Biotest

From Nature for Life

QUARTERLY STATEMENT
1 JANUARY TO 30 SEPTEMBER 2019

CONTENTS

BUSINESS PERFORMANCE

A. AT A GLANCE

In the first nine months of financial year 2019, the Biotest Group recorded revenue of € 294.9 million (same period of the previous year: € 289.6 million). This equates to an increase of 1.8% over the previous year. After a slow start in the year, seen at the end of the first quarter, the decline in revenues of just under 12% was made up for in the second and third quarters and reversed into slight growth.

EBIT at Group level amounted to € –8.2 million in the first nine months of financial year 2019 (same period of the previous year: € 5.1 million).

Plasma Service Europe GmbH, Dreieich, Germany, a 100% subsidiary of Biotest AG, acquired a plasmapheresis centre in Hanover, Germany in January 2019. In addition, in April 2019, Biotest received the operating permit for the ninth plasmapheresis centre in Hungary from the Hungarian health authority OTH. The centre is located in the capital city of Budapest. Thus, the Group has expanded its own network of plasma collection stations in Europe to 21 centres to secure the long-term supply of plasma. Three more plasma collection centres will follow in financial year 2020.

Furthermore, in January 2019, Biotest received the extension of the approved indications of Intratect® in 22 European countries to include the neurological indications chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN), as well as an extension in the area of secondary immunodeficiencies (SID).

In March 2019, Biotest received approval in 13 European countries for a preparation with half of the solvent volume of the Factor VIII drug Haemoctin® SDH.

At its meeting on 7 March 2019, the Supervisory Board appointed Dr Michael Ramroth Chairman of the Board of Management of Biotest AG with effect from 1 May 2019.

Biotest received an additional insurance compensation payment of € 5.5 million in April.

At the Annual General Meeting 2019 on 7 May 2019, Biotest AG's shareholders approved the distribution of a dividend of € 0.04 per preference share. A total amount of around € 0.8 million was distributed.

In the first nine months of the year, good progress was made on the Biotest Next Level expansion project at the Dreieich site. The qualifications of the clean rooms and media systems are in progress so that they can be approved by the Darmstadt Regional Council (Regierungspräsidium Darmstadt, Germany) in November 2019. In parallel, the commissioning of the processing plants was started and their approval by the Darmstadt Regional Council is expected for 2020.

Biotest signed a 5-year financing agreement for a volume of € 240 million on 24 June 2019. This will finance the further steps towards the commissioning of the Biotest Next Level facilities in the years to come. The closing of the financing agreement took place on 2 July 2019.

Due to the presentation in millions of euros, rounding differences of +/– one decimal place are possible when the amounts shown are totaled.

Unless stated otherwise, the information and explanations in this nine month report relate to continuing operations.

Result of operations

In the first nine months of 2019, the Biotest Group generated revenue of € 294.9 million, after € 289.6 million in the same period of the previous year. This 1.8% increase is mainly due to the positive sales development in the Therapy segment. The reasons for this were the intensified sale of selected plasma products in attractive markets and rising sales volumes. These positive effects (+5.3% compared to the same period of the previous year) were partially offset by lower sales in the Plasma & Services segment (–27.0%) due to reduced contract manufacturing to expand capacities for in-house production.

SALES BY SEGMENT

in € million	**Q1–Q3 2019**	Q1–Q3 2018	Change in %
Therapy	266.1	252.8	5.3
Plasma & Services	23.5	32.2	–27.0
Other Segments	5.3	4.6	15.2
Biotest Group	**294.9**	**289.6**	**1.8**

Revenue increased in three sales regions. At 40.1%, Central Europe made the largest contribution to sales, as in the same period of the previous year (38.1%). Despite higher revenue, marketing and distribution costs were lower than in the same period of the previous year.

SALES BY REGION

in € million	**Q1–Q3 2019**	Q1–Q3 2018	Change in %
Central Europe	118.3	110.3	7.3
Eastern and Southern Europe	53.8	50.0	7.6
Intercontinental	60.3	53.3	13.1
Middle East, Africa and France	62.5	76.0	–17.8
Biotest Group	**294.9**	**289.6**	**1.8**

EBIT for the first nine months of financial year 2019 amounted to € –8.2 million (same period of the previous year: € 5.1 million). This includes expenses for the Biotest Next Level project of € 49.7 million (same period of the previous year: € 37.8 million) and income from insurance compensation of € 9.5 million. The year-on-year decline in EBIT is primarily due to higher production costs, which were caused by the increase in costs for the start-up phase of the new Biotest Next Level manufacturing site. In addition, an 8.7% increase in research and development costs had a negative impact on EBIT. The increase is due to the production of clinical material for the development projects IgG Next Generation and Trimodulin. Other operating expenses were higher than in the same period of the previous year due to the write-off of a distribution license in the amount of € 2.6 million. The EBIT margin for the first nine months of the current financial year was –2.8% after 1.8% in the same period of the previous year.

EBIT BY SEGMENT

in € million	**Q1–Q3 2019**	Q1–Q3 2018	Change in %
Therapy	–5.7	8.2	>–100
Plasma & Services	–0.3	0.2	>–100
Other Segments	–2.3	–3.3	30.3
Biotest Group	**–8.2**	**5.1**	**>–100**

The EBIT of the existing product business without the expenses for Biotest Next Level (€ 49.7 million) and for monoclonal antibodies (€ 1.1 million) was € 42.6 million, compared to € 46.0 million in the previous year. The adjusted EBIT margin for the first nine months of the current financial year was 14.4%, compared to 15.9% for the same period of the previous year.

ADJUSTED EBIT

in € million	**Q1–Q3 2019**	Q1–Q3 2018	Change in %
EBIT	–8.2	5.1	>–100
Expenses for Biotest Next Level*	49.7	37.8	31.5
Expenses for monoclonal antibodies	1.1	3.1	–64.5
Adjusted EBIT	**42.6**	**46.0**	**–7.4**

* The research and development cost for products that can be produced only at the new facility were added to the costs for Biotest Next Level.

EBIT from discontinued operations amounted to € 0.0 million in the reporting period after € 196.5 million in the same period of the previous year. In the same period of the previous year, EBIT from discontinued operations included the currency translation differences of the companies reclassified to the income statement as part of the deconsolidation of the US companies.

The financial result for the first nine months of 2019 in the amount of € 6.3 million improved by € 23.2 million year-on-year (same period of the previous year: € –16.9 million). This was mainly due to income of € 14.3 million from the valuation at fair value as of the reporting date of the surrender claim against trustee of the underlying shares in ADMA Biologics Inc., USA, as well as lower financial expenses. In the previous year, these were burdened by prepayment penalties and waiver fees in the amount of € 9.3 million.

Earnings after taxes from continuing operations therefore improved to € –2.9 million in the first nine months of 2019 compared with € –6.6 million in the same period of the previous year.

Earnings after taxes from discontinued operations amounted to € 0.0 million in the first nine months of 2019 after € 197.5 million in the same period of the previous year.

For the first nine months of 2019, Biotest Group's total earnings after taxes (EAT) were € –2.9 million (same period of the previous year: € 190.9 million). This results in earnings per share of € –0.08 after € 4.81 in the same period of the previous year.

Financial Position

The total assets of the Biotest Group increased from € 1,042.3 million as of 31 December 2018 to € 1,091.0 million as of 30 September 2019. The increase in noncurrent assets by € 35.3 million to € 582.5 million as of 30 September 2019 is mainly attributable to the first-time application of IFRS 16 Leases and the associated recognition of rights of use in the amount of € 26.2 million. Current assets increased by € 13.4 million compared with the reporting date of 31 December 2018 to € 508.5 million as of the reporting date of 30 September 2019. These changes are based on several effects: Inventories increased by € 49.0 million to secure sales planned for the coming months, while trade receivables decreased by € 13.9 million. Other assets also decreased by € 16.0 million and other financial assets by € 12.2 million. This was due in particular to a decrease in tax receivables and the surrender claim against trustee from the sale of shares in ADMA Biologics Inc. Cash and cash equivalents increased by € 3.6 million to € 65.5 million as of 30 September 2019 in the first nine months of financial year 2019.

Under total equity and liabilities, equity amounted to € 491.7 million as of 30 September 2019 (31 December 2018: € 495.2 million). As a result, the equity ratio at the end of the first nine months reached a solid 45.1%. Debt increased to € 599.3 million (31 December 2018: € 547.1 million). This increase was mainly due to the drawing of the new loan in the amount of € 50.0 million and the recognition of lease liabilities corresponding to the activation of rights of use in accordance with IFRS 16 Leases.

Cash Flow

The Biotest Group reported operating cash flow from continuing operations of € –31.5 million in the first nine months of 2019, which was mainly caused by negative EBIT of € –8.2 million, by changes in working capital and by payments for financing costs resulting from taking up a new loan. In the same period of the previous year, operating cash flow amounted to € –61.5 million. Cash flow from investing activities for continuing operations amounted to € –9.0 million in the period from January to September 2019 (same period of the previous year: € –35.5 million), which was mainly caused by payments for investments in fixed assets and proceeds from the partial sale of shares in ADMA Biologics Inc. Cash flow from financing activities for continuing operations was € 44.1 million in the first nine months of 2019 (same period of the previous year: € –61.0 million). This was mainly caused by a new loan assumption.

Impact of new accounting standards

IFRS 16 Leases

As of 1 January 2019, IFRS 16 superseded the previous standards on accounting for leases. In the first-time adoption of IFRS 16, Biotest applies the simplified modified retrospective approach with no impact on equity. The comparative figures for the previous year have not been adjusted. For leased assets of low value and for short-term leases (less than twelve months), use is made of the application simplifications and the payments are recognised as an expense in the income statement on a straight-line basis. Furthermore, the new regulations are not applied to leases of intangible assets. The leasing liabilities are shown as part of the financial liabilities.

This had the following effects on the balance sheet as of 30 September 2019: Assets of € 26.2 million are disclosed as right-of-use assets, which mainly relate to right-of-use buildings. At the

same time, financial liabilities increased by € 26.7 million. This includes the assets from finance leases with a carrying amount of € 3.0 million previously recognised in accordance with IAS 17, which were reclassified from property, plant and equipment to right-of-use assets.

In the income statement, the Group's operating result improved by € 0.1 million, while interest expenses rose by € 0.4 million.

B. RESEARCH AND DEVELOPMENT

The costs of research and development in the first nine months of financial year 2019 amounted to € 39.4 million and were thus in line with the comparable period of previous years (Q1-Q3 2018: € 36.2 million; Q1-Q3 2017: € 41.8 million). A complete list of all research and development projects is included in the 2018 Annual Report (pages 18 to 21). Biotest was able to make further progress with the following research and development projects in the period from January to September 2019:

RESEARCH & DEVELOPMENT PROGRESS
IN THE FIRST NINE MONTHS OF 2019

Therapeutic area Haematology	
Fibrinogen	Phase III clinical trials in congenital and acquired fibrinogen deficiency are proceeding according to plan.
Therapeutic area Clinical Immunology	
IgG Next Generation	Phase III study in PID (Primary immune deficiencies), recruitment of adults and children has been completed. The one-year treatment phase runs until the end of Q1 2020. Phase III study in ITP (Immune thrombocytopenia) completed. 34 patients were treated in the study. The evaluation of the data is currently taking place. Initial results confirm the expectations regarding efficacy and safety.
Therapeutic area Intensive Care Medicine	
Trimodulin	Coordination with the U.S. Food and Drug Administration (FDA), EMA (European Medicines Agency) and Paul-Ehrlich-Institut took place. Phase III study and paediatric development plan in preparation.

The monoclonal antibody BT-061 was sold to a partner in July 2019. The transfer of the project to the partner is in progress. All activities on the immunoconjugate BT-062, including the clinical studies, have been completed and the development project BT-062 is therefore finalised. The licensing activities for the monoclonal antibody BT-063 are still underway.

C. MARKETING AND DISTRIBUTION

The first nine months of 2019 were dominated by a worldwide undersupply of immunoglobulins and rising prices. This was primarily due to the high demand for IgG products in the high-priced US market, driven by better diagnosis and additional applications. This led to increased product allocation to the USA by other manufacturers at the expense of the other markets. All major plasma product manufacturers are currently expanding their plasma collection and production capacities to respond to increased demand.

In contrast to IgG, prices for albumin have fallen as of recently. This can be explained by the good supply of albumin to the market due to the interlinked production, with a relatively slower growth of the albumin market.

Price pressure in the market for plasmatic coagulation factors increased further in the first nine months of 2019 as a result of recombinant alternatives with long half-lives and new competitors in the field of haemophilia A.

Cytotect®CP was newly approved in Italy and Spain in the third quarter of 2019. New approvals were also granted for the following products: Fovepta® in Algeria, Hepatect® CP in Algeria, Fovepta® in Indonesia and Albiomin® in Hong Kong.

In Turkey, marketing authorisations were transferred to a new distribution partner.

MARKETING & DISTRIBUTION PROGRESS IN THE FIRST NINE MONTHS OF 2019

Therapeutic area Clinical Immunology	
Intratect®	The addition of the neurological indications chronic inflammatory demyelinating polyneuropathy (CIDP) and multifocal motor neuropathy (MMN) in the area of secondary immunodeficiencies (SID) was implemented in numerous markets of relevance for Biotest. Implementation in other countries is proceeding according to plan.
Cytotect® CP, Varitect® CP, Hepatect® CP/ Zutectra®	As part of the 19th Congress of the European Society for Organ Transplantation (ESOT), one of the largest international transplant congresses, Biotest held a very successful symposium on hyperimmunoglobulins in September 2019. More than 200 participants underscored the high interest in the special products Hepatect® CP/Zutectra and Cytotect® CP and their use in transplantation.
Albiomin®	The distribution contract for the import of albumin to China was signed. The first import to China is planned for the fourth quarter of 2019. The demand for albumin as a raw material in cell and tissue therapy is increasing on the world market. Biotest will continue to expand this market segment.
Therapeutic area Haematology	
Haemoctin®	Approval has been granted in other countries (e.g. the United Kingdom and Hungary).
Plasma & Services	
The Biotest Group opened a plasma collection centre in Hanover, Germany in January 2019 and Biotest also received the operating permit for the ninth plasma collection centre in Hungary in April 2019. By 30 September 2019, Biotest is operating 21 plasma collection centres in Europe.	

D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. CHANGE IN OUTLOOK REPORT

The Biotest Group's outlook has not changed significantly from its presentation in the 2018 Annual Report (page 27 to 30).

Partnering efforts are more complex and time-consuming than expected, therefore the possibility of forecasting without partnering cannot be ruled out. EBIT of € –15 to –35 million could then be expected, while EBIT of € –5 to +5 million is forecast if partnering agreements are successfully concluded.

II. RISK REPORT

The risk situation of the Biotest Group has not changed significantly since the presentation in the Annual Report 2018 (pages 30 to 39).

Due to the new financing, the financing risk is now considered low by the Management Board (before as medium).

III. OPPORTUNITIES REPORT

The opportunities situation of the Biotest Group has not changed significantly compared to the presentation in the Annual Report 2018 (pages 39 and 40).

E. SUPPLEMENTARY REPORT

On 8 November 2019, Biotest Real Estate Corporation, Wilmington (Delaware), USA, a 100% subsidiary of Biotest AG, sold a property in Boca Raton, Florida, USA.

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 September 2019

in € million	**Q3 2019**	Q3 2018	**Q1–Q3 2019**	Q1–Q3 2018
Revenue	99.8	88.9	294.9	289.6
Cost of sales	–70.5	–55.1	–210.7	–191.9
Gross profit	**29.3**	**33.8**	**84.2**	**97.7**
Other operating income	2.4	3.9	12.9	7.0
Marketing and distribution costs	–11.9	–11.7	–35.5	–37.3
Administrative expenses	–7.1	–7.8	–22.5	–23.8
Research and development costs	–11.8	–13.4	–39.4	–36.2
Other operating expenses	–3.3	–0.6	–4.9	–2.6
Change in impairments on financial assets measured at amortised cost	–0.4	0.2	–3.1	0.3
Operating profit	**–2.7**	**4.4**	**–8.2**	**5.1**
Fair value adjustments on financial instruments measured at fair value	–	–0.7	11.6	–4.0
Financial income	1.2	2.0	4.3	10.3
Financial expenses	–2.9	–7.5	–9.6	–23.2
Financial result	**–1.7**	**–6.2**	**6.3**	**–16.9**
Earnings before taxes	**–4.4**	**–1.8**	**–1.9**	**–11.8**
Income taxes	–0.5	3.2	–1.0	5.2
Earnings after taxes from continuing operations	**–4.9**	**1.3**	**–2.9**	**–6.6**
Earnings after taxes from discontinued operations	–	3.8	–	197.5
Earnings after taxes (total)	**–4.9**	**5.1**	**–2.9**	**190.9**
Attributable to:				
Equity holders of the parent	**–4.9**	**5.1**	**–2.9**	**190.9**
thereof from continuing operations	–4.9	1.3	–2.9	–6.6
thereof from discontinued operations	–	3.8	–	197.5
Earnings per share in €	**–0.13**	**0.13**	**–0.08**	**4.81**
thereof from continuing operations	–0.13	0.03	–0.08	–0.18
thereof from discontinued operations	–	0.10	–	4.98

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 September 2019

in € million	30 September 2019	31 December 2018
ASSETS		
Non-current assets		
Intangible assets	13.9	16.4
Property, plant and equipment	515.6	512.7
Right-of-use assets	26.2	–
Investments in joint ventures	1.9	1.9
Other assets	7.7	0.2
Other financial assets	10.0	7.4
Deferred tax assets	7.2	8.6
Total non-current assets	**582.5**	**547.2**
Current assets		
Inventories	257.3	208.3
Contract assets	33.2	30.5
Trade receivables	104.8	118.7
Current income tax assets	0.2	0.4
Other assets	6.9	22.9
Other financial assets	34.1	46.3
Cash and cash equivalents	65.5	61.9
	502.0	**489.0**
Assets held for sale	6.5	6.1
Total current assets	**508.5**	**495.1**
Total assets	**1,091.0**	**1,042.3**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	235.2	53.9
Share of profit or loss attributable to equity holders of the parent	–2.9	181.7
Equity attributable to equity holders of the parent	**491.7**	**495.0**
Non-controlling interests	–	0.2
Total equity	**491.7**	**495.2**
Non-current liabilities		
Provisions for pensions and similar obligations	90.1	88.9
Other provisions	2.9	1.2
Financial liabilities	403.8	328.7
Other liabilities	0.2	–
Deferred tax liabilities	1.2	2.7
Total non-current liabilities	**498.2**	**421.5**
Current liabilities		
Other provisions	20.9	22.6
Current income tax liabilities	2.8	2.8
Financial liabilities	6.9	0.7
Contract liabilities	–	2.5
Trade payables	40.1	73.4
Other liabilities	30.5	23.6
Total current liabilities	**101.1**	**125.6**
Total liabilities	**599.3**	**547.1**
Total equity and liabilities	**1,091.0**	**1,042.3**

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 September 2019

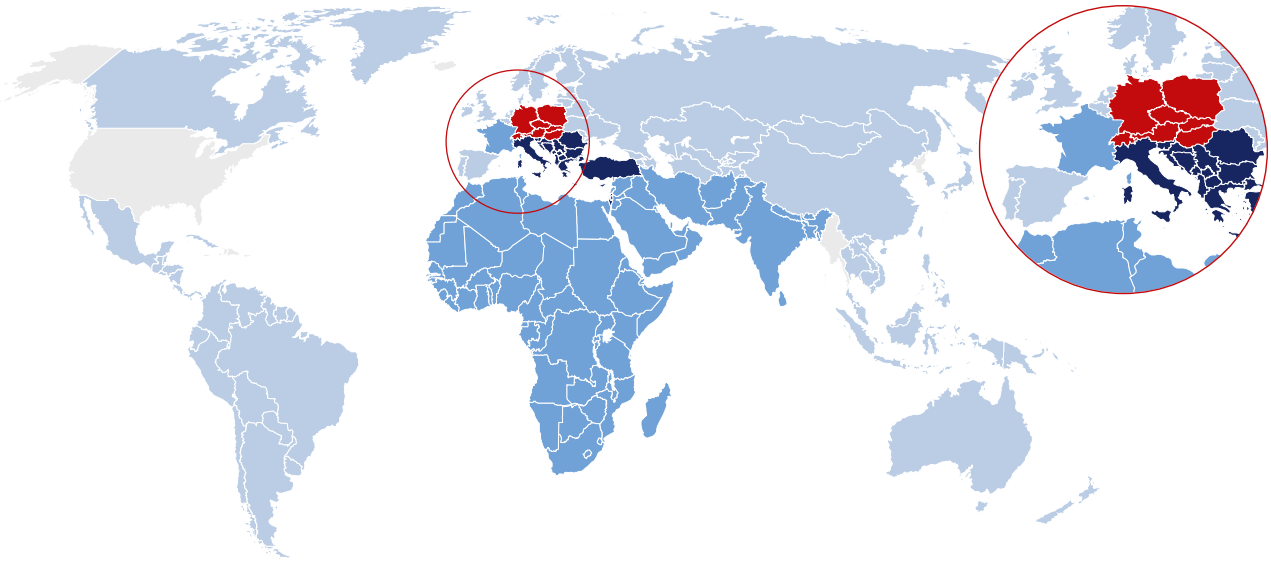
in Millionen €	**Q1–Q3 2019**	Q1–Q3 2018
Operating cash flow before changes in working capital	16.0	27.7
Cash flow from changes in working capital	–37.0	–84.9
Interest and taxes paid	–10.5	–4.3
Cash flow from operating activities from continuing operations	**–31.5**	**–61.5**
Cash flow from operating activities from discontinued operations	–	–0.5
Cash flow from operating activities total	**–31.5**	**–62.0**
Cash flow from investing activities from continuing operations	–9.0	–35.5
Cash flow from investing activities from discontinued operations	–	256.3
Cash flow from investing activities total	**–9.0**	**220.8**
Cash flow from financing activities from continuing operations	44.1	–61.0
Cash flow from financing activities from discontinued operations	–	–
Cash flow from financing activities total	**44.1**	**–61.0**
Cash changes in cash and cash equivalents	**3.6**	**97.8**
Exchange rate-related changes in cash and cash equivalents	–	–0.5
Cash and cash equivalents on 1 January	61.9	22.3
Cash and cash equivalents on 30 September	**65.5**	**119.6**
thereof from discontinued operations	–	–
thereof from continuing operations	**65.5**	**119.6**

Dreieich, 14 November 2019
Biotest Aktiengesellschaft
Board of Management

Dr Michael Ramroth
Chairman of the
Board of Management

Dr Georg Floß
Member of the
Board of Management

THE FOUR SALES REGIONS OF BIOTEST



FINANCIAL CALENDAR

30 MARCH 2020
Annual Report 2020

8 MAY 2020
Three-month report for 2020
Annual General Meeting

13 AUGUST 2020
Half-year report for 2020

12 NOVEMBER 2020
Nine-month report for 2020

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