2015 after a negative  $\in$  -34.6 million in the same period of the previous year. This was because the cash flow position from the change in working capital is now significantly positive.

Cash flow from investing activities amounted to  $\leqslant -113.4$  million in the period under review after  $\leqslant -87.3$  million in the previous year. In particular, this item includes outflows for other assets and financial fixed assets in the amount of  $\leqslant 85.7$  million (previous year: outflow of  $\leqslant 69.5$  million). Adjusted for these payments relating to financial investments made as part of short-term and mid-term financial planning, cash flow from investing activities amounted to  $\leqslant -27.7$  million after  $\leqslant -17.8$  million in the previous year.

Cash flow from financing activities amounted to €-1.2 million in the first six months of 2015 after €+7.3 million in the same period of the previous year. In line with planning, cash and cash equivalents declined further from €179.4 million as of 31 December 2014 to €96.8 million at the end of the first half-year of 2015.

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

The Biotest Group continued on its growth path in the period from January to June 2015. Sales increased by 8.9% compared with the same period of the previous year. Due to the significant increase in research and development costs, unabsorbed production costs and the continued price pressure in some regions, EBIT declined from € 26.5 million in the previous year to € 2.3 million. Overall, the Biotest Group has the resources to drive forward its operating business as planned.

Following the end of the cooperation with AbbVie and the discontinuation of the clinical development of tregalizumab (BT-061), the EBIT forecast for 2015 of around  $\leqslant$  50 million has been reduced by  $\leqslant$  25–30 million.

On the other hand, potential is provided by the entry of plasma protein preparations into other regional markets as well as further developments in the area of monoclonal antibodies and plasma proteins over the medium- and long-term. The Biotest Group's sustainable strong financial position and balanced financing structure are the foundation for its planned future growth.

#### C. SUPPLEMENTARY REPORT

The 1:3 share split resolved by the Annual Shareholders' Meeting on 7 May 2015 was implemented on 15 July 2015 after the amendments to the Articles of Association concerning a capital increase from Company funds that were also resolved by the Annual Shareholders' Meeting had been entered in the commercial register on 22 June 2015. Each ordinary and preference share has a notional interest in the share capital of EUR 1.00, meaning that the share capital of Biotest AG now amounts to € 39,571,452.00 and is divided into 19,785,726 ordinary shares and 19,785,726 preference shares.

Following a detailed analysis of the data from the phase IIb "TREAT 2b Study" of tregalizumab (BT-061) for rheumatoid arthritis, BT-061 showed a dose-dependent effect on cells in the immune system which did not translate into clinical efficacy. As a result, Biotest will discontinue the clinical development of tregalizumab (BT-061). Pre-clinical work is currently being performed to determine whether tregalizumab (BT-061) could be of benefit in treating other diseases.

## D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

#### I. OUTLOOK

## A. EXPECTED DEVELOPMENTS IN THE MARKET ENVIRONMENT

According to current studies, global demand for immunoglobulin volumes will continue to increase by 6-8% annually over the coming years. The prices of these preparations are coming under increasing pressure throughout the world due to growing fractionation capacities. Although the prices remained constant in the US market, a certain price pressure was recorded in specific product areas and regions. This trend will continue in 2015 and 2016.

The Biotest Group also expects the global market volume for plasmatic clotting factors to increase by around 2% p.a. until 2020.<sup>12</sup> 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.<sup>13</sup>

Further sales across all product groups are forecast up to 2018 in connection with new and extended marketing authorisations.<sup>14</sup>

There is also 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 6.5 billion. Furthermore, the treatment of various solid tumours with indatuximab ravtansine (BT-062) offers significant additional sales opportunities following marketing authorisation for corresponding indications.

- 12 Marketing Research Bureau (2014), Global forecast of the factor VIII market 2013 to 2020
- 13 Marketing Research Bureau (2014), Albumin Usage and Demand Forecast in China 2013 – 2020
- 14 Evaluate Pharma, Yearly product sales by indication, 23 January 2014

#### B. EXPECTED PERFORMANCE OF THE BIOTEST GROUP

#### Revenue and earnings

The Board of Management confirms its sales forecast as published in the 2014 Annual Report. Following very strong sales growth in the last two financial years, the Board of Management expects an increase in sales in the low single-digit percentage range for this year.

The significant increase in costs and continued price pressure in individual product areas and regions are having a noticeable effect on earnings. In addition, the cost for the planned capacity expansion at the Dreieich site is having a more pronounced impact than in the 2014 financial year. Costs relating to the "Biotest Next Level" expansion project that is now underway will probably be twice as high in 2015 as in 2014. As Biotest works together with partners in developing new preparations, the R&D costs incurred in the current financial year depend to a large extent on the progress made in these projects and the resulting further decisions. Following the discontinuation of the clinical development of tregalizumab (BT-061), the Board of Management is forecasting EBIT in the range of € 20−25 million as previously announced.

#### Financial status

As forecast, Biotest will maintain a balanced financing structure in 2015 in terms of the ratio of debt to equity as well as the ratio of short-term to long-term debt financing.

Capital expenditure of up to € 118.4 million is planned for the Biotest Group for the 2015 financial year, of which a substantial portion is attributable to the "Biotest Next Level" project. However, further capital expenditure will also be incurred for the expansion of existing and the construction of new plasma centres in the US for BPC and for the completion of construction work on the plasma goods receipt area and virological laboratories at Dreieich.

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 also has solid financing available for the long term.

#### II. RISK REPORT

The Biotest Group's risk situation has not changed materially from the presentation set out in the 2014 Annual Report (pages 26 to 33) with the exception of the new developments regarding BT-061.

If Bivigam® fails to achieve the forecast sales volumes in the second half of the year, the recognition of a write-down may become necessary.

#### III. OPPORTUNITIES REPORT

The Biotest Group's opportunity situation has not changed materially from the presentation set out in the 2014 Annual Report (see pages 33 and 34) with the exception of the new developments regarding BT-061.

## CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 June 2015

in € million	Q2 2015	Q2 2014	H1 2015	H1 2014
Revenue	145.2	141.9	287.7	264.1
Cost of sales	-96.9	-83.1	-195.0	-154.1
Gross profit	48.3	58.8	92.7	110.0
Other operating income	1.0	1.5	2.1	2.9
Distribution costs	-16.2	-17.8	-34.1	-33.0
Administrative expenses	-8.7		-16.9	-16.9
Research and development costs	-21.5	-17.2	-40.1	-34.4
Other operating expenses	-0.7	-1.7	-1.4	-2.1
Operating profit	2.2	15.8	2.3	26.5
Financial result			-0.2	-4.8
Earnings before taxes	-2.1	13.9	2.1	21.7
Income tax		-5.1	-4.3	-7.9
Earnings after taxes	-3.6	8.8	-2.2	13.8
Equity holders of the parent	-3.6	8.8	-2.2	13.8
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €	-0.28	0.67	-0.17	1.05

## CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 June 2015

in € million	H1 2015	H1 2014
Consolidated profit for the period	-2.2	13.8
Exchange difference on translation of foreign operations		1.5
Income tax effect	0.0	0.0
Other comprehensive income net of tax		
to be reclassified to profit or loss in subsequent periods		1.5
Other comprehensive income after tax	14.3	1.5
Total comprehensive income after tax	12.1	15.3
Attributable to:		
Equity holders of the parent	12.1	15.3
Non-controlling interests	0.0	0.0

## CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 June 2015

in € million	30 June 2015	31 December 2014
ASSETS		
Non-current assets		
Intangible assets	54.1	50.2
Property, plant and equipment	307.2	282.3
Investments in associates	1.3	1.3
Other financial investments	25.1	5.2
Other assets	0.9	0.8
Deferred tax assets	14.1	13.5
Total non-current assets	402.7	353.3
Current assets		
Inventories	243.6	246.0
Trade receivables	168.9	181.6
Current income tax assets	6.8	4.6
Other assets	133.4	67.7
Cash and cash equivalents	96.8	179.4
Total current assets	649.5	679.3
Total assets	1,052.2	1,032.6
EQUITY AND LIABILITIES	_     _	
Equity	_     _	
Subscribed capital	33.8	33.8
Share premium	225.6	225.6
Retained earnings	226.7	201.5
Shares of profit or loss attributable to equity holders of the parent	-2.2	19.2
Equity attributable to equity holders of the parent	483.9	480.1
Non-controlling interests	0.1	0.1
Total equity	484.0	480.2
Liabilities		
Provision for pensions and similar obligations	78.6	77.5
Other provisions	7.1	6.3
Financial liabilities	338.3	325.8
Other liabilities	1.4	2.5
Deferred tax liabilities	11.8	11.4
Total non-current liabilities	437.2	423.5
Other provisions	20.5	23.5
Current income tax liabilities	4.0	8.6
Financial liabilities	10.1	6.1
Trade payables	55.0	55.5
Other liabilities	41.4	32.7
Liabilities from deferred revenue	0.0	2.5
Total non-current liabilities	131.0	128.9
Total liabilities	568.2	552.4
Total equity and liabilities	1,052.2	1,032.6

## CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 June 2015

in € million	2015	2014
Operating cash flow before changes in working capital	18.6	42.4
Cash flow from changes in working capital	26.1	-62.8
Interest and taxes paid	-13.5	-14.2
Cash flow from operating activities	31.2	-34.6
Cash flow from investing activities	-113.4	-87.3
Cash flow from financing activities	-1.2	7.3
Cash changes in cash and cash equivalents	-83.4	-114.6
Exchange rate-related changes in cash and cash equivalents	0.8	0.0
Cash and cash equivalents on 1 January	179.4	204.4
Cash and cash equivalents on 30 June	96.8	89.8
thereof within cash flow from investing activities		
Cash outflow into other assets	-65.2	-64.7
Cash outflow into financial assets	-20.5	-4.8
Cash flow from investing activities adjusted for payments		
due to financial investments in the scope of short-term financial disposition	-27.7	-17.8

## CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 June 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 1 January 2014	33.8	225.6	-0.4	201.6	460.6	0.1	460.7
Gains/losses recognised directly in equity			1.5		1.5		1.5
Profit for the period				13.8	13.8		13.8
Total comprehensive income	0.0	0.0	1.5	13.8	15.3	0.0	15.3
Dividend payments				-7.9	-7.9	_	-7.9
Balance on 30 June 2014	33.8	225.6	1.1	207.5	468.0	0.1	468.1
Balance on 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	0.0	-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

#### SELECTED NOTE DISCLOSURES

#### METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 30 June 2015 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 2015 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 those IFRSs that are mandatory for financial years beginning on or after 1 January 2015.

These interim consolidated financial statements were approved for publication by the Board of Management on 11 August 2015.

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

in € million	H1 2015	H1 2014
Operating profit (EBIT)	2.3	26.5
Financial result	-0.2	-4.8
Earnings before taxes (EBT)	2.1	21.7
Income taxes	-4.3	-7.9
Earnings after taxes (EAT)	-2.2	13.8

#### SEGMENT REPORTING

of the Biotest Group for the period from 1 January to 30 June 2015

		Revenue	
in € million	H1 2015	H1 2014	Change in %
Therapy	196.3	202.6	-3.1
Plasma & Services	87.0	57.3	51.8
Other Segments	4.4	4.2	4.8
Biotest Group	287.7	264.1	8.9

	EBIT	
H1 2015	H1 2014	Change in %
-11.2	20.6	-154.4
14.9	7.5	98.7
-1.4	-1.6	12.5
2.3	26.5	-91.3

	Revenue from third parties by customer's geographical location			
in € million	H1 2015	H1 2014	Change in %	
Germany	61.5	51.6	19.2	
Rest of Europe	82.5	95.5	-13.6	
USA	63.3	38.2	65.7	
Rest of America	5.3	4.5	17.8	
Middle East and Africa	55.0	62.6	-12.1	
Other Asia and Pacific	20.1	11.7	71.8	
Biotest Group	287.7	264.1	8.9	

## QUARTER-TO-QUARTER COMPARISON

by business segments

			Revenue		
in € million	Q2/2015	Q1/2015	Q4/2014	Q3/2014	Q2/2014
Therapy	98.0	98.3	111.8	95.4	109.6
Plasma & Services	44.8	42.2	51.2	48.5	29.8
Other Segments	2.4	2.0	9.1	1.9	2.5
Biotest Group	145.2	142.5	172.1	145.8	141.9
			EBIT		
			<del></del>		
	Q2/2015	Q1/2015	<b>EBIT</b> Q4/2014	Q3/2014	Q2/2014
in € million Therapy	Q2/2015 -4.8	Q1/2015 -6.4	<del></del>	Q3/2014 -1.0	Q2/2014 13.5
	-		Q4/2014		
Therapy	-4.8	-6.4	Q4/2014 7.9	-1.0	13.5
Therapy Plasma & Services		-6.4 7.1	Q4/2014 7.9 8.9	-1.0 10.6	13.5

## OTHER NOTE DISCLOSURES

## Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2014				Currency trans- lation differences	Carrying amount as of 30 June 2015
Intangible assets	50.2	1.0	0.0	-0.8	3.7	54.1
Property, plant & equipment	282.3	31.4	0.0	-14.5	8.0	307.2
Total	332.5	32.4	0.0	-15.3	11.7	361.3

On 30 June 2015, the purchase obligation for non-current assets amounted to 34,1 in €. million.

## Employees

## by operating functions

full-time equivalents	30 June 2015	31 December 2014	Change in %
Marketing and distribution	208	203	2.5
Administration	251	231	8.7
Production	1,566	1,516	3.3
Research and development	193	208	-7.2
Biotest Group	2,218	2,158	2.8

#### Financial instruments as of 30 June 2015

In € million	Carrying amount	Fair value
Assets		
Trade receivables	168.9	168.9
Other assets		
Other receivables	133.9	133.9
Derivatives not designated as hedging instruments	0.4	0.4
Other financial investments	25.1	25.1
Equity and liabilities		
Trade payables	55.0	55.0
Financial liabilities	348.4	354.5
Other liabilities	40.2	40.2
Derivatives not designated as hedging instruments	2.6	2.6

#### 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.

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 at 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 € 3.4 million from Biotest in the first six months. As of 30 June 2015, Biotest had receivables from BioDarou P.J.S. Co. and Plasma Gostar Pars P.J.S. totalling € 4.6 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**

The 1:3 share split resolved by the Annual Shareholders' Meeting on 7 May 2015 was implemented on 15 July 2015 after the amendments to the Articles of Association concerning the capital increase from Company funds that were also resolved by the Annual Shareholders' Meeting had been entered in the commercial register on 22 June 2015. Each ordinary and preference share now has a notional interest in the share capital of EUR 1.00, meaning that the share capital of Biotest AG now amounts to € 39,571,452.00 and is divided into 19,785,726 ordinary shares and 19,785,726 preference shares.

Following a detailed analysis of the data from the phase IIb "TREAT 2b Study" of tregalizumab (BT-061) for rheumatoid arthritis, BT-061 showed a dose-dependent effect on cells in the immune system which did not translate into clinical efficacy. As a result, Biotest will discontinue the clinical development of tregalizumab (BT-061). Pre-clinical work is currently being performed to determine whether tregalizumab (BT-061) could be of benefit in treating other diseases.

#### 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 net assets, liabilities, financial position and profit or loss 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 2015 Biotest Aktiengesellschaft Board of Management

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

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Dr. Georg Floß

Member of the Board of Management

#### FINANCIAL CALENDAR

#### 10 November 2015

Nine-month report for 2015

#### 10 November 2015

Analyst conference

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This quarterly report contains forward-looking statements on overall economic development as well as on the business earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments. The forward-looking statements are only valid at the time of publication of this quarterly report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

