Biotest

From Nature for Life

QUARTERLY STATEMENT 9 MONTHS 2016
1 JANUARY TO 30 SEPTEMBER 2016

KEY FIGURES

BIOTEST GROUP		Q1–Q3 2016	Q1–Q3 2015	Change in %
Revenue	€ million	**455.6**	417.9	9.0
thereof:				
Germany	€ million	**83.8**	94.3	-11.1
Rest of world	€ million	**371.8**	323.6	14.9
thereof:				
Therapy	€ million	**296.3**	288.0	2.9
Plasma & Services	€ million	**154.1**	123.2	25.1
Other Segments	€ million	**5.2**	6.7	-22.4
EBITDA	€ million	**44.5**	5.4	724.1
Operating profit (EBIT)	€ million	**26.1**	-82.0	131.8
EBIT in % of revenue	*%*	***5.7***	*-19.6*	
Earnings before taxes	€ million	**16.1**	-85.2	118.9
Earnings after taxes	€ million	**-1.7**	-88.0	98.1
Financing				
Cash flow from operating activities	€ million	**46.9**	34.2	37.1
Depreciation and amortisation	€ million	**18.4**	87.4	-78.9
		30 September 2016	31 Dezember 2015	
Equity	€ million	**407.0**	412.3	-1.3
Equity ratio	*%*	***42.3***	*42.8*	
Employees (full-time equivalents)	amount	**2,474**	2,271	8.9

KEY SHARE FIGURES

Ordinary share

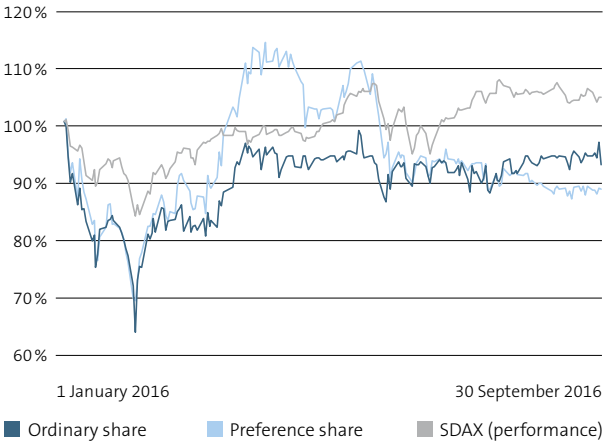
Ticker/ISIN	BIO / DE0005227201
Number of shares	19.785.726
Closing price (30 September 2016)*	16.76 €
Highest/lowest price*	18.00 € / 11.91 €
Performance 9 months	-6.9 %
Performance SDAX 9 months	+3.9 %
Market capitalisation (30 September 2016)	331.6 Mio. €

Preference share

Ticker/ISIN	BIO3 / DE0005227235
Number of shares	19.785.726
Closing price (30 September 2016)*	12.82 €
Highest/lowest price*	16.46 € / 10.40 €
Performance 9 months	-12.3 %
Performance SDAX 9 months	+3.9 %
Market capitalisation (30 September 2016)	253.7 Mio. €

*Closing prices on Xetra trading system at Deutsche Börse AG

BIOTEST SHARE PRICE CHART



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Ladies and gentlemen,

In the first nine months of 2016, we were able to increase both sales and EBIT year on year. Biotest AG is well on schedule to achieve its targets for the year. For 2016, we still anticipate a sales increase of a low-single-digit percentage and EBIT in the range of € 33 million to € 35 million.

In order to establish legal certainty in the investigation proceedings in progress since 2012 in connection with the Russia business, we have reached an agreement with the Frankfurt am Main public prosecutor's office and the Offenbach tax authority. Thus we do not expect any significant negative effects for the company in the future.

The focus of our strategy remains on our Biotest Next Level project. The investment programme will allow us to make much more effective use of plasma as a raw material in the future, to increase the yields in the production process and to improve our profitability. In the future, five instead of the current three products shall be obtained from a litre of plasma.

We are focussing on plasma protein products. In this area, our employees are working intensively on the development of new medicines such as IgG Next Generation (IVIG), IgM Concentrate and Fibrinogen.

By the end of 2020 at the latest, we want to more than double overall production capacity with Biotest Next Level and thus participate in the growing global demand for plasma proteins. By expanding our plasma collection centres we are laying the necessary foundation for this, as we use these centres to collect the raw material for our medicines, human blood plasma. In the first nine months of the year, we have opened a total of five new plasma collection centres, two of which in Hungary and three in the USA.

Our plans for the future are ambitious but realistic. In the current financial year, we have made significant progress in our important Biotest Next Level investment programme. Biotest AG is in a strong position for the future. Today, we are creating the structures and laying the foundations required to fully exploit tomorrow's opportunities in a growing market. We are looking forward to walking this path together with you.

Cordially yours,

Dr Bernhard Ehmer

Chairman of the Board of Management

BUSINESS PERFORMANCE

A. AT A GLANCE

Results of operations

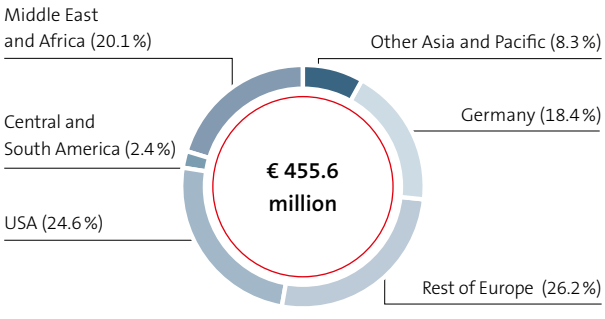
In the first nine months of 2016, the Biotest Group generated revenues of € 455.6 million, after € 417.9 million in the same period of the previous year. This corresponds to a percentage increase of 9.0 %. With an increase of 25.1 % compared to the same period of the previous year the Plasma & Services segment recorded the strongest sales increase.

SALES BY SEGMENT

in € million	Q1–Q3 2016	Q1–Q3 2015	Change in %
Therapy	296.3	288.0	2.9
Plasma & Services	154.1	123.2	25.1
Other Segments	5.2	6.7	-22.4
Biotest Group	**455.6**	**417.9**	**9.0**

In the regional analysis, Biotest generated sales growth in the regions USA, Central and South America, Middle East and Africa, as well as Other Asia and Pacific. The largest sales increase was generated in the USA at 43.5 %. In addition to significantly increased sales of blood plasma, this reflects the positive effect of the cooperation agreement concluded with Kedrion Biopharma Inc., USA, in January 2016. With a 24.6 % share in sales or sales of € 112.1 million in the first nine months, the USA is the Biotest Group's second-strongest sales market after Europe. In Europe, a sales decline of € 15.6 million or - 7.1 % was recorded in the first three quarters of 2016 compared to the same period of the previous year, which had been significantly influenced by non-recurring plasma sales. In absolute terms, Biotest generated sales of € 203.0 million in Europe in the first nine months.

SALES BY REGION



At Group level EBIT amounted to € 26.1 million in the first nine months of 2016 compared to the previous year's figure of € -82.0 million. The EBIT margin amounted to 5.7% after -19.6% in the previous year. While Biotest recorded negative EBIT of € -100.0 million in the core segment Therapy in the previous year, operating income was significantly improved to € -1.4 million in the first three quarters of 2016. The comparative period of the previous year was mainly influenced by an impairment on Therapy activities in the USA. EBIT in the Plasma & Services segment rose by 42.8% to € 28.7 million. The slightly negative EBIT in Other Segments was reduced from € -2.1 million in the same period of the previous year to € -1.2 million.

EBIT BY SEGMENT

in € million	**Q1–Q3 2016**	Q1–Q3 2015	Change in %
Therapy	-1.4	-100.0	98.6
Plasma & Services	28.7	20.1	42.8
Other Segments	-1.2	-2.1	42.9
Biotest Group	**26.1**	**-82.0**	**131.8**

The earnings after taxes in the amount of € -1.7 million (same period of the previous year: € -88.0 million) were reduced in the financial year by the one-time tax and interest expenses in connection with the agreement reached with the German tax authorities.

Cash flow

In the first nine months of 2016, the Biotest Group recorded a positive operating cash flow in the amount of € 46.9 million (same period of the previous year: € 34.2 million) despite the non-recurring tax payments. Cash flow from investing activities amounted to € -15.6 million for the period between January and September (same period of the previous year: € -125.6 million). Cash flow from financing activities of € 3.1 million was higher than in the previous year (€ -0.7 million).

Financial position

On the assets side of the statement of financial position, property, plant and equipment increased due to capital expenditure as part of the Biotest Next Level expansion project from € 317.2 million as of the reporting date 31 December 2015 to € 397.9 million as of 30 September 2016.

B. RESEARCH AND DEVELOPMENT

In the first nine months of 2016, research and development costs amounted to € 37.9 million (previous year: € 76.9 million). This reflects the reduction of activities in the area of monoclonal antibodies. A comprehensive list of all research and development projects is provided in the 2015 Annual Report (pages 16 to 19). Biotest also made further progress regarding a number of research and development products in the first nine months of 2016:

RESEARCH & DEVELOPMENT PROGRESS IN THE FIRST 9 MONTHS OF 2016

Indication Area Haematology	
Indatuximab ravtansine (BT-062)	In the phase I/IIa study (no. 989), dose escalation was completed, the maximum tolerated dose defined and recruitment ended. However, there are still patients undergoing treatment. The study is ongoing.
Indication Area Clinical Immunology	
BT-063	Completion of the first part of the IIa study (no. 990) in the second quarter. Data from part 1 of the study are currently being evaluated in an interim analysis. The results will serve as a basis for the planning of the second part of the study.
IgG Next Generation	Two approval studies were submitted to the authorities in several countries for approval: a phase III study (no. 991) on the treatment of patients with primary immune deficiencies (PID) and a phase III study (no. 992) on the treatment of immune thrombocytopenia (ITP). For study no. 991, the regulatory authorities in several countries, including the USA and Germany, have already approved the conduct of the clinical trial.
Indication Area Intensive Care Medicine	
IgM Concentrate	• Phase II study with patients with severe community-acquired pneumonia (sCAP) completed with good results: extraordinary relative reduction in mortality rate in a subgroup of patients (patients with a significant elevation in inflammatory markers) of over 50%. • The Paul Ehrlich Institute (PEI) supports Biotest's concept for the planned phase III study. Further consultations with the European EMA and the U.S. health authority FDA are planned.
Pentaglobin®	• Pentaglobin® is showing impressive results in the treatment of donor-specific antibodies following lung transplantations: relative reduction in the mortality rate of over 70%. • Retrospective analysis by the Hellenic Sepsis Study Group (HSSG) shows that complementary treatment with Pentaglobin® lowers the relative mortality rate by 33% in the case of infections with proven antibiotic resistance.
Fibrinogen	The Paul Ehrlich Institute (PEI) supports Biotest's plans for the phase III study in acquired fibrinogen deficiency.

C. MARKETING AND DISTRIBUTION

A list of significant marketing and distribution activities in 2015 is provided in the 2015 Annual Report (pages 19 to 20). The following table summarises the progress made in the first nine months of 2016:

MARKETING & DISTRIBUTION PROGRESS IN THE FIRST 9 MONTHS OF 2016

Indication Area Clinical Immunology	
Fovepta®	• Market launch in Saudi Arabia and Libya in May • Marketing authorisation granted in Brazil in the third quarter
Intratect® 50 g/l (5%)	• Marketing authorisation granted in Brazil in the first quarter • Start of sales in Libya in May • First sales in Slovenia • Very good sales development in Indonesia after market launch in the first quarter • Market launch in Bulgaria in July • Start of cooperation with distribution partner in Argentina
Intratect® 100 g/l (10%)	• Marketing authorisation granted in Australia and Jordan • Market launch in Portugal in June

Zutectra®	• The results of the ZEUS (Zutectra Early Use) study were published in March • The early use of Zutectra® was launched in Germany • In France, sales of Zutectra® continue to grow • Marketing authorisation granted in Brazil in August • Price approval for the early use of Zutectra® in Italy received in August
Cytotect®	Marketing authorisation granted for the prophylactic use of Cytotect® after transplantations in the Netherlands in the second quarter.
Hepatect®	Marketing authorisation granted in Brazil in the third quarter
Indication Area Intensive Care Medicine	
Albiomin® (20 % and 5 %)	Start of marketing in Switzerland
Pentaglobin®	Market launch in Brazil in the first quarter
Indication Area Haematology	
Haemoctin®	With regard to inhibitor development, the SIPPET study shows a considerable advantage for plasmatic factor VIII products containing von Willebrandt factor in comparison to recombinant preparations.
Haemonine®	First sales in Algeria in September

D. SUPPLEMENTARY REPORT

On 4 November 2016, the Finanzamt Offenbach am Main (tax office Offenbach am Main) served to Biotest AG altered tax assessments for corporate tax, solidarity tax and trade tax for the years 2005 until 2008. The alterations relate to Biotest AG's Russia business. Compared to the tax assessments served on 3 August 2016, which has already been reported on by the company, there is a decrease in tax and interest expenses of € 6.9 million. Whereas the original total claim of the tax office had been € 21.4 million, the tax and interest expenses now come to a total of € 14.5 million. Biotest AG accepts these altered tax assessments.

Biotest is in advanced discussions with the investigative authorities as to the completion of the summary proceedings regarding a fine. The prosecutor has already applied for the fine at the responsible court. The liability resulting thereof in the amount of € 1.0 million was already included as a provision in the results as of 30 September 2016.

In the meantime, the authorities discontinued the investigations against several defendants from Biotest AG. According to information from the authorities, discontinuations of further investigations will follow. The authorities still investigate against three of the company's managers.

Based on these developments, the company assumes that no further significant negative effects for the company are to be expected from the Russian business.

E. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. CHANGE IN OUTLOOK REPORT

The Board of Management continues to expect an increase in sales in the low-single-digit percentage range for 2016. On 23 March 2016, Biotest increased the EBIT forecast for 2016 by more than 10 %. The company now expects EBIT in the range of € 33 to 35 million.

II. RISK REPORT

The Biotest Group's risk situation has not changed materially from the presentation set out in the 2015 Annual Report (pages 27 to 33) except the facts outlined hereafter.

Some of the risks described regarding the investigations by the Frankfurt public prosecutor's office have materialised as set out in the supplementary report. Based on these developments, the company assumes that no further significant negative effects for the company are to be expected from the investigation proceedings.

The immunoglobulin manufacturing plant of Biotest Pharmaceuticals Corp. in Boca Raton, Florida, USA, received a warning letter from the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2014. The warning letter expressed concerns regarding several deficiencies observed during a 2014 inspection related to the facility's compliance with current good manufacturing practice (cGMP). In the first quarter of 2016, the FDA performed a follow-up inspection and noted again several observations in connection with the American cGMP.

A face-to-face discussion was held with the FDA on 26 August 2016. At this meeting, senior managers of the company presented the latest information on the current situation with regard to this issue and discussed the improvements made to the manufacturing process and the progress achieved in connection with the problems identified in the inspection carried out in 2016. The FDA positively took the information on board. The company continues to cooperate closely with the FDA to address all their concerns.

Up to now the issues noted have not caused any interruption to the manufacturing at the facility, and the FDA has continued to approve manufactured batches for sale. Currently there are several batches under evaluation by the FDA with the decision for release pending because of a technical deviation within the manufacturing process. In the past, comparable material was approved by the FDA. In the third quarter of 2016, some of the batches in question were inspected and approved within the internal quality systems. If the remaining batches will not be released, a depreciation of up to € 6.5 million will be necessary in 2016.

III. OPPORTUNITIES REPORT

The Biotest Group's opportunities situation has not changed materially from the presentation set out in the 2015 Annual Report (pages 33 to 34) with the exception of the aforementioned cooperation agreement with Kedrion Biopharma Inc.

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 September 2016

in € million	Q3 2016	Q3 2015	Q1–Q3 2016	Q1–Q3 2015
Revenue	149.5	130.2	455.6	417.9
Cost of sales	-110.3	-149.4	-322.0	-344.4
Gross profit	**39.2**	**-19.2**	**133.6**	**73.5**
Other operating income	0.7	-0.3	2.1	1.8
Marketing and distribution costs	-11.2	-17.7	-41.3	-51.8
Administrative expenses	-7.9	-9.8	-28.1	-26.7
Research and development costs	-11.9	-36.8	-37.9	-76.9
Other operating expenses	-1.0	-0.5	-2.3	-1.9
Operating profit	**7.9**	**-84.3**	**26.1**	**-82.0**
Financial result	-5.7	-3.0	-10.0	-3.2
Earnings before taxes	**2.2**	**-87.3**	**16.1**	**-85.2**
Income taxes	-11.6	1.5	-17.8	-2.8
Earnings after taxes	**-9.4**	**-85.8**	**-1.7**	**-88.0**
Attributable to:				
Equity holders of the parent	-9.4	-85.8	-1.7	-88.0
Non-controlling interests	0.0	0.0	0.0	0.0
Earnings per share in €	**-0.23**	**-2.17**	**-0.04**	**-2.22**

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 September 2016

in € million	2016	2015
Operating cash flow before changes in working capital	47.3	6.4
Cash flow from changes in working capital	24.9	43.4
Interest and taxes paid	-25.3	-15.6
Cash flow from operating activities	**46.9**	**34.2**
Cash flow from investing activities	-15.6	-125.6
Cash flow from financing activities	3.1	-0.7
Cash changes in cash and cash equivalents	**34.4**	**-92.1**
Exchange-rate-related changes in cash and cash equivalents	0.0	1.0
Cash and cash equivalents on 1 January	53.8	179.4
Cash and cash equivalents on 30 September	**88.2**	**88.3**
thereof cash flow from investing activities from changes in other financial assets	79.9	- 70.2
Cash flow from investing activities adjusted for financial investments in the scope of short term financial disposition	**-95.5**	**-55.4**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 September 2016

in € million	30 September 2016	31 Dezember 2015
ASSETS		
Non-current assets		
Intangible assets	43.9	44.7
Property, plant & equipment	397.9	317.2
Investments in associates	2.2	3.5
Other assets	1.0	1.0
Other financial assets	0.9	0.8
Deferred tax assets	13.2	8.7
Total non-current assets	**459.1**	**375.9**
Current assets		
Inventories	186.8	218.7
Trade receivables	165.3	173.9
Current income tax assets	5.6	5.8
Other assets	15.6	13.8
Other financial assets	41.8	120.8
Cash and cash equivalents	88.2	53.8
Total current assets	**503.3**	**586.8**
Total assets	**962.4**	**962.7**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	149.2	235.3
Share of profit or loss attributable to equity holders of the parent	-1.7	-82.5
Equity attributable to equity holders of the parent	**406.9**	**412.2**
Non-controlling interests	0.1	0.1
Total equity	**407.0**	**412.3**
Liabilities		
Provision for pensions and similar obligations	75.1	72.6
Other provisions	7.7	6.6
Financial liabilities	330.6	335.5
Other liabilities	1.8	2.2
Deferred tax liabilities	12.0	7.7
Total non-current liabilities	**427.2**	**424.6**
Other provisions	23.0	27.5
Current income tax liabilities	4.5	4.3
Financial liabilities	17.2	9.1
Trade payables	47.5	53.1
Other liabilities	36.0	31.8
Total current liabilities	**128.2**	**125.8**
Total liabilities	**555.4**	**550.4**
Total equity and liabilities	**962.4**	**962.7**

NET DEBT

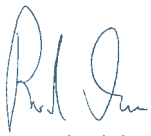
in € million	30 September 2016	31 Dezember 2015
Financial liabilities to financial institutions	344.2	340.8
Liabilities from finance leases	3.6	3.8
Financial liabilities	**347.8**	**344.6**
Cash and cash equivalents	88.2	53.8
Financial investments in other current financial assets*	40.0	119.9
Liquid assets and financial assets as part of the short-term financial disposition	**128.2**	**173.7**
Net debt	**219.6**	**170.9**

*Current financial investments of surplus cash and cash equivalents are included in other current financial assets.

SCHEDULE OF ASSETS – NET PRESENTATION

in € million	Carrying amount as of 31 Dec 2015	Capital expenditure	Net disposals	Depreciation and amortisation	Currency translation differences	Carrying amount as of 30 Sep 2016
Intangible assets	44.7	1.3	0.0	-1.2	-0.9	43.9
Property, plant & equipment	317.2	99.4	-0.4	-17.2	-1.1	397.9
Total	**361.9**	**100.7**	**-0.4**	**-18.4**	**-2.0**	**441.8**

Dreieich, 10 November 2016
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

30 March 2017	Annual Report 2016	10 May 2017	Annual General Meeting
30 March 2017	Financial statements press conference 2016	14 August 2017	Half-Year Report 2017
10 May 2017	Quarterly Statement as of 31 March 2017	14 November 2017	Quarterly Statement as of 30 September 2017

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