

NINE-MONTH REPORT 2014 BIOTEST AG



KEY FIGURES

BIOTEST GROUP		Q1–Q3 2014	Q1–Q3 2013	Change in %
Revenue	in € million	409.9	367.5	11.5
thereof:				
Germany	in € million	76.6	70.2	9.1
Rest of world	in € million	333.3	297.3	12.1
thereof:				
Therapy	in € million	298.0	284.1	4.9
Plasma & Services	in € million	105.8	76.1	39.0
Other Segments	in € million	6.1	7.3	–16.4
EBITDA	in € million	59.7	63.3	–5.7
Operating profit (EBIT)	in € million	35.3	39.9	–11.5
<i>EBIT in % of revenue</i>	%	8.6	10.9	
Earnings before taxes	in € million	32.3	36.0	–10.3
Earnings after taxes	in € million	19.3	24.0	–19.6
Cash flow from operating activities	in € million	–39.1	–19.8	–97.5
Depreciation and amortisation	in € million	24.4	23.4	4.3
		30 September 2014	31 December 2013	
Equity	in € million	486.8	460.7	5.7
<i>Equity ratio</i>	%	52.2	52.0	
Employees (full-time equivalents)	amount	2,137	1,997	7.0

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INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 SEPTEMBER 2014

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 as well as 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 three of these indication areas. The Company covers all essential stages in the value chain from pre-clinical and clinical development – which is conducted in collaboration with internationally renowned partners for certain projects – to global marketing.

A. SEGMENTS OF THE BIOTEST GROUP

The Company's operations are divided into the following segments: Therapy, Plasma & Services and Other Segments. The Therapy segment includes products and development projects assigned to each of the three indication areas. Plasma sales and toll manufacturing are combined under the Plasma & Services segment. In Other Segments, Biotest reports its merchandise business as well as any cross-divisional costs not allocated to the Therapy or Plasma & Services segments.

B. PERSONNEL

The Biotest Group employed a staff of 2,137 full-time equivalents as of 30 September 2014. This number has increased by 7.0 % compared to the 31 December 2013 reporting date (1,997 full-time equivalents).

II. GROUP STRATEGY

The core element of the Biotest strategy is a clear focus on marketing and selling and the further development of biological products in the three defined indication areas. Aside from systematically advancing its own research and development pipeline, the Company is focusing on its authorisation and marketing and selling activities to further internationalise its business and on diversifying its product portfolio. In addition to the successful expansion of the product portfolio in European markets, including the establishing of a Group subsidiary in France, the focus is on the US, Asia and South America.

The Biotest Group has decided to expand production capacity at its company headquarters at Dreieich so as to continue to participate in future global market growth. The production capacity will be doubled by 2018/19 in the "Biotest Next Level" project. The purpose of this project is not only to strengthen the Company's competitiveness in the global market, but also to contribute to achieving a sales target of € 1 billion by 2020.

III. RESEARCH AND DEVELOPMENT (GENERAL)

Research and development are the foundation for the Biotest Group's future growth under the corporate strategy. Significant potential will be exploited in this area through the further development of existing products and new developments. In addition to research and development in the area of plasma proteins, great importance is attached to the development of monoclonal antibodies. A detailed list of current research and development projects is provided in the "Research and development" section of the 2013 Annual Report. Current developments are explained in the "Business performance" section of this report.

B. ECONOMIC REPORT

I. BUSINESS AND GENERAL FRAMEWORK

According to the International Monetary Fund (IMF) the global economy has lost momentum over the last few months and the outlook for the future is also subdued. This is mainly attributable to the increasing uncertainty caused by political crises, in Russia, Ukraine, Syria or Iraq, for example. Experts at the IMF now expect the global economy to grow by 3.3% following a plus of the same amount in the previous year.¹ The forecast was lowered by 0.1 percentage points compared to the last projection made in June. Although it is expected that the eurozone's economy will grow – the aggregate gross domestic product is now likely to increase by 0.8% in 2014 following a decline of 0.4% for 2013 as a whole – the 0.3% reduction in the forecast is further evidence of this growing uncertainty. The German economy is likely to continue to underpin this now modest growth. In their joint economic forecast, the leading German economic research institutes expect GDP to increase by 1.3%. An increase of 1.9% had been expected six months ago.² According to experts, the weaker global economy and subdued domestic investment activity had a dampening effect on economic growth.

In contrast, the upward trend in the US economy appears intact for the most part. According to current US Federal Reserve Bank data, the US economy is set to grow by 2.0% to 2.2% for 2014 as a whole.³ This is equivalent to a slight downwards revision of 0.1 percentage points compared to the June projection. Nevertheless, the US Federal Reserve is also pointing to a possible cooling down of the global economy and the risks that this poses to the US economy.

In principle, the Biotest Group is only marginally dependent on economic cycles due to the high level of unmet medical needs throughout the world. However, it cannot be excluded that the operating business will be impacted, particularly by local crises.

1 International Monetary Fund (IMF), *World Economic Outlook*, October 2014

2 Joint economic forecast project group, *joint economic forecast*, 9 October 2014

3 Board of Governors of the Federal Reserve System, *Minutes of the Federal Open Market Committee*, 8 October 2014

II. INDUSTRY-SPECIFIC FRAMEWORK

Market researchers expect the global market for intravenous immunoglobulins (IVIg) to grow by an average rate of 6–8% per year.⁴ The prices for these preparations have remained broadly stable on the global markets. However, there was a slight price increase of 2% in the US at the beginning of 2014. Prices in the EU are still about 25–30% below those in the US.⁵ According to the Plasma Protein Therapeutics Association (PPTA) the German market for IVIGs grew by 7% in the first five months of 2014 compared to the same period in the previous year.⁶ At the same time price trends were largely stable in Germany. The Biotest product Intratect® was able to maintain its market share in Germany during the period under review.⁷ In the opinion of the Biotest Group there is growing pressure on prices in the other European markets.

There is continued strong demand for Factor VIII preparations as well as for the Biotest product Haemoctin®. Revenue generated by this product group in Germany in the first five months of 2014 increased by 5% compared to the same period in the previous year.⁸ It is forecast that the global market will grow by 4% p.a. until 2020.⁹ An increase of about 2% p.a. is expected for the plasmatic Factor VIII preparations and of about 6% p.a. for the recombinant Factor VIII preparations segment. The recombinant segment will benefit considerably from the introduction of new Factor VIII preparations, which, however, could also intensify competition and thereby significantly increase price pressure in the market as a whole.

Worldwide demand for human plasma, the raw material of all Biotest plasma protein products, is also growing constantly. The plasma collected over the past few months was about 8–10% above the previous year amounts in both the US and Europe.¹⁰

After safety warnings were issued in June 2013 by the FDA and European Pharmacovigilance Risk Assessment Committee (PRAC) regarding solutions containing hydroxyethyl starch

4 Goldman Sachs: *Global: Medical Technology: Medical Supplies*, 25 August 2014

5 UBS Investment Research, *June-14 Plasma Price & Supply Survey*, 18 September 2014

6 Plasma Protein Therapeutics Association (PPTA), *as of: May 2014*

7 IMS Health Germany, *as of: September 2014*

8 Plasma Protein Therapeutics Association (PPTA), *as of: May 2014*

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

10 Plasma Protein Therapeutics Association (PPTA), *as of: April and May 2014*

(HES), the market for human albumin showed a clear upward trend particularly in Europe, recording growth rates of 6% on average.¹¹ It is expected that solutions containing HES will also continue to lose market share in the current year and that this will be offset on an ongoing basis by replacement products such as crystalloids or human albumin.

III. BUSINESS PERFORMANCE

A. AT A GLANCE

The Biotest Group was able to further increase its pace of growth recorded in the first half of the year in the first nine months of 2014. The Group generated revenue of € 409.9 million in the period between January and September 2014. This represents an increase of 11.5% compared to the same period in the previous year (€ 367.5 million)

Revenue increases were achieved in all regions of the world with the exception of a slight decrease in sales in the US market. These were particularly marked in Asia (+20.3%) and in Central and South America (+19.3%), whereas Germany (+9.1%) and the rest of Europe (+8.7%) recorded pleasing growth.

The Biotest Group is also investing considerable funds in the development of new products and the further development of its existing products. Despite the increase in sales, operating profit (EBIT) decreased from € 39.9 million to € 35.3 million (-11.5%) as a result of this increase in research and development costs, costs relating to the commencement of the capacity expansion and overall lower margin business.

The extensive research and development work currently underway could create significant value for the future. This is demonstrated by the good current results of Biotest's current Civacir® study that were recently presented to the Congress of the American Association for the Study of Liver Diseases (AASLD). Following receipt of marketing authorisation, Civacir® will be used for the prophylaxis of hepatitis C re-infection following liver transplantation. The successful conclusion of patient recruitment for the phase IIb trial (TREAT 2b) with Tregalizumab (BT-061) highlights the positive progress made by the Biotest Group's research and development.

Despite the challenging environment, the Board of Management expects for 2014 a sales increase above 7% and an operating result (EBIT) in the range of the previous year. The business development of the Biotest Group for the 2014 fiscal year will continue to be assessed positively.

B. RESEARCH AND DEVELOPMENT

Research and development costs increased by € 6.9 million (+15.5%) in the first nine months of the current financial year to € 51.3 million (same period in the previous year: € 44.4 million). The R&D division employed 194 full-time equivalents as of the 30 September 2014 reporting date (31 December 2013: 171). The Biotest Group's development projects are detailed in the 2013 Annual Report in the "Research and Development" section starting on page 14 of the Group management report.

In the first nine months of 2014, Biotest made good progress in current studies and development projects. On 9 November 2014 Biotest presented positive results from the first part of the pivotal phase III trial (no. 988) with Civacir® at the AASLD conference in Boston, USA. Civacir® is investigated for prophylaxis of hepatitis C reinfection following a liver transplantation. The study results show no reinfection in the treatment group receiving the highest Civacir® dosage, whereas reinfection occurred in approximately 35% of the patients in the control group despite prior treatment with new virostatics. More than half of the planned patients have already been included in the trial and further suitable patients are being recruited at the participating study sites.

Patient recruitment has concluded for the TREAT 2b (T-cell **RE**gulating **A**rthritis **T**rial **2b**, no. 986) clinical phase IIb study of the monoclonal antibody tregalizumab (BT-061), which started in 2013. More than 300 patients have been enrolled in the double-blind, randomised, placebo-controlled study in 84 clinical sites in 14 countries. Treatment of the patients is going according to plan. In the main part of the trial, the treatment duration is 24 weeks. Patients who respond to the treatment can continue the therapy for a further six months in an extension phase. Biotest expects that the study endpoints can be assessed at the end of the first quarter of 2015. First results will then be published in the second quarter of 2015.

¹¹ IMS Health Germany, as of: December 2013

Data collection has concluded in the clinical phase I/IIa trial (no. 975) after treatment of the last patient with indatuximab ravtansine (BT-062) for monotherapy of multiple myeloma, a malignant disease of the bone marrow. In the third quarter of 2014, the last patient was enrolled in the phase II combination study (no. 983), in which indatuximab ravtansine (BT-062) is given in combination with lenalidomide and dexamethasone. In preparation for phase III, the study is being extended by a further combination with pomalidomide and dexamethasone. Production of indatuximab ravtansine (BT-062) was advanced to a larger scale. The advantages of scale result in a significant reduction in production costs.

The ongoing phase III trial (no. 963) investigates repeated administration of the product Cytotect 70 (BT-094) for the prevention of cytomegalovirus (CMV) infection in an unborn child when the mother has primary CMV infection during pregnancy. In July 2014 a trial protocol amendment on early conclusion of patient recruitment was submitted to the authorities. In the second half of 2015, the data regarding the primary endpoint will be available.

In the first part of the clinical phase I/II trial (no. 984) of the fibrinogen concentrate, which is under development, more than half of the patients enrolled in the study have already been treated. The pharmacokinetic properties, tolerability and safety were evaluated by using the concentrate in patients with congenital fibrinogen deficiency.

Another 100 patients were enrolled in the phase II trial (no. 982) with IgM Concentrate in the past nine months of the current financial year. The number of enrolled patients is now 140, with a planned total of 160 patients.

The preparation Zutectra® has received marketing authorization in the EU since 2009 for the indication of prevention of hepatitis B virus (HBV) reinfection in patients six months after a liver transplant due to HBV-induced liver failure. The aim of the ZEUS (Zutectra Early USE, no. 987) phase III trial is to obtain marketing authorisation on the basis of the trial data for the use of Zutectra® just one to two weeks after the transplantation. The trial will probably be concluded in the fourth quarter of 2014 and the final report is expected at the beginning of 2015.

C. MARKETING AND DISTRIBUTION

Following the receipt of market authorisation for Intratect® 100 g/l (10% solution) in October 2012 under the decentralised European marketing authorisation procedure, Biotest launched the product in several countries in Europe and the Near and Middle East in the 2013 financial year. In the first nine months of 2014 Biotest commenced sales in these countries. Applications for further marketing authorisations in the international area have been submitted to national authorities so that sales can also begin in these countries following marketing authorisation.

Furthermore, on 31 October 2014 Biotest received marketing authorisation for Albiomin 20% in China. With its distribution partner Wanbang Biopharmaceuticals, Shanghai, China – a subsidiary of the Fosun Pharmaceuticals Group, one of China's largest pharmaceutical companies – Biotest expects to be on the Chinese market with Albiomin 20% from 2015 onwards. First sales are expected beginning of 2015 after the batch release by the authorities.

Biotest also obtained new marketing authorisations for the product Hepatect® CP in Norway, Finland and Iran. Hepatect® is used for prophylaxis of HBV reinfection after a liver transplant because of HBV-induced liver failure. Fovepta®, a hyperimmune globulin that was developed for newborns, is used immediately after birth and offers effective protection for babies of mothers suffering from hepatitis B. Fovepta was introduced in Vietnam and Algeria in 2014.

Biotest was also able to acquire additional distribution partners in the former CIS countries in line with its internationalisation strategy. Following the market authorisation of Intratect® and Haemocin®, the Pentaglobin® and albumin products were also introduced to these markets in the second quarter of 2014. Negative effects on our operating business in these regions cannot be excluded over the short and medium term due to the current political situation in Russia and the Middle East.

D. PRODUCTION

The US subsidiary, Biotest Pharmaceutical Corporation (BPC), opened two additional plasma collection centres in the first nine months of 2014. BPC now operates a total of 16 such centres in the US, in which blood plasma is collected as the basis material for the Biotest plasma protein products.

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

A. RESULTS OF OPERATIONS

The Biotest Group generated revenue of € 409.9 million in the first three quarters of 2014. This represents an increase of 11.5 % compared to the same period in 2013, in which sales of € 367.5 million were generated. The pace of growth recorded during the first half of the year continued to increase in the months from July to September. Sales increased significantly in the Plasma & Services (+ 39.0%) and Therapy (+ 4.9%) segments.

SALES BY SEGMENT

in € million	Q1–Q3 2014	Q1–Q3 2013	Change in %
Therapy	298.0	284.1	4.9
Plasma & Services	105.8	76.1	39.0
Other segments	6.1	7.3	-16.4
Biotest	409.9	367.5	11.5

Sales growth of the Biotest Group in the first nine months of 2014 was generated on global markets. Sales increased significantly in Germany (+ 9.1%), in the rest of Europe (+ 8.7%) and especially in Asia (+ 20.3%). A positive trend was also evident in countries in Central and South America. Biotest recorded a 19.3% increase in sales in these countries, whereas sales declined slightly by 3.2% in the US. This is attributable, amongst other things, to the recall of Bivigam® lots and the resultant delay in marketing the preparation.

SALES BY REGION



As outlined in the Annual Report, costs for the recall were recognised in full in the 2013 financial year. Production of the preparation has been temporarily scaled down due to – also as a result of the recall – lower than anticipated sales of Bivigam®. This also had a negative impact on sales and profit in the first nine months of 2014, an effect that will also be seen in the fourth quarter.

The breakdown of Group sales has shifted further towards foreign markets due to, amongst other things, another substantial increase in sales in Asia. In the period between January and September the Biotest Group generated 81.3 % of its sales outside of Germany (same period in the previous year: 80.9%).

Production costs increased to € 245.5 million from € 213.4 million for the first nine months of 2013. The cost of sales ratio also increased disproportionately as a result of lower margin tender business and was 59.9% (same period in the previous year: 58.1%). This increase compared to the previous year is primarily attributable to the € 8.6 million reduction in the amount recognised on a pro rata basis under the percentage of completion method with regard to the upfront payment received from AbbVie. Marketing and distribution costs also increased significantly to € 55.1 million (ratio to sales: 13.4%). € 43.9 million was spent in this area in the previous year (ratio to sales: 11.9%). This reflected in particular the increase in commissions payable due to the significantly higher sales generated in international markets.

Administrative costs increased disproportionately from € 22.2 million to € 23.8 million. At 5.8%, the administrative expense ratio is below that for the same period in the previous year (6.0%) despite the increase in the number of employees.

Research and development costs increased by 15.5 % compared to the same period in the previous year due to the positive progress made in clinical trials with very good patient recruitment and the related increase in production volumes of clinical trial material (+€ 4.0 million). Costs in this area amounted in total to € 51.3 million for the first three quarters of 2014 compared to € 44.4 million for the comparable period in 2013. Their percentage of sales of 12.5 % was above that for the same period in the previous year (12.1%).

PRIMARY COST POOLS OF THE BIOTEST GROUP*

in € million	Q1–Q3 2014	as % of revenues	Q1–Q3 2013	as % of revenues
Production costs	–245.4	59.9	–213.4	58.1
Marketing and distribution costs	–55.1	13.4	–43.9	11.9
Administrative costs	–23.8	5.8	–22.2	6.0
Research and development costs	–51.3	12.5	–44.4	12.1
Other operating income and expenses	1.0	0.2	–3.7	1.0
Financial result	–3.0	0.7	–3.9	1.1

* Costs/expenses are denoted with a negative sign

Other operating expenses decreased from € 12.4 million for the first nine months of 2013 to the current level of € 3.5 million. A change in the cost allocation method is the main reason for this decrease: some costs previously disclosed under other operating expenses are now allocated directly to the functional areas. Other operating income of € 4.5 million was significantly lower than that for the same period in the previous year (€ 8.7 million), for the same reason.

Operating profit (EBIT) decreased compared to the same period in the previous year due to the substantial increase in expenses and amounted to € 35.3 million for the first nine months of 2014, 11.5% below the € 39.9 million for the same period in the previous year. Consequently, the EBIT margin decreased by 1.3 percentage points to 8.6%.

Low margin tender business, particularly in the Therapy segment, and higher costs for clinical trial material in the amount of € 4.0 million resulted in a decrease in EBIT. Charges of € 2.2 million incurred in expanding capacity also had a negative impact on earnings. The EBIT contributed by the Therapy segment fell by 21.0% to € 19.6 million (same period in the previous year: € 24.8 million), whereas the EBIT of the Plasma & Services segment increased by 9.0% to € 18.1 million.

The financial result amounted to € –3.0 million (same period in the previous year: € –3.9 million).

This resulted in earnings before taxes (EBT) of € 32.3 million for the Biotest Group compared to € 36.0 million for the same period in the previous year. Earnings after taxes (EAT) also decreased from € 24.0 million to € 19.3 million on an increased tax rate. Earnings per share were – also as a result of the increased number of shares by way of the capital increase in the summer of 2013 – € 1.46 compared to € 1.96 for the first nine months of 2013.

KEY FINANCIAL PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	Q1–Q3 2014	Q1–Q3 2013	Change in %
EBIT	35.3	39.9	–11.5
EBT	32.3	36.0	–10.3
EAT	19.3	24.0	–19.6
Earnings per share in €	1.46	1.96	–25.5

B. FINANCIAL POSITION

Total assets of the Group increased slightly to € 932.1 million as of the 30 September 2014 reporting date compared to € 886.5 million as of 31 December 2013.

On the assets side both current and non-current assets increased. Property, plant and equipment (increase from € 254.9 million to € 266.2 million) and other non-current financial assets (increase from € 0.2 million to € 5.2 million) increased in particular. Other non-current financial assets include previous cash and cash equivalents which are not yet required for the “Biotest Next Level” investment project and were invested on an interest-bearing basis for terms of more than twelve months.

Current assets increased by 5.7% to € 594.5 million (31 December 2013: € 562.5 million). Pre-production for the planned sales volume increases led to an increase in inventories to € 267.5 million (31 December 2013: € 227.0 million). Trade receivables increased as of the 30 September 2014 reporting date to € 173.9 million (31 December 2013: € 118.5 million). Cash and cash equivalents decreased to € 79.5 million (31 December 2013: € 204.4 million). Their planned reduction resulted from payments for investments made as well as the switch to financial investments with a term of more than three months, which are included in other assets (€ 64.6 million) and financial assets (€ 5.0 million).

On the liabilities side equity increased to € 486.8 million primarily as a result of the positive Group results (31 December 2013: € 460.7 million). The equity ratio remained almost unchanged at 52.2% compared to 52.0% as of 31 December 2013 despite the increase in total assets. Debt also increased to € 445.3 million (31 December 2013: € 425.8 million). Both non-current and current debt also increased slightly. Non-current financial liabilities in particular increased from € 226.2 million to a current level of € 241.8 million due to additional borrowings. The Biotest Group received an energy efficiency loan of about € 15.5 million from the Kreditanstalt für Wiederaufbau (KfW) at advantageous terms and conditions for the completed construction of its plasma goods receipt area. Trade payables increased only slightly from € 51.4 million to € 52.2 million, whereas other current liabilities increased significantly to € 44.2 million (31 December 2013: € 26.2 million).

C. FINANCIAL STATUS

Cash flow from operating activities amounted to € –39.1 million for the first three quarters of 2014. A significantly lower outflow of € 19.8 million was disclosed in the comparable period of the previous year. This is primarily attributable to increased interest and tax payments.

Cash flow from investing activities amounted to € –26.2 million in the period between January and September 2014 compared to € –18.1 million for the same period in the previous year. The additional purchase price payment made by Merck KGaA at the beginning of the past financial year in the amount of € 10.3 million in connection with the sale of the Microbiological Monitoring division was a positive component of this item in 2013.

In the first nine months of 2014 the Biotest Group generated a positive cash flow from financing activities of € 9.5 million due to the new borrowings described above and despite the dividends paid (€ –7.9 million) in the second quarter of 2014. This amounted to € 51.5 million in the same period in the previous year as a result of the successful capital increase. Taking into account the cash outflow into other assets as well as other financial assets in the amount of € 69.9 million, cash and cash equivalents decreased from € 204.4 million at the end of 2013 to a current level of € 79.5 million. Including the liquid assets invested in other financial assets and other assets it would amount to € 149.1 million.

D. OVERALL ASSESSMENT OF THE BUSINESS SITUATION OF THE COMPANY

The Biotest Group continued on its growth path in the first nine months of 2014. Sales increased by 11.5% compared to the same period in the previous year. EBIT decreased by 11.5% compared to the same period in the previous year due to the significant increase in costs, especially for research and development, and in part low-margin tender business. Biotest has the overall resources to drive forward the operating business as planned.

As the increase in Bivigam® sales also remained below expectations in the third quarter of 2014, production has been reduced temporarily. The numerous marketing and distribution measures that have been initiated will mainly have an impact in the 2015 financial year. The maximum sales potential of USD 100 million will therefore be achieved later than planned.

In addition, the market entry of plasma protein preparations into other lucrative regions that has already occurred or is upcoming, as well as further developments in the area of monoclonal antibodies over the medium- and long-term, will provide additional profit potential. The financial position that has been sustainably strengthened by the successful capital measures implemented in 2013, and the balanced financing structure form the foundation for the planned future growth of the Biotest Group.

C. EVENTS AFTER THE REPORTING DATE

The Frankfurt am Main public prosecutor's office again conducted a search of the premises of Biotest AG on 15 October 2014. The search is apparently due to the widening of the public prosecutor's investigation into the Company's business dealings with Russia, which the public prosecutor's office has been conducting since 2011 and which led to a search of the Company's premises on 8 May 2012. The same defendants as before are now accused of having also committed acts of embezzlement and bribery and related tax evasion in the Polish, Czech, Slovakian, former Yugoslavian and Kazakhstan markets. As in the case of the business dealings with Russia, Biotest AG firmly denies the allegations and will cooperate with the public prosecutor's office in clarifying the matter.

D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. OUTLOOK

A. EXPECTED DEVELOPMENTS IN THE MARKET ENVIRONMENT

According to current studies, global demand for immunoglobulins will continue to increase by 6–8% annually over the coming years. The prices of these preparations remained stable for the most part; there were minimal increases in the important US market.¹² The Biotest Group also intends to continue to benefit from this through the increased marketing of Bivigam®. Biotest also expects the global market volume for plasmatic clotting factors to increase by about 2% per year.¹³

After safety warnings were issued in 2013 by the FDA and the European PRAC (Pharmacovigilance Risk Assessment Committee) regarding solutions containing hydroxyethyl starch (HES), the market for these products collapsed by 60% in the second half of 2013 in the largest EU countries (Germany, Spain, France, Italy, Great Britain) compared to the same period in the previous year. The demand for replacement products such as crystalloids or human albumin increased markedly in the same period. Albumin recorded an increase of 6% in these markets but the demand could not be met fully on account of the limited availability.¹⁴ Further losses in the market share of HES-containing solutions are anticipated for the coming months, which will therefore continue to be offset by crystalloids and human albumin.

B. EXPECTED PERFORMANCE OF THE BIOTEST GROUP

Revenue and earnings

Despite the challenging environment, the Board of Management expects for 2014 a sales increase above 7% and an operating result (EBIT) in the range of the previous year. The business development of the Biotest Group for the 2014 fiscal year will continue to be assessed positively.

¹² Goldman Sachs: *Global: Medical Technology: Medical Supplies*, 25 August 2014

¹³ Market Research Bureau, *Forecast of the global coagulation factors concentrates market 2010 to 2025*, 2012

¹⁴ IMS Health Germany, *as of: June 2014*

Financial status

The cash flow forecasts also remain valid. In 2014 Biotest will maintain a balanced financing structure, both in terms of the ratio of debt to equity and the ratio of short-term to long-term debt financing. The Group will use a substantial portion of the cash and cash equivalents received as a result of the capital measures implemented in the past financial year for the “Biotest Next Level” project to cover the planned capacity expansion at Dreieich. The related increase in current assets will also be financed. A targeted increase in the marketing of additional Biotest preparations will result in a build-up of inventories of intermediates and final products. In addition, current assets will increase as a result of the expected growth in sales in this and following years and the full utilisation of the significantly increased albumin production capacity.

In addition to the organic growth described above and its financing, licensing of market-ready products could represent a future strategic option.

II. RISK REPORT

Despite the ongoing marketing and sales measures implemented for Bivigam®, there is the risk that market penetration will proceed at a significantly slower pace than expected.

The political situation in Russia, Libya, Israel and Iraq has deteriorated significantly due to the current crises. This is likely to have a negative impact on our operating business, which cannot yet be quantified.

Apart from this, the Biotest Group's risk situation has not changed materially since the 2013 Annual Report (pages 23 and 29).

III. OPPORTUNITIES

The Biotest Group's opportunity situation has not changed significantly since the 2013 Annual Report (pages 29 and 30).

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 September 2014

in € million	Q3 2014	Q3 2013	Q1–Q3 2014	Q1–Q3 2013
Revenue	145.8	124.2	409.9	367.5
Cost of sales	–91.3	–72.7	–245.4	213.4
Gross profit	54.5	51.5	164.5	154.1
Other operating income	1.6	2.2	4.5	8.7
Distribution costs	–22.1	–14.0	–55.1	–43.9
Administrative expenses	–6.9	–7.6	–23.8	–22.2
Research and development costs	–16.9	–14.1	–51.3	–44.4
Other operating expenses	–1.4	–4.0	–3.5	–12.4
Operating profit	8.8	14.0	35.3	39.9
Financial result	1.8	–1.4	–3.0	–3.9
Earnings before taxes	10.6	12.6	32.3	36.0
Income tax	–5.1	–3.9	–13.0	–12.0
Earnings after taxes	5.5	8.7	19.3	24.0
Attributable to:				
Equity holders of the parent	5.5	8.7	19.3	24.0
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €	0.41	0.65	1.46	1.96

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 September 2014

in € million	Q1–Q3 2014	Q1–Q3 2013
Consolidated profit for the period	19.3	24.0
Other gains/losses recognised directly in equity	0.0	–2.5
Exchange difference on translation of foreign operations	14.7	–2.1
Other comprehensive income to be reclassified to profit or loss in subsequent periods	14.7	–4.6
Other comprehensive income after tax	14.7	–4.6
Total comprehensive income after tax	34.0	19.4
Attributable to:		
Equity holders of the parent	34.0	19.4
Non-controlling interests	0.0	0.0

CONSOLIDATED STATEMENT OF FINANCIAL POSITION of the Biotest Group as of 30 September 2014

in € million	30 September 2014	31 December 2013
ASSETS		
Non-current assets		
Intangible assets	48.7	48.1
Property, plant and equipment	266.2	254.9
Investments in associates	1.6	1.6
Other financial investments	5.2	0.2
Other assets	1.9	0.7
Deferred tax assets	14.0	18.5
Total non-current assets	337.6	324.0
Current assets		
Inventories	267.5	227.0
Trade receivables	173.9	118.5
Current income tax assets	3.5	1.0
Other assets	70.1	11.6
Cash and cash equivalents	79.5	204.4
Total current assets	594.5	562.5
Total assets	932.1	886.5
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	33.8	33.8
Share premium	225.6	225.6
Retained earnings	208.0	169.2
Shares of profit or loss attributable to equity holders of the parent	19.3	32.0
Equity attributable to equity holders of the parent	486.7	460.6
Non-controlling interests	0.1	0.1
Total equity	486.8	460.7
Liabilities		
Provision for pensions and similar obligations	60.2	59.1
Other provisions	5.9	5.4
Financial liabilities	241.8	226.2
Other liabilities	0.0	0.5
Deferred tax liabilities	7.7	7.8
Liabilities from deferred revenue	0.0	2.5
Total non-current liabilities	315.6	301.5
Other provisions	16.9	24.5
Current income tax liabilities	4.9	10.0
Financial liabilities	7.3	5.3
Trade payables	52.2	51.4
Other liabilities	44.2	26.2
Liabilities from deferred revenue	4.2	6.9
Total current liabilities	129.7	124.3
Total liabilities	445.3	425.8
Total equity and liabilities	932.1	886.5

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 September 2014

in € million	2014	2013
Operating cash flow before changes in working capital	59.4	63.2
Cash flow from changes in working capital	-76.8	-75.8
Interest and taxes paid	-21.7	-7.2
Cash flow from operating activities	-39.1	-19.8
Cash flow from investing activities	-26.2	-18.1
Cash flow from financing activities	9.5	51.5
Cash changes in cash and cash equivalents	-55.8	13.6
Exchange rate-related changes in cash and cash equivalents	0.5	-0.1
Cash and cash equivalents on 1 January	204.4	57.2
Cash outflow into other assets	-64.6	0.0
Cash outflow into financial assets	-5.0	0.0
Cash and cash equivalents on 30 September	79.5	70.7

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 September 2014

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 2013	30.0	153.3	8.1	177.9	369.3	0.1	369.4
Gains/losses recognised directly in equity	—	—	-2.1	-2.5	-4.6	—	-4.6
Profit for the period	—	—	—	24.0	24.0	—	24.0
Total comprehensive income	0.0	0.0	-2.1	21.5	19.4	0.0	19.4
Capital increase	3.8	72.3	—	—	76.1	—	76.1
Cost relating to the capital increase	—	—	—	-2.4	-2.4	—	-2.4
Dividend payments	—	—	—	-6.2	-6.2	—	-6.2
Balance on 30 September 2013	33.8	225.6	6.0	190.8	456.2	0.1	456.3
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

SELECTED NOTE DISCLOSURES

METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 30 September 2014 have been prepared in accordance with the International Financial Reporting Standards (IFRS), application of which is mandatory in the European Union. Accordingly, these interim consolidated financial statements as of 30 September 2014 have been prepared in accordance with IAS 34 Interim Financial Reporting and are presented in a condensed form compared to the consolidated financial statements. The IFRS comprise the International Financial Reporting Standards (IFRS) and International Accounting Standards (IAS) as well as the interpretations of the International Financial Reporting Interpretations Committee (IFRIC) and the interpretations of the Standing Interpretation Committee (SIC). The accounts of the Biotest Group are prepared in accordance with IFRS which are mandatory for financial years beginning on 1 January 2014.

These interim consolidated financial statements were approved for publication by the Board of Management on 12 November 2014.

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

in € million	Q1 – Q3 2014	Q1 – Q3 2013
Operating profit (EBIT)	35.3	39.9
Financial result	–3.0	–3.9
Earnings before taxes (EBT)	32.3	36.0
Income taxes	–13.0	–12.0
Earnings after taxes (EAT)	19.3	24.0

SEGMENT REPORTING

of the Biotest Group for the period from 1 January to 30 September 2014

in € million	Revenue			EBIT		
	Q1 – Q3 2014	Q1 – Q3 2013	Change in %	Q1 – Q3 2014	Q1 – Q3 2013	Change in %
Therapy	298.0	284.1	4.9	19.6	24.8	–21.0
Plasma & Services	105.8	76.1	39.0	18.1	16.6	9.0
Other Segments	6.1	7.3	–16.4	–2.4	–1.5	–60.0
Biotest Group	409.9	367.5	11.5	35.3	39.9	–11.5

in € million	Revenue from third parties by customer's geographical location		
	Q1 – Q3 2014	Q1 – Q3 2013	Change in %
Germany	76.6	70.2	9.1
Rest of Europe	130.1	119.7	8.7
North and South America	69.6	70.6	–1.4
Asia	117.4	97.6	20.3
Rest of world	16.2	9.4	72.3
Biotest Group	409.9	367.5	11.5

QUARTER-TO-QUARTER COMPARISON
by business segments

in € million	Revenue				
	Q3 / 2014	Q2 / 2014	Q1 / 2014	Q4 / 2013	Q3 / 2013
Therapy	95.4	109.6	93.0	102.1	98.6
Plasma & Services	48.5	29.8	27.5	26.4	24.1
Other Segments	1.9	2.5	1.7	4.8	1.5
Biotest Group	145.8	141.9	122.2	133.3	124.2

in € million	EBIT				
	Q3 / 2014	Q2 / 2014	Q1 / 2014	Q4 / 2013	Q3 / 2013
Therapy	-1.0	13.5	7.1	7.3	11.1
Plasma & Services	10.6	3.0	4.5	7.1	4.1
Other Segments	-0.8	-0.7	-0.9	-0.5	-1.2
Biotest Group	8.8	15.8	10.7	13.9	14.0
Earnings before taxes	10.6	13.9	7.8	11.8	12.6

OTHER NOTE DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2013	Capital expenditure	Net disposals	Depreciation and amortisation	Currency translation differences	Carrying amount as of 30 September 2014
Intangible assets	48.1	1.3	-0.1	-4.4	3.8	48.7
Property, plant & equipment	254.9	23.7	0.0	-20.0	7.7	266.3
Total	303.0	25.0	-0.1	-24.4	11.5	315.0

As of 30 September 2014, the Biotest Group had commitments to acquire fixed assets in the amount of € 24.3 million.

Employees

by operating functions

full-time equivalents	30 September 2014	31 December 2013	Change in %
Marketing and distribution	204	201	1.5
Administration	233	223	4.5
Production	1,506	1,402	7.4
Research and development	194	171	13.5
Biotest Group	2,137	1,997	7.0

Financial instruments as of 30 September 2014

in € million	Carrying amount	Fair value
Assets		
Trade receivables	173.9	173.9
Other assets		
Other receivables	71.9	71.9
Derivatives not designated as a hedging instrument	0.1	0.1
Other financial investments	5.2	5.2
Equity and liabilities		
Trade payables	52.2	52.2
Financial liabilities	249.1	259.5
Other liabilities	41.7	41.7
Derivatives not designated as a hedging instrument	2.5	2.5

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. 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.

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

In the case of derivative financial assets, the mark-to-market measurement performed is based on quoted exchange rates and yield curve structures obtainable on the market. Fair value classification takes place in hierarchy level 2.

The fair values of financial liabilities are measured as the present values of payments relating to the debt based on the respective applicable yield curve as well as the analysed credit spread curve for each currency.

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

BUSINESS RELATIONSHIPS WITH RELATED PARTIES AND/OR COMPANIES

The Biotest Group maintains reportable business relationships with the associated company BioDarou P.J.S. Co., Teheran, Iran, and its subsidiary, Plasma Gostar Pars P.J.S, Teheran, Iran.

Both companies acquired goods and services totalling € 8.7 million from Biotest in the first six months. Receivables due to Biotest from BioDarou P.J.S. Co. and Plasma Gostar Pars P.J.S amount to € 7.4 million as of 30 September 2014.

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 Frankfurt am Main public prosecutor's office again carried out a search of the premises of Biotest AG on 15 October 2014. The search is apparently due to a widening of the public prosecutor's investigation into the Company's business dealings with Russia, which the public prosecutor's office has been conducting since 2011 and which led to a search of the Company's premises on 8 May 2012. The same defendants as before are now accused of having also committed acts of embezzlement and bribery and related tax evasion in the Polish, Czech, Slovakian, former Yugoslavian and Kazakhstan markets. As in the case of the business dealings with Russia, Biotest AG firmly denies the allegations and will cooperate with the public prosecutor's office in clarifying the matter.

Dreieich, 12 November 2014
Biotest Aktiengesellschaft
Board of Management



Prof. Dr. Gregor Schulz
Chairman of the Board
of Management



Dr. Michael Ramroth
Member of the Board
of Management



Dr. Georg Floß
Member of the Board
of Management



Dr. Bernhard Ehmer
Member of the Board
of Management

FINANCIAL CALENDAR

24 March 2015

Financial statements press conference

24 March 2015

2014 Annual Report

7 May 2015

Annual Shareholders' Meeting

7 May 2015

Report for the first quarter 2015

11 August 2015

Half-year report for 2015

10 November 2015

Analyst conference

10 November 2015

Nine-month report for 2015

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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.

