Biotest

From Nature for Life

REPORT FOR THE FIRST QUARTER 2015 OF BIOTEST AG

KEY FIGURES

BIOTEST GROUP		Q1 2015	Q1 2014	Change in %
Revenue	€ million	**142.5**	122.2	16.6
thereof:				
Germany	€ million	**32.2**	22.7	41.9
Rest of world	€ million	**110.3**	99.5	10.9
thereof:				
Therapy	€ million	**98.3**	93.0	5.7
Plasma & Services	€ million	**42.2**	27.5	53.5
Other Segments	€ million	**2.0**	1.7	17.6
EBITDA	€ million	**7.7**	18.5	–58.4
Operating profit (EBIT)	€ million	**0.1**	10.7	–99.1
EBIT in % of revenue	*%*	***0.1***	*8.8*	
Earnings before taxes	€ million	**4.2**	7.8	–46.2
Earnings after taxes	€ million	**1.4**	5.0	–72.0
Financing				
Cash flow from operating activities	€ million	**12.6**	–13.4	194.0
Depreciation and amortisation	€ million	**7.6**	7.8	–2.6
		31 March 2015	31 December 2014	
Equity	€ million	**502.9**	480.2	4.7
Equity ratio	*%*	***46.9***	*46.5*	
Employees (full-time equivalents)	amount	**2,188**	2,158	1.4

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INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 31 MARCH 2015

A. GROUP PRINCIPLES

I. BUSINESS MODEL OF THE GROUP

The Biotest Group, with its headquarters in Dreieich, Germany, is an international supplier of biological medicines. Products currently on the market and new developments are obtained from human blood plasma 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 of these three indication areas. Biotest covers all the important steps in the value-added chain, from preclinical and clinical development, conducted in some cases in collaboration with international partners, to global marketing.

A. SEGMENTS OF THE BIOTEST GROUP

The company is divided into the operative 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 the Other segments area Biotest reports on merchandising business and trans-sectoral costs that cannot be assigned to the Therapy or Plasma & Services segments.

B. PERSONNEL

The Biotest Group employed a staff of 2,188 full-time equivalents as of 31 March 2015. This number has increased by 1.4 % compared to the 31 December 2014 reporting date (2,158 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. In addition to continuously advancing its own research and development pipeline, the Company is pursuing to get marketing authorisation and to increase marketing activities to further internationalise its business, and to diversify its product portfolio. In addition to the successful expansion of the product portfolio in European markets, the focus is on the US, Asia and South America.

The Biotest Group is expanding production capacity at its company headquarters at Dreieich in order 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 further 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 amongst others 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, 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 2014 Annual Report. Recent progress is detailed in the “Business performance” section of this report.

B. ECONOMIC REPORT

I. BUSINESS AND GENERAL FRAMEWORK

According to the latest International Monetary Fund (IMF) "World Economic Outlook", the global economy is still growing at a slow pace. For this reason the IMF warns of a longer, sustained global growth crisis. Whilst developed national economies recorded a slight rise in growth rates, the increase is slowing down in emerging markets. Experts expect the global economy to grow by 3.5 % in the current year and 3.8 % in the coming year. The IMF has therefore kept its January forecast at about the same level.[1]

In January 2015 the European Central Bank (ECB) announced an expanded bond purchase programme aimed at stabilising prices. This is intended to be carried out in a monthly amount of € 60 billion until September 2016.[2] Growth in economic activity will be somewhat slow in 2015 at 1.7 % for the EU and 1.3 % in the euro area. An increase of 2.1 % (EU) and 1.9 % (eurozone) is expected for the coming year. One of the reasons for this development is that, according to the European Commission's latest forecast, the eurozone will slide into deflation this year.[3]

Leading German economic research institutes expect an increase of 2.1 % in Germany's gross domestic product in 2015. Geopolitical tensions, which had slowed the economy in the past summer, were more than offset by unexpected expansive stimuli, especially the collapse in the oil price and strong depreciation of the euro. According to the statisticians, the pace should slow down only slightly in the coming year.[4]

The US Federal Reserve expects growth of between 2.3 % and 2.7 % for the current year; in December 2014 it was still assuming an increase in economic output of between 2.6 % and 3.0 %. 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.[5]

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

II. INDUSTRY-SPECIFIC FRAMEWORK

The market for immunoglobulins and albumins, the best-selling products of the Biotest Group, continues to show stable growth. Demand is constantly increasing in established markets such as the US and Europe and in other regions of the world. Industry experts expect global demand to increase at an annual rate of 6 – 8 % as a long-term target range.[6]

EU prices for intravenous immunoglobulins (IVIG) are still 25 – 30 % below those in the United States.[7] The German market developed positively in 2014 in terms of quantities, while average prices remained at the previous year's level.[8] With the IVIG market growth in Germany, the Biotest preparation Intratect® was able to record gains and maintain its market share at an overall stable level on roughly constant prices. In general however, sustained price pressure can be observed in individual product areas and regions.

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

2 ECB, press release, 22 January 2015

3 European Commission, press release, 5 February 2015

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

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

6 Goldman Sachs: Global: Medical Technology: Medical Supplies, 25 August 2014

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

8 IMS Health Germany, as of: December 2014

The demand for plasma Factor VIII products is continuing to increase. The growth is being mainly driven by Factor VIII therapies that are becoming increasingly established in other regions. The market volume in Europe remained stable at the previous year's level.[9] Growth of 4 % p.a. is forecast for the global market until 2020.[10] An increase of about 2 % p.a. is expected for plasmatic Factor VIII preparations and of about 6 % for the recombinant Factor VIII preparations segment. The recombinant sector 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 overall market.

III. BUSINESS PERFORMANCE

A. AT A GLANCE

The Biotest Group again succeeded to increase revenues in the first three months of 2015. The Group generated revenue of € 142.5 million in the period from January to March 2015. This represents an increase of 16.6 % compared to the same period in the previous year (€ 122.2 million).

Substantial revenue increases were achieved in the US, Germany and the "Other Asia and Pacific" reporting region. Sales of plasma in particular increased in the US in addition to the continued increased marketing of Bivigam®. Biotest operates plasma collection centres for long-term cooperation partners who are active in other market segments. Increasing volumes of blood plasma were also sold in Germany.

The Biotest Group is continuing to invest considerable funds in the development of new products and further development of its existing products. Operating income (EBIT) decreased from € 10.7 million to € 0.1 million due to these increased research and development costs, costs incurred for the capacity expansion already underway, unabsorbed costs at the US subsidiary, Biotest Pharmaceutical Corporation (BPC), as well as sustained price pressure in individual product areas and regions. This sluggish earnings performance at the beginning of the year has already been reflected in the 2015 forecast made in March this year.

The extensive research and development work currently underway could create significant value for the future. This is confirmed by the good interim results of the current Civacir® study that were recently presented to the 50th International Liver Congress in Vienna, Austria. This preparation could be used for prophylaxis of hepatitis C reinfection after a liver transplantation.

B. RESEARCH AND DEVELOPMENT

Research and development costs increased by 8.1 % in the first three months of the current financial year to € 18.6 million (same period in the previous year: € 17.2 million). The R&D division employed 210 full-time equivalents as of the 31 March 2015 reporting date (31 December 2014: 208). 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.

In the first three months of 2015 Biotest achieved further success in nearly all ongoing studies and development projects. On 23 April 2015 Biotest presented positive interim results of the pivotal phase III study (no. 988) with Civacir® at the 50th International Liver Conference in Vienna, Austria. The product is intended for prophylaxis of hepatitis C reinfection after liver transplantation. The presented study results show a reinfection rate of only 5 % in the treatment group with the highest Civacir® dosage whereas reinfection still occurred in approximately 32 % of the patients in the control group despite prior treatment with new virostatic drugs. More than two thirds of the planned patients have now been included in the study. It is planned to present final data from all patients at the beginning of 2016.

Patient recruitment and the 24-week treatment phase in the main part of the clinical TREAT 2b (**T**cell **RE**gulating **A**rthritis **T**rial 2b, no. 986) phase IIb study, which started in 2013, for further development of the monoclonal antibody tregalizumab (BT-061), concluded at the end of February. Currently, patients are treated for a further six months in an extension phase, at own request. Biotest has now announced that after 12 weeks the primary study end point was not reached.

9 PPTA (2015)

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

Treatment of patients in the phase I/II study (no. 975) of indatuximab ravtansine (BT-062) for monotherapy of multiple myeloma, a malignant disease of the bone marrow, was concluded. The final clinical study report is expected in the second quarter of 2015, when the current data collection is complete.

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 ended and the treatment of the 47 patients who had already undergone intensive prior treatment is continuing. The first patient has now been enrolled in the extension arm of the study, in which the combination with pomalidomide and dexamethasone is investigated. In the course of preparations for the phase III study, the production process for the antibody was further optimised. By using scale effects and introducing other improvements a significant reduction of the manufacturing costs can be achieved. Initial production on a larger scale started in March as planned.

Twelve patients have been recruited to date 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).

In the first part of the clinical phase I/II study (no. 984) of the fibrinogen concentrate that is under development, 18 of the planned 20 patients have now been enrolled and treated. The pharmacokinetic properties, tolerability and safety were evaluated by using the concentrate in patients with congenital fibrinogen deficiency.

Recruitment of all 160 patients for the phase II study (no. 982) with IgM Concentrate has now been concluded. The study data are expected in the second half of 2015.

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 because of HBV-induced liver failure. The aim of the "ZEUS" phase III study (**Z**utectra **E**arly **US**e, no. 987) is to obtain approval with the study data for use of Zutectra® from just one week after the transplantation. The data were presented at the 50th International Liver Conference in Vienna. During the six-month prophylaxis with Zutectra® no hepatitis B virus reinfection was observed, while safety and tolerability were excellent. The study data were submitted to the European Medicines Agency (EMA).

In preparation for a phase IIa study (no. 990) in patients diagnosed with systemic lupus erythematosus (SLE), a toxicity study involving a three-month treatment period and subsequent follow-up was concluded. In addition, the trial drug for the clinical study was produced. This study documentation has now been finalised and submitted to the authorities.

C. MARKETING AND DISTRIBUTION

In the 2014 financial year Intratect® 100 g/l (10 % solution) received new marketing authorisation in Denmark, Norway, Mexico and Vietnam. Further marketing authorisations have been submitted to national authorities in other countries, so that sales could also begin in these countries after marketing authorisation is received. Intratect® 50 g/l (5 % solution) received the GMP certificate in Turkey, market launch is planned for the beginning of 2016.

Fovepta®, a hyperimmune globulin developed 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 new marketing authorisation in India. Marketing authorisation was also obtained in China and Sweden for the Biotest product Albiomin®.

D. PRODUCTION

At the end of March 2015 the US subsidiary, BPC, opened another plasma collection centre in Conway, Arkansas, USA. In addition, the centre in San Antonio, Texas, USA, moved to new, modern premises. BPC now operates a total of 18 such centres in the US, in which blood plasma is collected as the basis material for Biotest plasma protein products. Biotest thereby raises both its self-sufficiency rate and enables plasma sales to third parties to be increased.

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

A. RESULTS OF OPERATIONS

In the first quarter of 2015, the Biotest Group generated sales of € 142.5 million. This represents an increase of 16.6 % compared to the same period in 2014, in which sales of € 122.2 million were generated. Sales increased significantly in some areas in the Plasma & Services (+ 53.5 %) and Therapy (+ 5.7 %) segments.

SALES BY SEGMENT

in € million	Q1 2015	Q1 2014	Change in %
Therapy	98.3	93.0	5.7
Plasma & Services	42.2	27.5	53.5
Other Segments	2.0	1.7	17.6
Biotest Group	**142.5**	**122.2**	**16.6**

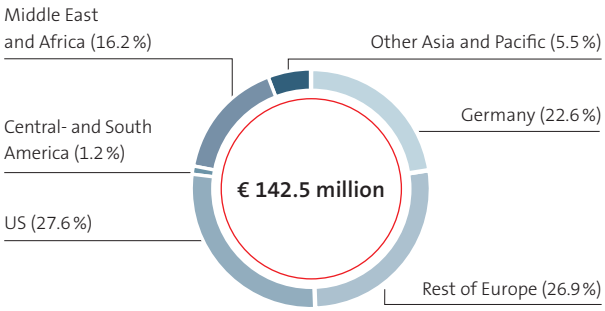
Biotest Group's sales growth was generated again globally in the first three months of 2015. Sales increased significantly in Germany and in the US. In North America the market relaunch of Bivigam® and increased sales of special and normal plasma in particular resulted in the doubling of sales. Plasma sales also increased in Germany.

A positive trend was evident in Central and South American countries. Biotest recorded a 6.2 % increase in sales in these countries. However, sales in Rest of Europe declined by 18.9 %. This was attributable to continued price pressure in individual product areas and regions.

The breakdown of Group sales has shifted slightly towards the domestic market due to the positive trend in Germany. In the period between January and March 2015 the Biotest Group generated 77.4 % of its sales outside of Germany (same period in the previous year: 81.4 %).

Production costs increased significantly to € 98.1 compared to € 71.0 million in the first three months of 2014. This was mainly attributable to unabsorbed costs arising as a result of the scaled down production of Bivigam® – and consequently intermediates as well – at the Boca Raton, Florida, USA, and Dreieich, Germany, locations. The lack of intermediates from the US resulted in lower utilisation of the Albumin production capacity at Dreieich. The manufacture of tregalizumab (BT-061) for study purposes also resulted in an increase in the production costs.

SALES BY REGION



The cost of sales ratio increased significantly from 58.1 % to 68.8 % for the above-mentioned reasons. Marketing and distribution costs also increased and amounted to € 17.9 million (percentage of sales: 12.6 %), 17.8 % above the previous year's level (€ 15.2 million, percentage of sales: 12.4 %). Increased commissions payable in particular had a noticeable impact in this regard.

Administrative expenses were reduced from € 9.1 million to € 8.2 million despite a further increase in the number of employees. Their percentage share of sales of 5.8 % was below that of the previous year (7.4 %).

Research and development costs increased by 8.1 % compared to the same period in the previous year due to the very good patient recruitment for various clinical trials and the related increase in production volumes of clinical trial material. Costs in this area amounted in total to € 18.6 million for the first three months of 2015 compared to € 17.2 million in the same period in the previous year. However, their percentage of sales decreased due to the substantial increase in sales. This was 13.1 % in the first quarter 2015 compared to 14.1 % in the same period in the previous year.

Other operating expenses of € 0.7 million were only slightly higher than the previous year's level (€ 0.4 million). Other operating income amounted to € 1.1 million (same period in the previous year: € 1.4 million).

ESSENTIAL P&L POSITIONS OF THE BIOTEST GROUP*

in € million	Q1 2015	% of sales	Q1 2014	% of sales
Production costs	−98.1	68.8	−71.0	58.1
Distribution costs	−17.9	12.6	−15.2	12.4
Administrative expenses	−8.2	5.8	−9.1	7.4
Research and development costs	−18.6	13.1	−17.2	14.1
Other operating income and expenses	0.4	0.3	1.0	0.8
Financial result	4.1	2.9	−2.9	2.4

* Costs/expenses are denoted with a negative sign

Operating profit (EBIT) decreased significantly compared to the same period in the previous year due to the substantial increase in costs/expenses, particularly production costs, and amounted to only € 0.1 million, well below € 10.7 million for the same period in the previous year. The EBIT margin therefore decreased significantly from 8.8 % in the first quarter 2014 to 0.1 %.

Increased R&D costs, the unabsorbed costs described above and continued price pressure in individual product areas and regions resulted in a negative EBIT, especially in the Therapy segment. Costs of € 1.1 million incurred in connection with the capacity expansion also had a negative impact on earnings, resulting in the decrease of EBIT for the Therapy segment to € −6.4 million (same period in the previous year: € + 7.1 million). However, EBIT of the Plasma & Services segment increased significantly by 57.8 % from € 4.5 million to € 7.1 million. This is due to the increase in sales of plasma to long-time cooperation partners.

The financial result amounted to € 4.1 million (same period in the previous year: € −2.9 million). This significant increase was among others attributable to the valuation date rating of a US dollar loan to Biotest Pharmaceutical Corp., the Group's US subsidiary, as of the reporting date.

This resulted in earnings before taxes (EBT) of € 4.2 million for the Biotest Group compared to € 7.8 million in the same period in the previous year. Earnings after taxes (EAT) also decreased from € 5.0 million to € 1.5 million on a significant increase in the tax rate, which is calculated on the basis of the income of the individual company and is mainly attributable to losses of the US subsidiary. Earnings per share were € 0.11 compared to € 0.38 for the first three months of 2014.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	Q1 2015	Q1 2014	Change in %
EBIT	0.1	10.7	−99.1
EBT	4.2	7.8	−46.2
EAT	1.4	5.0	−72.0
Earnings per share in €	0.11	0.38	−71.1

B. FINANCIAL POSITION

Total assets of the Group increased to € 1,072.2 million as of the 31 March 2015 reporting date compared to € 1,032.6 million as of 31 December 2014.

On the assets side both current and non-current assets increased. This was mainly due to currency effects. Intangible assets (increase from € 50.2 million to € 55.9 million) as well as property, plant and equipment (increase from € 282.3 million to € 297.3 million) increased in particular. About 90 % of the assets are financed on a long-term basis, proof of the sustainable financing structure.

Current assets increased slightly to € 697.3 million (31 December 2014: € 679.3 million). Inventories as well as trade receivables increased as a result of the rise in sales. Other current assets also increased significantly. They include interest-bearing investments previously disclosed under cash and cash equivalents and rose from € 67.7 million to € 121.8 million. Cash and cash equivalents decreased accordingly to € 125.0 million (31 December 2014: € 179.4 million). Their planned reduction also resulted from payments for capital expenditure of € 10.5 million and the above-described switch into short-term financial investments.

On the liabilities side equity increased further to € 502.9 million, as a result of currency effects (31 December 2014: € 480.2 million). The equity ratio remained almost unchanged at 46.9 % compared to 46.5 % as of 31 December 2014, despite the increase in total assets. Total debt also rose to € 569.3 million (31 December 2014: € 552.4 million). Both non-current and current debt also increased slightly. Non-current financial liabilities in particular increased from € 325.8 million to € 336.7 million due to additional borrowings. Trade payables decreased slightly from € 55.5 million to € 54.3 million, whilst other current liabilities increased significantly to € 40.2 million (31 December 2014: € 32.7 million).

C. FINANCIAL STATUS

Biotest AG generated positive cash flows of € 12.6 million in total from operating activities. There was an outflow of € 13.4 million in the comparable period in the previous year. A positive cash flow from the change in working capital was the reason for this development.

Cash flow from investing activities amounted to € –74.9 million in the period from January to March 2015 compared to € –31.4 million in the same period in the previous year. This item includes in particular outflows in other assets of € 64.1 million (same period in the previous year: outflow of € 19.9 million). Adjusted for these payments relating to financial investments made as part of short-term treasury management, cash flow from investing activities of € –10.8 million remained at about the level for the same period in the previous year (€ –11.5 million).

The Biotest Group again recorded a positive cash flow from financing activities of € 6.8 million in the first three months of 2015 compared to € 14.6 million in the same period in the previous year. Cash and cash equivalents decreased as planned from € 174.2 million as of 31 December 2014 to the current level of € 125.0 million taking into account the shift in current assets.

D. OVERALL ASSESSMENT OF THE COMPANY'S BUSINESS SITUATION

The Biotest Group continued on its growth path in the first three months of 2015. Sales increased by 16.6 % compared to the same period in the previous year. Due to the significant increase in costs, particularly in the research and development area, unabsorbed costs and continued price pressure in some regions, EBIT decreased, compared to the same period in the previous year, from € 10.7 million to € 0.1 million. Biotest has the resources to drive forward the operating business as planned.

The "TREAT 2b" Phase IIb study did not meet the primary endpoint. Full data from the study are expected until the end of May, they will be further analysed with external experts and AbbVie. If the further evaluation leads to the decision to discontinue the development of tregalizumab (BT-061), operating profit could be reduced in 2015 by a charge of € 25–30 million.

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

C. EVENTS AFTER THE REPORTING DATE

On 24 April 2015, after the end of the reporting period, Biotest published an ad hoc announcement of the first results from the TREAT2b phase IIb study [**T**cell **RE**gulating **A**rthritis **T**rial 2b] to evaluate the efficacy and safety of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis. After 12 weeks of treatment with tregalizumab (BT-061) in combination with methotrexat no statistically significant improvement in ACR 20 score (primary endpoint) could be shown when compared with placebo.

Patient safety in the TREAT IIb study was monitored frequently by the independent "data safety monitoring board" (DSMB). No safety concerns for tregalizumab (BT-061) were noted in the study.

The data are currently being shared with AbbVie, the collaboration partner, who will decide within 90 days whether to continue the co-development of tregalizumab (BT-061) with Biotest.

If further evaluation leads to discontinuation of the development of tregalizumab (BT-061), Biotest's operating profit could be reduced by € 25–30 million in 2015.

The competent Italian court has admitted the charges against 16 defendants, including three employees of Biotest Italia S.r.l., due to illegal pricing agreements. There was and is no investigation against the Biotest Italia S.r.l. as a Company.

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 are coming under increasing pressure throughout the world. Although the prices remained constant in the US market, a certain price pressure was recorded at specific product areas and regions. This trend will continue in 2015.

Biotest also expects the global market volume for plasmatic clotting factors to increase by about 2 % per year until 2020.[11] The start of sales of Albiomin® 20 % in China offers new sales potential in a market, for which an average growth of 10 % per year until 2020 is predicted.[12]

Further increases in sales are forecast up to 2018 in all product groups as a result of new or extensions to existing market authorisations.[13]

There is also significant future sales potential for the Biotest Group in the area of monoclonal antibodies. Preparations to treat multiple myeloma (Biotest development project indatuximab ravtansine (BT-062)) generated worldwide sales of USD 6.5 billion. Furthermore, the treatment of various solid tumours with indatuximab ravtansine (BT-062) offers significant additional sales opportunities following market authorisation for corresponding indications. Whether Tregalizumab (BT-061) can contribute to future earnings can be estimated only after the complete analysis of the study data.

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

12 Marketing Research Bureau (2014), Albumin Usage and Demand Forecast in China 2013 – 2020

13 Evaluate Pharma, Yearly product sales by indication, 23 January 2014

B. EXPECTED PERFORMANCE OF THE BIOTEST GROUP

Revenue and earnings

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

The significant increase in costs and continued price pressure at specific product areas and regions are having a noticeable effect on earnings. In addition, the cost for the planned capacity expansion at Dreieich is having a stronger impact than in the 2014 financial year. Costs relating to the already started "Biotest Next Level" expansion project will probably be twice as high in 2015 as in 2014. As Biotest works together with partners in developing new preparations, R&D costs incurred in the financial year depend to a large extent on the progress made in these projects and the resulting further decisions. However, the Board of Management expects that the Biotest Group will continue to perform positively and is aiming for EBIT in the range of some € 50 million. This amount could be reduced by € 25–30 million if, as an outcome of the results of the "TREAT 2b" Phase IIb study with tregalizumab (BT-061), the further development of this antibody is fully discontinued.

Due to current preparations for other clinical studies and associated production of clinical trial material, the Board of Management expects research and development costs to be higher in the first half of 2015 than in the second half. Consequently, the contribution to the EBIT guidance should be significantly higher in the second half of the year than in the preceding period, unless the described extraordinary expenditures due to the possible discontinuation of the development of tregalizumab (BT-061) occur.

Financial status

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

Capital expenditure of up to € 118.4 million is planned for the Biotest Group for the 2015 financial year, of which a substantial portion is attributable to the "Biotest Next Level" project. However, further capital expenditure will be incurred for the expansion of existing and the building of new plasma centres in the US for BPC and for completing the construction of 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 meet the increase in investments as well as the increase in sales and the associated working capital. The company's growth program 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) except for the new development with the TREAT 2b study.

III. OPPORTUNITIES REPORT

The Biotest Group's opportunity situation has not changed materially from the presentation set out in the 2014 Annual Report (see pages 33 and 34) except for the new development with the TREAT 2b study.

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 March 2015

in € million	Q1 2015	Q1 2014
Revenue	142.5	122.2
Cost of sales	−98.1	−71.0
Gross profit	**44.4**	**51.2**
Other operating income	1.1	1.4
Distribution costs	−17.9	−15.2
Administrative expenses	−8.2	−9.1
Research and development costs	−18.6	−17.2
Other operating expenses	−0.7	−0.4
Operating profit	**0.1**	**10.7**
Financial result	4.1	−2.9
Earnings before taxes	**4.2**	**7.8**
Income tax	−2.8	−2.8
Earnings after taxes	**1.4**	**5.0**
Attributable to:		
Equity holders of the parent	1.4	5.0
Non-controlling interests	0.0	0.0
Earnings per share in €	**0.11**	**0.38**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 31 March 2015

in € million	Q1 2015	Q1 2014
Consolidated profit for the period	**1.4**	**5.0**
Exchange difference on translation of foreign operations	21.3	0.0
Income tax effect	0.0	0.0
Other comprehensive income to be reclassified to profit or loss in subsequent periods	**21.3**	**0.0**
Other comprehensive income after tax	**21.3**	**0.0**
Total comprehensive income after tax	**22.7**	**5.0**
Attributable to:		
Equity holders of the parent	22.7	5.0
Non-controlling interests	0.0	0.0

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 March 2015

in € million	31 March 2015	31 December 2014
ASSETS		
Non-current assets		
Intangible assets	55.9	50.2
Property, plant and equipment	297.3	282.3
Other financial investments	5.2	5.2
Other assets	1.0	0.8
Deferred tax assets	14.2	13.5
Total non-current assets	**374.9**	**353.3**
Current assets		
Inventories	251.6	246.0
Trade receivables	191.1	181.6
Current income tax assets	7.8	4.6
Other assets	121.8	67.7
Cash and cash equivalents	125.0	179.4
Total current assets	**697.3**	**679.3**
Total assets	**1,072.2**	**1,032.6**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	33.8	33.8
Share premium	225.6	225.6
Retained earnings	242.0	201.5
Shares of profit or loss attributable to equity holders of the parent	1.4	19.2
Equity attributable to equity holders of the parent	**502.8**	**480.1**
Non-controlling interests	0.1	0.1
Total equity	**502.9**	**480.2**
Liabilities		
Provision for pensions and similar obligations	77.8	77.5
Other provisions	8.2	6.3
Financial liabilities	336.7	325.8
Other liabilities	0.7	2.5
Deferred tax liabilities	13.4	11.4
Total non-current liabilities	**436.8**	**423.5**
Other provisions	22.1	23.5
Current income tax liabilities	8.2	8.6
Financial liabilities	7.7	6.1
Trade payables	54.3	55.5
Other liabilities	40.2	32.7
Liabilities from deferred revenue	0.0	2.5
Total current liabilities	**132.5**	**128.9**
Total liabilities	**569.3**	**552.4**
Total equity and liabilities	**1,072.2**	**1,032.6**

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 March 2015

in € million	2015	2014
Operating cash flow before changes in working capital	8.3	18.3
Cash flow from changes in working capital	17.1	−25.4
Interest and taxes paid	−12.8	−6.3
Cash flow from operating activities	**12.6**	**−13.4**
Cash flow from investing activities	−74.9	−31.4
Cash flow from financing activities	6.8	14.6
Cash changes in cash and cash equivalents	**−55.5**	**−30.2**
Exchange rate-related changes in cash and cash equivalents	1.1	0.0
Cash and cash equivalents on 1 January	179.4	204.4
Cash and cash equivalents on 31 March	**125.0**	**174.2**
thereof within cash flow from investing activities		
Cash outflow into other assets	−64.1	−19.9
Cash outflow into financial assets	0.0	0.0
Cash flow from investing activities adjusted for payments due to financial investments in the scope of short-term financial disposition	**−10.8**	**−11.5**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 31 March 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	—	—	—	—	0.0	—	0.0
Profit for the period	—	—	—	5.0	5.0	—	5.0
Total comprehensive income	**0.0**	**0.0**	**0.0**	**5.0**	**5.0**	**0.0**	**5.0**
Dividend payments	—	—	—	—	**0.0**	—	**0.0**
Balance on 31 March 2014	**33.8**	**225.6**	**−0.4**	**206.6**	**465.6**	**0.1**	**465.7**
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	—	—	21.3	—	21.3	—	21.3
Profit for the period	—	—	—	1.4	1.4	—	1.4
Total comprehensive income	**0.0**	**0.0**	**21.3**	**1.4**	**22.7**	**0.0**	**22.7**
Dividend payments	—	—	—	—	0.0	—	0.0
Balance on 31 March 2015	**33.8**	**225.6**	**40.7**	**202.7**	**502.8**	**0.1**	**502.9**

SELECTED NOTE DISCLOSURES

METHOD OF PREPARATION

The interim consolidated financial statements of Biotest AG and its subsidiaries as of 31 March 2015 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 31 March 2015 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 2015.

These interim consolidated financial statements were approved for publication by the Board of Management on 7 May 2015.

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

in € million	Q1 2015	Q1 2014
Operating profit (EBIT)	**0.1**	**10.7**
Financial result	4.1	−2.9
Earnings before taxes (EBT)	**4.2**	**7.8**
Income taxes	−2.8	−2.8
Earnings after taxes (EAT)	**1.4**	**5.0**

SEGMENT REPORTING

of the Biotest Group for the period from 1 January to 31 March 2015

	Revenue			EBIT		
in € million	Q1 2015	Q1 2014	Change in %	Q1 2015	Q1 2014	Change in %
Therapy	98.3	93.0	5.7	−6.4	7.1	−190.1
Plasma & Services	42.2	27.5	53.5	7.1	4.5	57.8
Other Segments	2.0	1.7	17.6	−0.6	−0.9	33.3
Biotest Group	**142.5**	**122.2**	**16.6**	**0.1**	**10.7**	**−99.1**

	Revenue from third parties by customer's geographical location		
in € million	Q1 2015	Q1 2014	Change in %
Germany	32.2	22.7	41.9
Rest of Europe	38.3	47.2	−18.9
USA	39.3	19.1	105.8
Rest of America	1.7	1.6	6.2
Middle East and Africa	23.1	26.5	−12.8
Other Asia and Pacific	7.9	5.1	54.9
Biotest Group	**142.5**	**122.2**	**16.6**

QUARTER-TO-QUARTER COMPARISON

by business segments

	Revenue				
in € million	**Q1/2015**	Q4/2014	Q3/2014	Q2/2014	Q1/2014
Therapy	98.3	111.8	95.4	109.6	93.0
Plasma & Services	42.2	51.2	48.5	29.8	27.5
Other Segments	2.0	9.1	1.9	2.5	1.7
Biotest Group	**142.5**	**172.1**	**145.8**	**141.9**	**122.2**

	EBIT				
in € million	**Q1/2015**	Q4/2014	Q3/2014	Q2/2014	Q1/2014
Therapy	–6.4	7.9	–1.0	13.5	7.1
Plasma & Services	7.1	8.9	10.6	3.0	4.5
Other Segments	–0.6	1.3	–0.8	–0.7	–0.9
Biotest Group	**0.1**	**18.1**	**8.8**	**15.8**	**10.7**
Earnings before taxes (EBT)	**4.2**	**14.6**	**10.6**	**13.9**	**7.8**

OTHER NOTE DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2014	Capital expenditure	Net disposals	Depreciation and amortisation	Currency translation differences	Carrying amount as of 31 March 2015
Intangible assets	50.2	0.4	0.0	–0.4	5.7	55.9
Property, plant & equipment	282.3	10.1	0.0	–7.2	12.1	297.3
Total	**332.5**	**10.5**	**0.0**	**–7.6**	**17.8**	**353.2**

As of 31 March 2015, the Biotest Group had commitments to acquire fixed assets in the amount of € 33.8 million.

Employees

by operating functions

full-time equivalents	**31 March 2015**	31 December 2014	Change in %
Marketing and distribution	211	203	3.9
Administration	242	231	4.8
Production	1,525	1,516	0.6
Research and development	210	208	1.0
Biotest Group	**2,188**	**2,158**	**1.4**

Financial instruments as of 31 March 2015

In € million	Carrying amount	Fair value
Assets		
Trade receivables	191.1	191.1
Other assets		
Other receivables	122.5	122.5
Derivatives not designated as hedging instruments	0.3	0.3
Other financial investments	5.2	5.2
Equity and liabilities		
Trade payables	54.3	54.3
Financial liabilities	344.4	354.7
Other liabilities	37.5	37.5
Derivatives not designated as hedging instruments	3.4	3.4

Fair value hierarchy

The financial instruments recognised at fair value in the statement of financial position are to be assigned under IFRS 7.27A to a three-level fair value measurement hierarchy. The level reflects the closeness to the market of the data used to calculate fair value. Fair value hierarchy levels are described below:

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

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

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

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

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

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

The Biotest Group maintains reportable relationships with the associate 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 € 2.0 million from Biotest in the first three months. Biotest receivables from BioDarou P.J.S. Co. and Plasma Gostar Pars P.J.S. amount to € 7.4 million as of 31 March 2015.

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

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

EVENTS AFTER THE REPORTING DATE

On 24 April 2015, after the end of the reporting period, Biotest published an ad hoc announcement of the first results from the TREAT2b phase IIb study [**T**cell **RE**gulating **A**rthritis **T**rial 2b] to evaluate the efficacy and safety of tregalizumab (BT-061) in patients with moderate to severe rheumatoid arthritis. After 12 weeks of treatment with tregalizumab (BT-061) in combination with methotrexat no statistically significant improvement in ACR 20 score (primary endpoint) could be shown when compared with placebo.

Patient safety in the TREAT IIb study was monitored frequently by the independent "data safety monitoring board" (DSMB). No safety concerns for tregalizumab (BT-061) were noted in the study.

The data are currently being shared with AbbVie, the collaboration partner, who will decide within 90 days whether to continue the co-development of tregalizumab (BT-061) with Biotest.

If further evaluation leads to discontinuation of the development of tregalizumab (BT-061), Biotest's operating profit could be reduced by € 25–30 million in 2015.

The competent Italian court has admitted the charges against 16 defendants, including three employees of Biotest Italia S.r.l., due to illegal pricing agreements. There was and is no investigation against the Biotest Italia S.r.l. as a Company.

Dreieich, 7 May 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

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.