Biotest

From Nature for Life

NINE-MONTH REPORT 2015 BIOTEST AG

KEY FIGURES

BIOTEST GROUP		Q1–Q3 2015	Q1–Q3 2014	Change in %
Revenue	€ million	**417.9**	409.9	2.0
thereof:				
Germany	€ million	**94.3**	76.6	23.1
Rest of world	€ million	**323.6**	333.3	–2.9
thereof:				
Therapy	€ million	**288.0**	298.0	–3.4
Plasma & Services	€ million	**123.2**	105.8	16.4
Other Segments	€ million	**6.7**	6.1	9.8
EBITDA	€ million	**5.4**	59.7	–91.0
Operating profit (EBIT)	€ million	**–82.0**	35.3	–332.3
EBIT in % of revenue	*%*	***–19.6***	*8.6*	
Earnings before taxes	€ million	**–85.2**	32.3	–363.8
Earnings after taxes	€ million	**–88.0**	19.3	–556.0
Financing				
Cash flow from operating activities	€ million	**34.2**	–39.1	187.5
Depreciation and amortisation	€ million	**87.4**	24.4	258.2
		30 September 2015	31 December 2014	
Equity	€ million	**398.2**	480.2	–17.1
Equity ratio	*%*	***41.4***	*46.5*	
Employees (full-time equivalents)	amount	**2,215**	2,158	2.6

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II. GROUP STRATEGY

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 2,215 full-time equivalents as of 30 September 2015. This represents an increase of 2.6 % compared with 31 December 2014 (2,158 full-time equivalents).

II. GROUP STRATEGY

The core element of Biotest's strategy is a clear focus on 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 marketing authorizations on internationalisation and diversification of its portfolio.

Since 2013, the Biotest Group is expanding its production capacity at its headquarters at Dreieich in order to continue participating in future global market growth. The product portfolio will be expanded and production capacity will be doubled by 2019/20 as part of the "Biotest Next Level" ("BNL") project. The aim of this project is to further strengthen the Company's profitability and hence its competitiveness on the global markets, thereby laying the foundations for continued growth.

Biotest is also seeking to enter into strategic partnerships with suitable partners in selected areas.

In its antibody portfolio, Biotest will continue with the current pre-clinical and clinical activities until the next milestones with the aim of advancing the respective projects with suitable partners who will co-finance the future development and marketing.

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 actively pursues opportunities for developing products together with partners in order to minimise development risks and reduce development costs by synergy effects.

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. While developed economies saw a slight acceleration in growth rates, the upward trend is slowing in the emerging markets. In its October forecast, the IMF made a slight downward revision to its estimate of global economic growth compared with the summer forecast published in July 2015. Global economic output is now expected to increase by 3.1 % rather than 3.3 % in the current year.[1] The experts also lowered their forecast for 2016 from 3.8 % in July to 3.6 %.

In their joint diagnosis for autumn, the leading German economic research institutes also downwardly revised their forecast for the German gross domestic product. Their new estimate is for growth of 1.8 % in 2015.[2] In spring their estimate was a growth in gross domestic product of 2.1 %. The researchers expect the German economy to grow by 1.8 % in 2016.[3]

The European Commission is currently also forecasting economic growth to be 1.8 % for the EU and 1.5 % for the euro zone in 2015.[4] An increase of 2.1 % (EU) and 1.9 % (euro zone) is expected 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.

By contrast, the US Federal Reserve slightly increased its forecast for economic growth in the USA in September. It now expects growth of 2.1 %[5] compared with the maximum of 2.0 % announced in June 2015.[6]

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

II. INDUSTRY-SPECIFIC FRAMEWORK

Immunoglobulins and albumins, the best-selling products of the Biotest Group, are seeing stable growth in established markets such as the USA and Europe as well as in other regions of the world. For example, industry experts expect the market for intravenous immunoglobulins (IVIG) to see a global increase in demand within a long-term range of 6 – 8 % annually.[7] To meet this heightened demand, the industry is increasingly collecting source plasma. For example, plasma collections in the USA rose by around 8 % year-on-year in the first four months of 2015.[8] However, 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.[9] The market volume for immunoglobulins in the USA has increased slightly of late, Europe however, has seen considerably stronger growth.[10] The German market has also recorded positive development in terms of sales volumes in the year to date.[11] Average prices on the German hospital market remained largely unchanged as against the previous year.[12] With the IVIG market growth in Germany, the Biotest preparation Intratect® was able to record revenue gains and maintain its share of the overall market at a stable level with largely constant prices, as it did in the previous year.

1 International Monetary Fund (IMF), World Economic Outlook, October 2015

2 Joint diagnosis project group, joint diagnosis, Autumn 2015, 8 October 2015

3 Joint diagnosis project group, joint diagnosis, Spring 2015, 16 April 2015

4 European Commission: European Economic Forecast, Spring 2015, 5 May 2015

5 Board of the Governors of the Federal Reserve System, minutes of the federal open market committee, 17 September 2015

6 Board of the Governors of the Federal Reserve System, minutes of the federal open market committee, 17 June 2015

7 Goldman Sachs: Global: Medical Technology: Medical Supplies, 18 May 2015

8 PPTA, as of April 2015

9 UBS Investment Research, Plasma Pharmaceuticals: Jun-15 Plasma Price & Supply Survey: We call tight supply inside 2yrs, 2 September 2015

10 PPTA, as of May 2015; IMS Health, as of June 2015

11 IMS Health, as of June 2015

12 IMS Health, as of June 2015

There is still considerable excess demand for human albumin, meaning that prices in the Near and Middle East remain attractive. 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 is expected to grow by 4 % p. a. until 2020.[13] An increase of 2 % p. a. is forecasted for plasmatic factor VIII products and around 5 % p. a. for the recombinant factor VIII products segment. 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 in the respective country.

III. BUSINESS PERFORMANCE

A. AT A GLANCE

The Biotest Group recorded slightly higher sales in the first nine months of 2015 than in the same period of the previous year. The Group generated revenue of € 417.9 million in the period from January to September 2015, representing a year-on-year increase of 2 % (previous year: € 409.9 million).

Substantial revenue growth was recorded in Germany and the "Other Asia and Pacific" reporting region in particular. In Germany, revenue increased by 23.1 % to € 94.3 million in the period from January to September. In the region "Other Asia and Pacific" revenue even increased by 58.3 % to € 29.6 million in the same period. Although revenue in the USA rose by 24.4 % to € 78.1 million, this development failed to meet expectations. In the world's largest market for immunoglobulins, the USA, the supply situation has changed dramatically in recent months. Supply has increased significantly, making it harder for Biotest and other companies to realise higher prices.

Operating income (EBIT) declined from € 35.3 million to € –82.0 million in the period from January to September. This was attributable primarily to impairments totalling € 84 million in connection with the company's US therapy activities.

As there has been a significant deterioration in the market prospects for the Hepatitis C product Civacir®, which is in development, the revaluation of the project resulted in the recognition of impairment on intangible assets and inventories in the amount of € 13 million.

In addition, impairment of € 14 million was recognised in respect of invertory of the Bivigam® that are at risk of expiry due to the unexpected downturn in revenue over the past two months following the better than expected development in the first half of 2015. The inventory dates back to pre-production for the US market entry two years ago. As the anticipated revenue was not generated, they are not expected to be sold in full before their expiry date.

The current sales development of the Bivigam® and the significant deterioration in the market prospects for the Civacir® project triggered an impairment test of the corresponding assets in the USA. This resulted in the recognition of impairment on the manufacturing facility, parts of the buildings and intangible assets in the amount of € 55 million. Biotest aims to significantly increase sales of Bivigam® through additional marketing measures. It is also currently evaluating the options for improving the utilisation of the manufacturing facility by toll manufacturing and/or the co-marketing of the Bivigam®.

Operating income also continues to be impacted by increased research and development costs, particularly in connection with the termination of the cooperation with AbbVie on the development of tregalizumab (BT-061), expenses for capacity expansion (Biotest Next Level), unabsorbed costs at Biotest Pharmaceuticals Corporation and price pressure in individual product areas and regions.

13 Marketing Research Bureau, Global Forecasts of the Factors VIII and IX, 2014

B. RESEARCH AND DEVELOPMENT

In the first nine months of 2015, research and development costs increased by 49.9 % to € 76.9 million (previous year: € 51.3 million). Of this figure, 54.0 % relates to monoclonal antibody (mAb) development projects (previous year: 47.0 %). 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.

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

Recruitment has been completed for the first part of the clinical phase I/II study (no. 984) of fibrinogen that is under development. This part of the study 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 haemorrhage or when undergoing operations.

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 pre-clinical studies have been conducted with respect to 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. Biotest believes that Pentaglobin® offers considerable future potential in terms of use on antibiotic-resistant bacteria.

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" (**Z**utectra **E**arly **US**e, no. 987), Biotest has now successfully demonstrated the use of Zutectra® in the early phase following liver transplantation. This application will make a major contribution to ensuring better patient care. Biotest's aim is to use the study data to obtain marketing authorisation for the use of Zutectra® after the first week following transplantation. The study data has been submitted to the European Medicines Agency (EMA) and marketing authorisation is expected to be granted in the first quarter of 2016.

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

In April 2015, Biotest presented the positive interim results of the pivotal phase III study (no. 988) of Civacir® at the 50th International Liver Conference in Vienna, Austria. Patient recruitment for the clinical study was completed in the third quarter of 2015 with a total of 80 patients. Biotest will present additional data at the AASLD conference in November. Although the interim results of the phase III study for Civacir® were promising and the objectives of the study had been achieved to date, Biotest expects the market prospects to be substantially reduced as a result of the newly introduced, highly effective new antivirals whose use shortly after liver transplantation is now being investigated.

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

In the phase I/II study (no. 989), in which patients with 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 is in progress. 24 patients have already been treated with BT-062.

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

The phase II b study (TREAT 2b – **T**cell **RE**gulating **A**rthritis **T**rial 2b) of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis did not meet the primary endpoint in the second quarter of 2015. The study data was presented at the ACR conference in November. The company is currently using pre-clinical modelling systems to examine the alternative indications of BT-061 with potential for partnering.

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. Biotest has recorded encouraging growth in the meantime, as well as successfully delivering to Vietnam and Algeria.

Intratect® was launched in the private pharmaceutical sector in Mexico. The product Intratect® 100 g/l (10 %) is currently in the registration process in a number of countries, including the promising Middle East region as well as Australia, Colombia, Mexico, Algeria and other countries.

Hepatect® and Zutectra® were launched in additional markets in the first nine months of 2015. The new markets for Zutectra® included Israel, Singapore and Peru.

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

A number of scientific papers have given new impetus to the discussion on the use of Cytotect® to prevent CMV infection in heart and lung transplantations.[14] 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 % (200 g/l) received marketing authorisation in both Sweden and Norway in the first half of the year. The initial delivery of Albiomin to China has been initiated and is expected to take place before the end of November.

In the first nine months of 2015, Biotest opened two new plasma collection centres in the USA, in Conway, Arkansas, and Jacksonville, North Carolina. The two centres are currently being examined by the FDA. Biotest expects the necessary approvals required for the startup to be granted by the end of the year. The two new centres mean that Biotest now has a total of 18 plasma collection centres in the USA. It is also planning to open another three or four centres over the course of the next year.

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

A. RESULTS OF OPERATIONS

In the first nine months of 2015, the Biotest Group generated sales of € 417.9 million. This represents an increase of 2.0 % compared with the same period of 2014, in which sales of € 409.9 million were generated. While the Plasma & Services segment recorded significant sales growth (+ 16.4 %), sales in the Therapy segment were down slightly year-on-year (– 3.4 %).

14 Mainz University Medical Centre, Information on Lung Transplantation, 2013

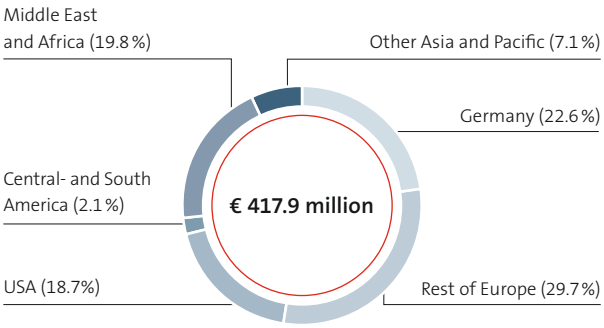
SALES BY SEGMENT

in € million	Q1–Q3 2015	Q1–Q3 2014	Change in %
Therapy	288.0	298.0	–3.4
Plasma & Services	123.2	105.8	16.4
Other Segments	6.7	6.1	9.8
Biotest Group	**417.9**	**409.9**	**2.0**

The Biotest Group's sales growth in the first nine months of 2015 was primarily generated in the US, in the Group's domestic market of Germany and in the Asia and Pacific region. Germany recorded growth of 23.1 %. In the Asia and Pacific region sales increased by 58.3 % to € 29.6 million in the period under review.

The positive performance of North and South America in the first half of the year continued in the third quarter, with Biotest recording revenue growth of 24.7 % to a total of € 86.8 million in the first nine months. Sales in the rest of Europe (excluding Germany) declined by 10.6 % to € 124.3 million. This was attributable to the continuing price pressure in individual product areas and regions, as well as negative exchange rate effects.

SALES BY REGION



The breakdown of Group sales for the first nine months has shifted slightly towards the domestic market due to the positive trend in Germany. In the period from January to September, the Biotest Group generated 77.4 % of its sales outside Germany (previous year: 81.3 %).

The impairments of € 84 million recognised in the third quarter are reflected in the cost of sales and research and development costs. The impairments primarily relate to the company's US therapy activities and include the full write-down of the manufacturing facilities, parts of the buildings and intangible assets in the USA, as well as inventory of products developed exclusively for the US market. The US plasma collection business is not affected.

As a result, research and development costs increased by 50.0 % year-on-year to € 76.9 million in the first nine months of 2015. This was due to increased expenses for the pre-production of tregalizumab (BT-061) in the first half of the year and the impairment recognised in the third quarter, which related in particular to the product Civacir®.

The cost of sales increased to € 344.4 million after € 245.4 million in the previous year. This includes the write-offs recognised as a result of an impairment test, which primarily related to intangible assets and property, plant and equipment.

By contrast, distribution costs decreased to € 51.8 million (percentage of sales: 12.4 %) after € 55.1 million in the previous year (percentage of sales: 13.4 %).

Administrative expenses increased to € 26.7 million in the period under review. Their percentage share of sales was 6.4 %, up slightly on the previous year (5.8 %).

ESSENTIAL P&L POSITIONS OF THE BIOTEST GROUP*

in € million	Q1–Q3 2015	% of sales	Q1–Q3 2014	% of sales
Production costs	–344.4	82.4	–245.4	59.9
Distribution costs	–51.8	12.4	–55.1	13.4
Administrative expenses	–26.7	6.4	–23.8	5.8
Research and development costs	–76.9	18.4	–51.3	12.5
Other operating income and expenses	–0.1	0.0	1.0	0.2
Financial result	–3.2	0.8	–3.0	0.7

* Costs/expenses are denoted with a negative sign

Other operating expenses declined from € 3.5 million in the first nine months of 2014 to € 1.9 million.

Operating income (EBIT) for the first nine months decreased to € –82.0 million (previous year: € + 35.3 million), largely as a result of impairments recognised in the third quarter of 2015. The impairments relate to the Therapy segment, meaning that EBIT in the Therapy segment declined to € –100.0 million (previous year: € + 19.6 million). By contrast, EBIT in the Plasma & Services segment increased by 11.0 %, from € 18.1 million to € 20.1 million. This success is due primarily to the growth in sales of plasma to long-standing cooperation partners.

The 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 € 4.4 million.

At € –3.2 million, the financial result was essentially unchanged as against the previous year (Q1–Q3 2014: € –3.0 million).

This resulted in earnings before taxes (EBT) of € –85.2 million for the Biotest Group compared with € + 32.3 million in the previous year. Earnings after taxes (EAT) amounted to € –88.0 million (previous year: € + 19.3 million). This corresponds to earnings per share of € –2.22 after € + 0.49 in the previous year. This decrease is attributable mostly to the impairments recognised in the third quarter.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	**Q1–Q3 2015**	Q1–Q3 2014	Change in %
EBIT	–82.0	35.3	–332.3
EBT	–85.2	32.3	–363.8
EAT	–88.0	19.3	–556.0
Earnings per share in €*	–2.22	0.49	–553.1

* prior year figures adjusted to the new number of shares

B. FINANCIAL STATUS

As a result of the impairments the total assets of the Group decreased from € 1,032.6 million as of 31 December 2014 to € 962.8 million as of 30 September 2015.

On the asset side, non-current assets increased from € 353.3 million as of 31 December 2014 to € 367.5 million as of 30 September 2015. This was attributable to the higher level of other non-current financial investments due to the long-term investment of surplus liquidity. Other financial assets totalled € 25.2 million at the reporting date (31 December 2014: € 5.2 million). Property, plant and equipment was unchanged year-on-year at € 282.3 million (previous year: € 282.3 million). Capital expenditure on replacement and expansion in the amount of € 66.3 million was offset by scheduled depreciation and impairments totalling € 74.1 million.

All in all, current assets decreased compared with year-end 2014. The investment of surplus liquidity in the amount of € 50.2 million and payments for capital expenditure in particular resulted in a decline of cash and cash equivalents from € 179.4 million to € 88.3 million. Trade receivables decreased from € 181.6 million to € 155.4 million as a result of the sales development in the third quarter of 2015.

86.5 % of total assets were financed by non-current debt and equity as of 30 September 2015, thereby reflecting the Biotest Group's healthy and sustainable financing structure.

On the liabilities side, reported equity decreased to € 398.2 million due to the net loss for the period (31 December 2014: € 480.2 million). Despite the impairments, the equity ratio was a solid 41.4 % as of 30 September 2015 compared with 46.5 % as of 31 December 2014. Total debt increased to € 564.6 million (31 December 2014: € 552.4 million). Non-current liabilities rose from € 423.5 million to € 435.1 million. Trade payables increased slightly to € 56.2 million (31 December 2014: € 55.5 million); the other current liabilities rose slightly to € 37.9 million (31 December 2014: € 32.7 million).

C. FINANCIAL POSITION

The company's operating cash flow remained positive after the first three quarters. Cash flow from operating activities amounted to € 34.2 million in the first nine months of 2015 after a negative € –39.1 million in the same period of the previous year. The positive operating cash flow is largely attributable to the reduction in working capital.

Cash flow from investing activities amounted to € –55.4 million in the period under review after € –26.2 million in the previous year. This figure primarily related to the further expansion of the production site in Dreieich as part of "Biotest Next Level".

Cash flow from financing activities amounted to € –0.7 million in the first nine months of 2015 after € +9.5 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 € 88.3 million as of 30 September 2015.

D. OVERALL ASSESSMENT OF THE COMPANY'S BUSINESS SITUATION

In the period from January to September 2015, the Biotest Group increased its sales by 2 % year-on-year, from € 409.9 million in the previous year to € 417.9 million.

The impairments totalling € 84 million in the third quarter represent a non-recurring event. They related primarily to the company's US therapy activities. The US plasma collection business was not affected. Similarly, the expansion of production at the company's headquarters in Dreieich, amounting to capital expenditure of € 250 million until 2019, and its operating activities outside the US market will continue as planned.

EBIT decreased from € 35.3 million in the previous year to € –82.0 million largely due to the impairments. The termination of the cooperation with AbbVie and the impairments in particular prompted the Board of Management to issue a revised EBIT forecast. The Board of Management is now anticipating total EBIT of between € –72 million and € –77 million in 2015 as a whole.

Overall, the Biotest Group has the resources to advance its operating business as planned. With the expansion of production capacity at Dreieich as part of the "Biotest Next Level" ("BNL") project, the company is not only doubling its production capacity, but also reducing its costs per product unit. In future, Biotest intends to produce five instead of three products from each litre of blood plasma.

Potential for the future is also offered by the market entry of plasma protein preparations into additional regions and further developments of plasma proteins. Furthermore Biotest is seeking strategic partnerships with suitable partners in selected areas and specific business segments. Biotest will continue with its current pre-clinical and clinical activities in its antibody portfolio in order to identify suitable partners for future development and marketing.

The Biotest Group's solid financial position and balanced financing structure are the foundation for its planned future growth.

C. SUPPLEMENTARY REPORT

There were no events with a material influence on the results of operations, financial position and financial status after the reporting date.

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.[15]

Increased sales across all product groups are forecasted up to 2018 in connection with new and extended marketing authorisations.[16]

15 Marketing Research Bureau (2014), Global forecast of the factor VIII market 2013 to 2020

16 Kepler Cheuvreux Research, Pharma & Biotech, 5 March 2015

There is also future 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 additional sales opportunities following marketing authorisation for corresponding indications.

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.

Biotest expects to see a significant improvement in operating income (EBIT) of € 5–10 million for the fourth quarter of 2015.

In addition to the impairments recognised in the third quarter, earnings are being impacted by increased expenditure and sustained price pressure in individual product areas and regions. In addition, the cost of the planned capacity expansion at the Dreieich site is having a higher impact than in the 2014 financial year. Costs relating to the "Biotest Next Level" expansion project that is now underway are expected to be twice as high in 2015 as in 2014. The discontinuation of the clinical development of tregalizumab (BT-061) is also having an adverse effect on earnings. Accordingly, the Board of Management has lowered its earnings forecast for 2015 as a whole, and is now anticipating EBIT of between € –72 million and € –77 million.

Financial position

As forecasted, 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. In addition, further capital expenditure will also be made for the expansion of existing and the construction of new plasma centres in the USA at Biotest Pharmaceuticals Corporation as well as for the completion of constructing 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 tregalizumab (BT-061) and Civacir®.

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

With regard to the investigation initiated by the Frankfurt am Main public prosecutor's office in late 2011 concerning Biotest's business in Russia, the criminal proceedings against the former head of Biotest's representative office in Moscow and her husband are ongoing. In connection with this investigation, the fiscal authorities have examined the business expenses claimed by the Biotest AG in the period 2005–2008. This could potentially lead to charges for taxes and interest of up to € 16 million, although the legality of any such payments would naturally be carefully reviewed.

The impairments of € 84 million in the third quarter represent a non-recurring event.

III. OPPORTUNITIES REPORT

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

CONSOLIDATED STATEMENT OF INCOME

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

in € million	Q3 2015	Q3 2014	Q1–Q3 2015	Q1–Q3 2014
Revenue	130.2	145.8	**417.9**	409.9
Cost of sales	–149.4	–91.3	–344.4	–245.4
Gross profit	**–19.2**	**54.5**	**73.5**	**164.5**
Other operating income	–0.3	1.6	1.8	4.5
Distribution costs	–17.7	–22.1	–51.8	–55.1
Administrative expenses	–9.8	–6.9	–26.7	–23.8
Research and development costs	–36.8	–16.9	–76.9	–51.3
Other operating expenses	–0.5	–1.4	–1.9	–3.5
Operating profit	**–84.3**	**8.8**	**–82.0**	**35.3**
Financial result	–3.0	1.8	–3.2	–3.0
Earnings before taxes	**–87.3**	**10.6**	**–85.2**	**32.3**
Income tax	1.5	–5.1	–2.8	–13.0
Earnings after taxes	**–85.8**	**5.5**	**–88.0**	**19.3**
Attributable to:				
Equity holders of the parent	–85.8	5.5	–88.0	19.3
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €*	**–2.17**	**0.14**	**–2.22**	**0.49**

* prior year figures adjusted to the new number of shares

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

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

in € million	Q1–Q3 2015	Q1–Q3 2014
Consolidated profit for the period	**–88.0**	**19.3**
Exchange difference on translation of foreign operations	14.3	14.7
Income tax effect	0.0	0.0
Other comprehensive income net of tax to be reclassified to profit or loss in subsequent periods	**14.3**	**14.7**
Other comprehensive income after tax	**14.3**	**14.7**
Total comprehensive income after tax	**–73.7**	**34.0**
Attributable to:		
Equity holders of the parent	–73.7	34.0
Non-controlling interests	0.0	0.0

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 September 2015

in € million	30 September 2015	31 December 2014
ASSETS		
Non-current assets		
Intangible assets	43.5	50.2
Property, plant and equipment	282.3	282.3
Investments in associates	0.9	1.3
Other financial investments	25.2	5.2
Other assets	0.7	0.8
Deferred tax assets	14.9	13.5
Total non-current assets	**367.5**	**353.3**
Current assets		
Inventories	226.1	246.0
Trade receivables	155.4	181.6
Current income tax assets	9.7	4.6
Other assets	115.8	67.7
Cash and cash equivalents	88.3	179.4
Total current assets	**595.3**	**679.3**
Total assets	**962.8**	**1,032.6**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	33.8
Share premium	219.8	225.6
Retained earnings	226.7	201.5
Shares of profit or loss attributable to equity holders of the parent	−88.0	19.2
Equity attributable to equity holders of the parent	**398.1**	**480.1**
Non-controlling interests	0.1	0.1
Total equity	**398.2**	**480.2**
Liabilities		
Provision for pensions and similar obligations	79.1	77.5
Other provisions	6.9	6.3
Financial liabilities	336.4	325.8
Other liabilities	0.8	2.5
Deferred tax liabilities	11.9	11.4
Total non-current liabilities	**435.1**	**423.5**
Other provisions	20.8	23.5
Current income tax liabilities	3.8	8.6
Financial liabilities	10.8	6.1
Trade payables	56.2	55.5
Other liabilities	37.9	32.7
Liabilities from deferred revenue	0.0	2.5
Total current liabilities	**129.5**	**128.9**
Total liabilities	**564.6**	**552.4**
Total equity and liabilities	**962.8**	**1,032.6**

CONSOLIDATED CASH FLOW STATEMENT

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

in € million	2015	2014
Operating cash flow before changes in working capital	6.4	59.4
Cash flow from changes in working capital	43.4	−76.8
Interest and taxes paid	−15.6	−21.7
Cash flow from operating activities	**34.2**	**−39.1**
Cash flow from investing activities	−125.6	−95.8
Cash flow from financing activities	−0.7	9.5
Cash changes in cash and cash equivalents	**−92.1**	**−125.4**
Exchange rate-related changes in cash and cash equivalents	1.0	0.5
Cash and cash equivalents on 1 January	179.4	204.4
Cash and cash equivalents on 30 September	**88.3**	**79.5**
thereof within cash flow from investing activities		
Cash outflow into other assets	−50.2	−64.6
Cash outflow into financial assets	−20.0	−5.0
Cash flow from investing activities adjusted for payments due to financial investments in the scope of short-term financial disposition	**−55.4**	**−26.2**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 September 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	—	—	14.7	—	14.7	—	14.7
Profit for the period	—	—	—	19.3	19.3	—	19.3
Total comprehensive income	**0.0**	**0.0**	**14.7**	**19.3**	**34.0**	**0.0**	**34.0**
Dividend payments	—	—	—	−7.9	−7.9	—	−7.9
Balance on 30 September 2014	**33.8**	**225.6**	**14.3**	**213.0**	**486.7**	**0.1**	**486.8**
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
Capital increase from company funds	5.8	−5.8	—	—	0.0	—	0.0
Profit for the period	—	—	—	−88.0	−88.0	0.0	−88.0
Total comprehensive income	**5.8**	**−5.8**	**14.3**	**−88.0**	**−73.7**	**0.0**	**−73.7**
Dividend payments	—	—	—	−8.3	−8.3	—	−8.3
Balance on 30 September 2015	**39.6**	**219.8**	**33.7**	**105.0**	**398.1**	**0.1**	**398.2**

SELECTED NOTE DISCLOSURES

METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 30 September 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 September 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 10 November 2015.

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

in € million	**Q1–Q3 2015**	Q1–Q3 2014
Operating profit (EBIT)	**–82.0**	**35.3**
Financial result	–3.2	–3.0
Earnings before taxes (EBT)	**–85.2**	**32.3**
Income taxes	–2.8	–13.0
Earnings after taxes (EAT)	**–88.0**	**19.3**

SEGMENT REPORTING

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

	Revenue			**EBIT**		
in € million	**Q1–Q3 2015**	Q1–Q3 2014	Change in %	**Q1–Q3 2015**	Q1–Q3 2014	Change in %
Therapy	288.0	298.0	–3.4	–100.0	19.6	–610.2
Plasma & Services	123.2	105.8	16.4	20.1	18.1	11.0
Other Segments	6.7	6.1	9.8	–2.1	–2.4	12.5
Biotest Group	**417.9**	**409.9**	**2.0**	**–82.0**	**35.3**	**–332.3**

	Revenue from third parties by customer's geographical location		
in € million	**Q1–Q3 2015**	Q1–Q3 2014	Change in %
Germany	94.3	76.6	23.1
Rest of Europe	124.3	139.0	–10.6
USA	78.1	62.8	24.4
Rest of America	8.7	6.8	27.9
Middle East and Africa	82.9	106.0	–21.8
Other Asia and Pacific	29.6	18.7	58.3
Biotest Group	**417.9**	**409.9**	**2.0**

QUARTER-TO-QUARTER COMPARISON

by business segments

	Revenue				
in € million	**Q3/2015**	Q2/2015	Q1/2015	Q4/2014	Q3/2014
Therapy	91.7	98.0	98.3	111.8	95.4
Plasma & Services	36.2	44.8	42.2	51.2	48.5
Other Segments	2.3	2.4	2.0	9.1	1.9
Biotest Group	**130.2**	**145.2**	**142.5**	**172.1**	**145.8**

	EBIT				
in € million	**Q3/2015**	Q2/2015	Q1/2015	Q4/2014	Q3/2014
Therapy	−88.8	−4.8	−6.4	7.9	−1.0
Plasma & Services	5.2	7.8	7.1	8.9	10.6
Other Segments	−0.7	−0.8	−0.6	1.3	−0.8
Biotest Group	**−84.3**	**2.2**	**0.1**	**18.1**	**8.8**
Earnings before taxes (EBT)	**−87.3**	**−2.1**	**4.2**	**14.6**	**10.6**

OTHER NOTE DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2014	Capital expenditure	Depreciation and amortisation	Impairment	Currency translation differences	Carrying amount as of 30 September 2015
Intangible assets	50.2	2.8	−1.3	−12.0	3.8	43.5
Property, plant & equipment	282.3	66.3	−21.8	−52.3	7.8	282.3
Total	**332.5**	**69.1**	**−23.1**	**−64.3**	**11.6**	**325.8**

As of 30 September 2015, the Biotest Group had commitments to acquire fixed assets in the amount of € 148.6 million.

Employees

by operating functions

full-time equivalents	**30 September 2015**	31 December 2014	Change in %
Marketing and distribution	208	203	2.5
Administration	265	231	14.7
Production	1,560	1,516	2.9
Research and development	182	208	−12.5
Biotest Group	**2,215**	**2,158**	**2.6**

Financial instruments as of 30 September 2015

In € million	Carrying amount	Fair value
Assets		
Trade receivables	155.4	155.4
Other assets		
Other receivables	116.3	116.3
Derivatives not designated as hedging instruments	0.2	0.2
Other financial investments	25.2	25.2
Equity and liabilities		
Trade payables	56.2	56.2
Financial liabilities	347.2	351.1
Other liabilities	40.4	40.4
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 proximity to the market of the data used to calculate fair value. The fair value hierarchy levels are described below:

Level 1: quoted prices for identical assets or liabilities in active markets,

Level 2: information other than quoted prices that is directly (such as prices) or indirectly (such as derived from prices) observable, and

Level 3: information on assets and liabilities that is not based on observable market data.

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

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

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 € 7.2 million from Biotest in the first nine months. As of 30 September 2015, Biotest had receivables from BioDarou P.J.S. Co. and Plasma Gostar Pars P.J.S. totalling € 6.5 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

There were no significant events after the end of the reporting period.

RESPONSIBILITY STATEMENT

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, 10 November 2015
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

23 March 2016
Financial statements
press conference 2015

12 May 2016
Report for the first quarter 2016

12 May 2016
Annual Shareholders' Meeting

11 August 2016
Half-year report for 2016

10 November 2016
Nine-month report for 2016

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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.