

# HALF-YEAR REPORT 2014 BIOTEST AG



### **KEY FIGURES**

BIOTEST GROUP		H1 2014	H1 2013	Change in %
Revenue	in € million	264.1	243.3	8.5
thereof:				
Germany	in € million	51.6	47.3	9.1
Rest of world	in € million	212.5	196.0	8.4
thereof:				
Therapy	in € million	202.6	185.5	9.2
Plasma & Services	in € million	57.3	52.0	10.2
Other Segments	in € million	4.2	5.8	-27.6
EBITDA	in € million	42.5	41.4	2.7
Operating profit (EBIT)	in € million	26.5	25.9	2.3
EBIT in % of revenue	<u> </u>	10.0	10.6	
Earnings before taxes	in € million	21.7	23.4	-7.3
Earnings after taxes	in € million	13.8	15.3	-9.8
Cash flow from operating activities	in € million	-34.6	-13.4	-158.2
Depreciation and amortisation	in € million	16.0	15.5	3.2
		30 June 2014	31 December 2013	
Equity	in € million	468.1	460.7	1.6
Equity ratio		51.2	52.0 	
Employees (full-time equivalents)	amount	2,130	1,997	6.7

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#### INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 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. Biotest covers all the 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 have been 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 2,130 full-time equivalents as of 30 June 2014. This number has increased by 6.7% 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 the further development of biological products in the three defined indication areas. Aside from systematically continuing its own research and development pipeline, the Company is focusing on authorisation and marketing 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 subsidiary in France, the focus is on the US, Asia and South America.

The Biotest Group decided to expand the production capacity at its company headquarters at Dreieich so as to continue to participate in future global market growth. Production capacity will be doubled by 2018/19 under 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 the sales target of € 1 billion by 2020.

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

Research and development lay 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 continues to gain momentum. Experts expect global growth of 3.6 % for 2014 following a 3.0 % rise in the past year. This will be mainly driven by industrialised nations, whereas growth in emerging countries will be somewhat subdued.¹ The economy in the eurozone has also been on an upward trend since the middle of 2013. Following a further decline of 0.4% in the aggregate gross domestic product (GDP) for 2013 as a whole, the Institute for the World Economy (IfW) expects economic output in the eurozone to increase by 1.0 % in 2014.² This growth will be underpinned by positive developments in Germany. In the first quarter of 2014, Germany's GDP was 0.8 % higher than in the last quarter of the previous year.³ The IfW is forecasting a 2.0 % increase for the entire year.⁴

According to current US Federal Reserve Bank data, the US economy is also set to continue to grow further by 2.1% to 2.3% for 2014 as a whole. However, experts have revised their forecast downwards by 0.7 percentage points since March on the basis of the subdued start to the current year caused by weather conditions. Nonetheless, large-scale tapering of its bond purchase programme shows that the US Federal Reserve Bank is also assuming a sustained recovery of the US economy.<sup>5</sup>

On the other hand, the economic environment has deteriorated significantly due to the political crises in Russia, Iraq, Israel and Libya. Negative effects on the operating business in these countries cannot be excluded

#### II. INDUSTRY-SPECIFIC FRAMEWORK

Market researchers expect the global market for intravenous immunoglobulins (IVIG) to continue to grow by an average rate of 7–8% per year.<sup>6</sup> There was a slight price increase of about 2% in the US at the beginning of 2014. Prices in the EU are still about 25% below those achievable in the USA for immunoglobulins.<sup>7</sup> The German market for IVIGs grew by about 5% compared to the previous quarter. The average price of these preparations was largely stable in German hospitals. A comparison with the first quarter of 2013 shows that the Biotest preparation Intratect® performed well over the course of the year.<sup>8</sup>

There is also continued strong demand for Factor VIII preparations as well as for the Biotest product Haemoctin®. Revenue generated by this product group in Germany in 2013 increased by 6% compared to the same period in the previous year. Various recombinant Factor VIII preparations are currently being introduced to the market. This will lead to increased price pressure over the short- and medium-term.

The demand for human plasma is also growing constantly. Blood plasma is the raw material of all Biotest plasma protein products. The number of plasma collection centres in the US increased by about 12% in 2013 compared to the previous year. The number of plasma centres in the US is also increasing steadily and grew by 4% in 2013. Source plasma amounts also increased, recording 5% growth in 2013 for the European market compared to the previous year.<sup>10</sup>

After safety warnings were issued in June 2013 by the FDA and European PRAC (Pharmacovigilance Risk Assessment Committee) regarding solutions containing hydroxthyl starch (HES), the market for human albumin showed a clear upward trend, recording growth rates of 5-6% on average. <sup>11</sup> 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 human albumin amongst others.

- 1 International Monetary Fund (IMF), World Economic Outlook, April 2014
- 2 Institute for the World Economy, forecast centre, 12 June 2014
- 3 Federal Statistical Office (DESTATIS), detailed results regarding economic output in Q1 2014, 23 May 2014
- 4 Institute for the World Economy, forecast centre, 12 June 2014
- 5 Board of Governors of the Federal Reserve System, Minutes of the Federal Open Market Committee, 18 June 2014
- 6 Morgan Stanley Research, Ig Survey: growth and share OK, AD surprises, 29 October 2013
- 7 UBS Investment Research, Dec-13 Plasma Price & Supply Survey, 10 February 2014
- 8 IMS Health Germany, as of: June 2014
- 9 Plasma Protein Therapeutics Association (PPTA), March and April 2014
- 10 Plasma Protein Therapeutics Association (PPTA), March and April 2014
- 11 IMS Health Germany, as of: June 2014

#### **III. BUSINESS PERFORMANCE**

#### A. AT A GLANCE

The Biotest Group was again able to significantly increase revenues in the first half of 2014, recording growth of 8.5% compared to the same period in the previous year. The Group generated revenue of  $\in$  264.1 million in the period under review compared to  $\in$  243.3 million for the same period in the previous year.

Significant sales increases were achieved in Asia ( $\pm 21.5\%$ ). Sales in the German home market ( $\pm 9.1\%$ ) and the rest of Europe ( $\pm 8.3\%$ ) were also significantly above those for the same period in the previous year.

Rising research and development costs as well as the € 6.2 million decrease in the amount recognised in revenue on a pro rata basis according to the percentage of completion method with regard to the upfront payment received from AbbVie and costs relating to the start of the expansion as part of "Biotest Next Level" resulted in only a moderate increase in operating profit (EBIT) from € 25.9 million to € 26.5 million (+ 2.3 %) despite the increase in sales.

As outlined in the Annual report, the financial impact of the recall of the Bivigam® lots has already been recognised in the financial year 2013. The recall and the competitive situation in the US market had a negative impact on the sales and profit development in the first six months 2014. This effect will stay for the entire financial year. Despite the increased marketing of human albumin and the continuing internationalisation of the business and therefore the good business performance, the lower sales and profit contribution of Bivigam® could not be compensated.

Due to the political crisis in Russia and Near East further negative impacts on the operative business cannot be excluded.

In addition, due to a positive development of clinical studies (i.e. enlargement of the clinical study IIb with tregalizumab (BT-061) including the accelerated production of clinical study material for a phase III trial as well as accelerated production of additional clinical study material for Civacir®) higher R&D expenses for the financial year 2014 are expected.

Based on the reasons given above, the Management Board revises its guidance. A sales increase in the range of 7% and an operating result (EBIT) slightly above previous year is expected. The business development of the Biotest Group for the 2014 fiscal year will continue to be assessed positively.

#### B. RESEARCH AND DEVELOPMENT

R&D costs increased by € 4.1 million ( $\pm$ 13.5%) in the first half of the year to € 34.4 million (same period in PY: € 30.3 million). The R&D division employs 190 full-time equivalents (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.

Biotest was able to make significant progress in various studies and development projects during the first six months of the current financial year. Patient recruitment for the "TREAT 2b" (Tcell REgulating Arthritis Trial 2b, no. 986) phase IIb clinical trial started in 2013 to further develop the monoclonal antibody tregalizumab (BT-061) is close to completion. More than 300 patients will be included by the end of the recruitment in the double-blind, randomised and placebo-controlled study in 84 clinical centres in 14 countries. The study is expected to be completed in the first half of 2015 with the first results being available then.

The last patient was treated with Indatuximab Ravtansine (BT-062) in the phase I/IIa study (no. 975) for the monotherapy of multiple myeloma, a malignant disease of the bone marrow. The patient recruitment (n = 46) for a phase II combination study (no. 983) in which Indatuximab Ravtansine (BT-062) is administered in combination with Lenalidomid and Dexamethason has also been completed. Preparations are already underway for the manufacture of the clinical material for the subsequent phase III.

A toxicity study involving a three-month treatment period and subsequent follow-up was successfully completed as preparation for conducting a phase II study with the monoclonal antibody BT-063 for the treatment of patients diagnosed with systemic lupus erythematosus (SLE).

Patient recruitment was also completed of the first part of the phase III study (no. 988) with Civacir®. These results will be presented at the AASLD (American Association of Liver Disease) congress in Boston, USA, in November 2014. Additional patients are now being recruited for the second part of the study at the participating centres. Civacir® will be used for the prophylaxis of hepatitis C re-infection after liver transplantation. The previous data show that this re-infection occurs in about 40% of the patients in the control group despite pre-treatment with virostatics. No re-infection has been observed to date in the group treated with the highest Civacir®-dosage.

Patient recruitment has also been completed for the phase III "ZEUS" study (**Z**utectra **E**arly **US**e, no. 987) for Zutectra®. Zutectra® has been authorised in the European Union since 2009 for the indication and of prevention of hepatitis B virus (HBV) re-infection for patients six months after liver transplantation due to HBV-induced liver insufficiency. The objective is to use the ZEUS study data to obtain marketing authorisation for the use of Zutectra® one to two weeks after transplantation. The study is expected to be completed in the fourth quarter of 2014.

#### 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 was able to launch the product in several countries in Europe and the Near and Middle East in the 2013 financial year. In the first half of 2014 Biotest also commenced marketing activities in additional European countries and numerous Gulf States. 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 authorisation.

Biotest was also able to acquire additional distribution partners in the CIS countries in line with its internationalisation strategy. Following the marketing authorisation of Intratect® and Haemoctin®, 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 overall political situation in Russia and the Middle East.

Marketing authorisation for Hepatect® CP in Norway was renewed in the first half of 2014. Hepatect® is used for the prophylaxis of hepatitis B virus (HBV) (re-)infection following liver transplantation due to liver failure caused by HBV. Additional applications to renew international marketing authorisations were also submitted.

#### D. PRODUCTION

The US subsidiary, Biotest Pharmaceutical Corporation (BPC), opened two additional plasma centres in the first half of 2014. BPC now operates a total of 16 centres in the US, which collect blood plasma that is the basis material for Biotest plasma protein products.

The expanded human albumin facility at Dreieich commenced operations in the first quarter of 2014 as planned. Both the time and cost budgets were on plan. There is now significantly increased capacity available at Dreieich for the production of human albumin.

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

#### A. RESULTS OF OPERATIONS

The Biotest Group generated revenue of € 264.1 million in the first half of 2014 despite the € 6.2 million decrease in the amount recognised in revenue according to the percentage of completion method with regard to the upfront payment received from AbbVie. This represents an 8.5% increase compared to the same period in 2013, in which revenue of € 243.3 million was recorded. Sales increased in the Therapy (+9.2%) and Plasma & Services (+10.2%) segments.

SALES BY SEGMENT

Other Segments Biotest Group	4.2 <b>264.1</b>	5.8 <b>243.3</b>	-27.6 <b>8.5</b>
Plasma & Services	57.3	52.0	10.2
Therapy	202.6	185.5	9.2
in € million	H1 2014	H1 2013	Change in %

#### PRIMARY COST POOLS OF THE BIOTEST GROUP\*

in € million	H1 2014	in % of sales	H1 2013	in % of sales
Production costs	-154.1	58.3	-140.7	57.8
Marketing and distribution costs	-33.0	12.5	-29.9	12.3
Administrative costs	-16.9	6.4	-14.6	6.0
Research and development costs	-34.4	13.0		12.5
Other operating income and expenses	0.8	0.3		0.8
<u>Financial result</u>	-4.8	1.8	-2.5	1.0

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

Sales growth of the Biotest Group in the first half of 2014 was achieved on domestic and international markets. Sales in the German home market increased by 9.1% and in the rest of Europe by 8.3%. A significant increase of 21.5% in sales in Asia was also achieved, which was mainly attributable to a higher volume of tender business transacted in the second quarter of 2014. Biotest generated 28.9% of Group sales in the emerging markets of this region.

The breakdown of domestic and foreign sales remained almost constant due to the pleasing developments in the German market. In the first half of 2014 the Biotest Group generated 80.5% of its sales outside of Germany (same period in the previous year: 80.6%).

In absolute terms, production costs increased in line with the rise in sales. These rose to  $\in$  154.1 million from  $\in$  140.7 million in the first half of 2013. Marketing and distribution costs increased slightly disproportionately to  $\in$  33.0 million (same period in the previous year:  $\in$  29.9 million). At 12.5%, the ratio to sales was marginally above that for the first six months of the previous year (12.3%).

SALES BY REGION



Administrative expenses increased significantly from  $\leqslant$  14.6 million to  $\leqslant$  16.9 million. In addition to the 6.3% increase in the number of employees, the primary reason for this development was a change in the cost allocation: some costs previously disclosed under other operating expenses are now allocated directly to the functional areas. The administrative expense ratio, which increased from 6.0% to 6.4%, is not comparable to that for the same period in the previous year.

Research and development costs increased by  $\leqslant$  4.1 million (+13.5%) compared to the same period in the previous due to the positive progress made by clinical trials and the related very good recruitment of patients. Research and development costs totalled  $\leqslant$  34.4 million in the first half of 2014 compared to  $\leqslant$  30.3 million for the comparable period in 2013. Their percentage of sales of 13.0% was also above that for the same period in the previous year (12.5%).

The change in the cost allocation method is particularly evident in other operating expenses. These decreased from  $\in$  8.4 million in the first six months of 2013 to the current level of  $\in$  2.1 million. Other operating income of  $\in$  2.9 million was significantly lower than that for the first six months of the previous year ( $\in$  6.5 million).

Operating profit (EBIT) increased compared to the same period in the previous year despite the renewed increase in costs, in particular for expanded research and development activities, and the  $\in$  6.2 million reduction in the amount recognised in revenue on a pro rata basis under the percentage of completion method with regard to the upfront payment received from AbbVie, and amounted to  $\in$  26.5 million for the first half of 2014, 2.3% above the  $\in$  25.9 million for the same period in the previous year. The EBIT margin decreased from 10.6% to 10.0% in contrast to the stronger growth in sales.

Whereas EBIT contributed by the Therapy segment increased substantially from  $\in$  13.7 million to  $\in$  20.6 million (+50.4%), that of the Plasma & Services segment decreased by 40.0% to  $\in$  7.5 million. This decrease was mainly attributable to the changed cost allocation, under which costs incurred are now directly allocated to this segment. Relevant costs incurred for process developments were charged on a pro rata basis for products and services of the Plasma & Services segment, which adversely impacted the earnings of this segment.

The financial result amounted to  $\leqslant$  -4.8 million (same period in the previous year:  $\leqslant$  -2.5 million). The capital measures successfully implemented in the past financial year were particularly evident in this regard. The fully placed promissory note of  $\leqslant$  210.0 million, amongst other things, gave rise to an increase in interest expense.

This resulted in earnings before taxes (EBT) of € 21.7 million for the Biotest Group compared to € 23.4 million for the same period in the previous year. Earnings after taxes (EAT) also decreased from € 15.3 million to € 13.8 million on an almost constant tax rate. Earnings per share were — also as a result of the increased number of shares by way of the capital increase - € 1.05 compared to € 1.31 for the first half of 2013.

KEY FINANCIAL PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	H1 2014	H1 2013	Change in %
EBIT	26.5	25.9	2.3
EBT	21.7	23.4	-7.3
EAT	13.8	15.3	-9.8
Earnings per share in €	1.05	1.31	-19.8

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

Total assets of the Group increased slightly to € 914.3 million as of the 30 June 2014 reporting date compared to € 886.5 million as of 31 December 2013.

On the assets side both current and non-current assets increased. Whereas intangible assets increased only slightly, other non-current financial assets rose to € 5.0 million (31 December 2013: € 0.2 million). These 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 3.9 % to € 584.7 million. Preproduction for the planned sales volume increases led to an increase in inventories to € 263.7 million (31 December 2013: € 227.0 million). Trade receivables increased as of 30 June 2014 to € 154.4 million (31 December 2013: € 118.5 million). Cash and cash equivalents decreased to € 89.8 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.

On the liabilities side equity increased to € 468.1 million primarily as a result of the positive Group results (31 December 2013: € 460.7 million), whereas the equity ratio fell slightly to 51.2% compared to 52.0% as of 31 December 2013 as a result of the balance sheet extension. Debt also increased to € 446.2 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 € 241.1 million due to additional borrowings. The Biotest Group received an energy efficiency loan of € 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 from € 51.4 million to € 58.0 million as of the reporting date.

#### C. FINANCIAL STATUS

Cash flow from operating activities amounted to  $\leqslant$  -34.6 million in the first half of 2014. A significantly lower outflow of  $\leqslant$  13.4 million was disclosed in the comparable period of 2013. The reasons for this development are the increase in the working capital required in 2014 due to the strong sales growth and increased interest and tax payments.

Cash flow from investing activities amounted to  $\[ \] -17.8 \]$  million in the period between January and June 2014 compared to  $\[ \] -3.8 \]$  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 half of 2014 the Biotest Group generated a positive cash flow from financing activities of  $\in$  7.3 million due to the new borrowings described above and despite the dividends paid ( $\in$  -7.9 million) in the second quarter of 2014. This amounted to  $\in$  57.3 million for the same period in the previous year as a result of the successful capital increase. Cash and cash equivalents decreased from  $\in$  204.4 million at the end of 2013 to a current level of  $\in$  89.8 million taking into account the outflow of funds of a total of  $\in$  69.5 million into other assets and other financial investments.

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

The Biotest Group has continued its growth path in the first half year of 2014. Sales could be increased by 8,5 % compared to the previous year period. Despite increased expenses, especially for research & development, the EBIT increased by 2,3 % compared to the previous year period. The business development of the Biotest Group for the 2014 fiscal year will continue to be assessed positively.

All in all, the Biotest group has all resources to develop the business according to plan. Bivigam® sales came in lower as expected due to the recall and a stronger competitive impact.

Since the increase of Bivigam sales has been below our expectations, we will temporary reduce the production. The numerous marketing and selling activities that have been initiated will have primarily an effect in the financial year 2015. Reaching of the maximum sales potential of USD 100 million per year will be delayed. In addition, market entries of plasma proteins that have

already occurred or are upcoming in further lucrative geographical areas as well as middle- or long term the developments in the area of the monoclonal antibodies, will provide further profit potential. The sustainable strengthened financial position, by the successfully realised by corporate financing actions in the year 2013, as well as the balanced financing structure constitute the basis for the planed future growth of the Biotest group.

#### C. EVENTS AFTER THE REPORTING DATE

On 9 July 2014 Biotest AG announced that the Supervisory Board has appointed Dr. Bernhard Ehmer as a full member of the Board of Management with effect from 1 November 2014. As of 1 January 2015 Dr. Ehmer will assume the chairmanship of the Board of Management from Professor Dr. Gregor Schulz, who, as planned, is retiring for age reasons after 12 years.

# 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 grow at an annual rate of 7–8% over the coming years. Biotest Group anticipates supply will increase at a slightly higher rate, such that these products will continue to be subject to price pressure despite increased demand. Nevertheless, market entry into the US, the largest immunoglobulin market in the world, as a result of the market launch of Bivigam® in 2013 provides additional sales opportunities that were not previously available. Biotest also expects the global market volume for plasmatic clotting factors to increase by about 2% per year. Supply the supply supply the supply supply a supply su

- 12 Morgan Stanley Research, Ig Survey: growth and share OK, AD surprises, 29. October 2013
- 13 Market Research Bureau (2012), Forecast of the global coagulation factors concentrates market 2010 to 2025

In addition, the resumption of sales of human albumin in China offers significant medium-term sales potential. It is expected that marketing authorisation will be received here in the second half of 2014.

After safety warnings were issued in 2013 by the FDA and the European PRAC (Pharmacovigilance Risk Assessment Committee) regarding solutions containing hydroxethyl 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. Demand for replacement products such as crystalloids and human albumin increased significantly in the same period. Albumin recorded an increase, whereby demand could not be fully satisfied due to limited availability as observed by Biotest. It is expected that HES will continue to lose market share in 2014 and that this will be offset on an ongoing basis by crystalloids and human albumin.

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

#### Revenue and earnings

The Management Board revises its guidance. Now, a sales increase in the range of 7% and an operating result (EBIT) slightly above previous year is expected. The business development of the Biotest Group for the 2014 fiscal year will continue to be assessed positively.

#### Financial status

The cash flow forecasts remain valid. In 2014 Biotest will maintain a balanced financing structure, in terms of both 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 planned increase in inventories is also to be financed. The 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 also represent a future strategic option.

#### II. RISK REPORT

Despite the ongoing marketing and sales measures for Bivigam® there exists 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. Negative effects on our operating business cannot be excluded.

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 June 2014

in € million	Q2 2014	Q2 2013	H1 2014	H1 2013
Revenue	141.9	124.6	264.1	243.3
Cost of sales	-83.1	-71.4	-154.1	-140.7
Gross profit	58.8	53.2	110.0	102.6
Other operating income	1.5	3.7	2.9	6.5
Distribution costs	-17.8	-15.1	-33.0	-29.9
Administrative expenses	-7.8	-7.6	-16.9	-14.6
Research and development costs	-17.2	-15.8	-34.4	-30.3
Other operating expenses	-1.7	-4.3	-2.1	-8.4
Operating profit	15.8	14.1	26.5	25.9
Financial result			-4.8	-2.5
Earnings before taxes	13.9	12.4	21.7	23.4
Income tax				-8.1
Earnings after taxes	8.8	8.3	13.8	15.3
Attributable to:	_			
Equity holders of the parent	8.8	8.3	13.8	15.3
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €	0.67	0.72	1.05	1.31

# CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 June 2014  $\,$ 

in € million	H1 2014	H1 2013
Consolidated profit for the period	13.8	15.3
Exchange difference on translation of foreign operations	1.5	0.5
Other comprehensive income to be reclassified to profit or loss in subsequent periods	1.5	0.5
Other comprehensive income after tax		0.5
Total comprehensive income after tax	15.3	15.8
Attributable to:		
Equity holders of the parent	15.3	15.8
Non-controlling interests	0.0	0.0

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 June 2014

in € million	30 June 2014	31 December 2013
ASSETS		
Non-current assets		
Intangible assets	46.4	48.1
Property, plant and equipment	257.1	254.9
Investments in associates	1.6	1.6
Other financial investments	5.0	0.2
Other assets	0.7	0.7
Deferred tax assets	18.8	18.5
Total non-current assets	329.6	324.0
Current assets	_	
Inventories	263.7	227.0
Trade receivables	154.4	118.5
Current income tax assets	2.2	1.0
Other assets	74.6	11.6
Cash and cash equivalents	89.8	204.4
Total current assets	584.7	562.5
Total assets	914.3	886.5
EQUITY AND LIABILITIES	_	
Equity	-     -	
Subscribed capital	33.8	33.8
Share premium		225.6
Retained earnings		169.2
Shares of profit or loss attributable to equity holders of the parent	13.8	32.0
Equity attributable to equity holders of the parent	468.0	460.6
Non-controlling interests	0.1	0.1
Total equity	468.1	460.7
Liabilities		
Provision for pensions and similar obligations	60.0	59.1
Other provisions	6.2	5.4
Financial liabilities	241.1	226.2
Other liabilities	0.0	0.5
Deferred tax liabilities	7.8	7.8
Liabilities from deferred revenue	0.0	2.5
Total non-current liabilities	315.1	301.5
Other provisions	16.3	24.5
Current income tax liabilities	6.9	10.0
Financial liabilities	5.6	5.3
Trade payables	58.0	51.4
Other liabilities	38.3	26.2
Liabilities from deferred revenue	6.0	6.9
Total current liabilities	131.1	124.3
Total liabilities	446.2	425.8
Total equity and liabilities	914.3	886.5

## CONSOLIDATED CASH FLOW STATEMENT

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

in € million	2014	2013
Operating cash flow before changes in working capital	42.4	41.5
Cash flow from changes in working capital	-62.8	-50.4
Interest and taxes paid	-14.2	-4.5
Cash flow from operating activities	-34.6	-13.4
Cash flow from investing activities	-17.8	-3.8
Cash flow from financing activities	7.3	57.3
Cash changes in cash and cash equivalents	-45.1	40.1
Exchange rate-related changes in cash and cash equivalents	0.0	0.0
Cash and cash equivalents on 1 January	204.4	57.2
Cash outflow into other assets	-64.7	0.0
Cash outflow into financial assets	-4.8	0.0
Cash and cash equivalents on 30 June	89.8	97.3

# CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 June 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			0.5		0.5		0.5
Profit for the period				15.3	15.3		15.3
Total comprehensive income	0.0	0.0	0.5	15.3	15.8	0.0	15.8
Capital increase	3.8	72.3		_	76.1	_	76.1
Cost relating to the capital increase				-2.3	-2.3		-2.3
Dividend payments				-6.2	-6.2		-6.2
Balance on 30 June 2013	33.8	225.6	8.6	184.7	452.7	0.1	452.8
Balance on 1 January 2014	33.8	225.6	-0.4	201.6	460.6	0.1	460.7
Gains/losses recognised directly in equity			1.5		1.5		1.5
Profit for the period				13.8	13.8		13.8
Total comprehensive income	0.0	0.0	1.5	13.8	15.3	0.0	15.3
Dividend payments				-7.9	-7.9		-7.9
Balance on 30 June 2014	33.8	225.6	1.1	207.5	468.0	0.1	468.1

#### SELECTED NOTE DISCLOSURES

#### METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 30 June 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 June 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 11 August 2014.

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

in € million	H1 2014	H1 2013
Operating profit (EBIT)	26.5	25.9
Financial result	-4.8	-2.5
Earnings before taxes (EBT)	21.7	23.4
Income taxes	-7.9	-8.1
Earnings after taxes (EAT)	13.8	15.3

### SEGMENT REPORTING

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

		Revenue	
in € million	H1 2014	H1 2013	Change in %
Therapy	202.6	185.5	9.2
Plasma & Services	57.3	52.0	10.2
Other Segments	4.2	5.8	-27.6
Biotest Group	264.1	243.3	8.5

	EBIT	
Change in %	H1 2013	H1 2014
50.4	13.7	20.6
-40.0	12.5	7.5
-433.3	-0.3	-1.6
2.3	25.9	26.5

	Revenue from third parties by customer's geographical location			
in € million	H1 2014	H1 2013	Change in %	
Germany	51.6	47.3	9.1	
Rest of Europe	88.8	82.0	8.3	
North and South America	42.7	44.3	-3.6	
Asia	76.4	62.9	21.5	
Rest of world	4.6	6.8	-32.4	
Biotest Group	264.1	243.3	8.5	

# QUARTER-TO-QUARTER COMPARISON

by business segments

			Revenue		
in € million	Q2/2014	Q1/2014	Q4/2013	Q3/2013	Q2/2013
Therapy	109.6	93.0	102.1	98.6	94.2
Plasma & Services	29.8	27.5	26.4	24.1	26.0
Other Segments	2.5	1.7	4.8	1.5	4.4
Biotest Group	141.9	122.2	133.3	124.2	124.6
in € million	Q2/2014	Q1/2014	Q4/2013	Q3/2013	
					Q2/2013
Therapy	13.5	7.1	7.3	11.1	Q2/2013 6.6
Plasma & Services	13.5	7.1	7.3		6.6
	-     -			11.1	6.6 7.0
Plasma & Services	3.0	4.5	7.1	11.1	

#### OTHER NOTE DISCLOSURE

#### Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2013			Depreciation and amortisation		Carrying amount as of 30 June 2014
Intangible assets	48.1	0.9	-0.1	-2.9	0.4	46.4
Property, plant & equipment	254.9	14.6	0.0	-13.1	0.7	257.1
Total	303.0	15.5	-0.1	-16.0	1.1	303.5

As of 30 June 2014, the Biotest Group had commitments to acquire fixed assets in the amount of € 15.2 million.

#### **Employees**

#### by operating functions

full-time equivalents	30 June 2014	31 December 2013	Change in %
Marketing and distribution	204	201	1.5
Administration	233	223	4.5
Production	1,503	1,402	7.2
Research and development	190	171	11.1
Biotest Group	2,130	1,997	6.7

#### Financial instruments as of 30 June 2014

in € million	Carrying amount	Fair value
Assets		
Trade receivables	154.4	154.4
Other assets		
Other receivables	75.3	75.3
Derivatives not designated as a hedging instrument	0.0	0.0
Other financial investments	5.0	5.0
Equity and liabilities		
Trade payables	58.0	58.0
Financial liabilities	246.7	253.8
Other liabilities	36.8	36.8
Derivatives not designated as a hedging instrument	1.5	1.5

### 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 value 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

Biotest Group maintains reportable relationships with its associate BioDarou P.J.S. Co., Teheran/Iran and its subsidiary, Plasma Gostar Pars P.J.S, Teheran/Iran.

Both companies purchased goods and services totalling  $\le$  6.1 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  $\le$  8.5 million as of 30 June 2014.

As a related party of the Biotest Group, Kreissparkasse Biberach maintains the employees' custody accounts as part of the Long Term Incentive Programme.

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

#### **EVENTS AFTER THE REPORTING DATE**

On 9 July 2014 Biotest AG announced that the Supervisory Board has appointed Dr. Bernhard Ehmer as a full member of the Board of Management with effect from 1 November 2014. As of 1 January 2015 Dr. Ehmer will assume the chairmanship of the Board of Management from Professor Dr. Gregor Schulz, who, as planned, is retiring for age reasons after 12 years.

#### ASSURANCE BY THE LEGAL REPRESENTATIVES

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

To the best of our knowledge, and in accordance with the applicable accounting standards for interim financial reporting, the interim consolidated financial statements give a true and fair view of the financial position, cash flows and results of operations of the Group and the interim management report of the Group includes a true and fair view 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 Group's expected development for the remaining months of the financial year.

Dreieich, 11 August 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

M. Kamok

Dr. Georg Floß Member of the Board of Management

#### FINANCIAL CALENDAR

**12 November 2014** 2014 nine-months report

**12 November 2014** Analyst conference

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

