

# QUARTERLY STATEMENT AS OF 31 MARCH 2019



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### **BUSINESS PERFORMANCE**

### A. AT A GLANCE

Unless otherwise stated, the following figures relate exclusively to continuing operations.

In the first quarter of 2019, the Biotest Group reported revenue of  $\in$  77.5 million. This is a decrease of 11.9% over the  $\in$  88.0 million in sales during the same period of the previous year.

EBIT at Group level amounted to  $\leq -9.9$  million in the first three months of the 2019 financial year (same period of the previous year:  $\leq -3.0$  million).

Plasma Service Europe GmbH, Dreieich, Germany, a 100% subsidiary of Biotest AG, acquired a plasmapheresis centre in Hanover in January 2019. Another centre was opened in Budapest in April 2019. Thus, the Group has expanded its own network of plasma collection stations in Europe to 21 to secure the long-term supply of plasma.

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 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 as Chairman of the Board of Management of Biotest AG with effect from 1 May 2019.

#### **Result of operations**

In the first three months of 2019, the Biotest Group generated revenue of € 77.5 million, after € 88.0 million in the same period of the previous year. The decline of 11.9% is reflected in the Therapy and Plasma & Services segments. In the Therapy segment, an unexpected delay in the transfer of approval to a new distributor in Turkey and the planned reallocation of Albiomin® in particular to high-priced sales markets in the second half of 2019 caused the volume-related revenue decline. The lower sales in the Plasma & Services segment resulted primarily from reduced toll manufacturing to expand capacities for in-house production.

#### SALES BY SEGMENT

Other Segments Biotest Group	1.9	1.4	35.7
Plasma & Services	7.6	12.3	-38.2
Therapy	68.0	74.3	-8.5
in € million	Q1 2019	Q1 2018	Change in %

The decline in sales was evident in all four sales regions. At 42.5 %, Central Europe made the largest contribution to sales, as in the prior-year period (40.6%).

in € million	Q1 2019	Q1 2018	Change in %
Central Europe	32.9	35.7	-7.8
Eastern and Southern Europe	11.9	15.7	-24.2
Intercontinental Middle East, Africa	16.3	16.6	-1.8
and France	16.4	20.0	-18.0
Biotest Group	77.5	88.0	-11.9

DEVELOPMENT OF SALES BY REGIONS

EBIT from continuing operations was € –9.9 million in the first three months of 2019 (same period of the previous year: € -3.0 million). It includes expenses for the Biotest Next Level project of € -16.9 million (same period of the previous year: € –15.2 million) and income from insurance compensation in the amount of € 4 million. The weaker EBIT compared to the previous year is primarily due to lower sales. In addition, a 17.6% 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. For the first three months of the current financial year, the EBIT margin was -12.8% after -3.4% in the same period of the previous year. The lower sales as the cause of the EBIT development particularly affected the Therapy segment. In the Plasma & Services segment, earnings improved and a positive EBIT of € 1.2 million was achieved

EBIT BY SEGMENT

in€ million	Q1 2019	Q1 2018	Change in%
Therapy	-10.1	-2.1	>100
Plasma & Services	1.2	0.0	>100
Other Segments	-1.0	-0.9	-11.1
Biotest Group	-9.9	-3.0	>100

EBIT from discontinued operations amounted to  $\notin$  0.0 million in the reporting period after  $\notin$  35.3 million in the same period of the previous year. In the prior-year period, 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.

At  $\in$  9.0 million, the financial result for the first quarter of 2019 was  $\in$  16.8 million more positive than in the same period of the previous year ( $\in$  –7.8 million). This was mainly due to the income of  $\in$  10.7 million from the measurement at fair value as of the balance sheet date, which reflects the surrender claim against the trustee of the underlying shares in ADMA Biologics Inc., USA.

Earnings after taxes from continuing operations therefore improved to  $\notin -1.2$  million in the first quarter of 2019 compared with  $\notin -8.1$  million in the first quarter of the previous year.

Earnings after taxes from discontinued operations amounted to  $\notin$  0.0 million in the first three months of 2019 after  $\notin$  35.1 million in the same period of the previous year.

For the first quarter of 2019, Biotest Group's total earnings after taxes (EAT) were  $\notin$  -1.2 million (same period of the previous year:  $\notin$  27.0 million). This results in earnings per ordinary share of  $\notin$  -0.04 after  $\notin$  0.67 in the same period of the previous year.

#### **Financial position**

The balance sheet total of the Biotest Group increased slightly from  $\in$  1,042.3 million as of 31 December 2018 to  $\in$  1,044.6 million as of 31 March 2019. The  $\in$  21.3 million increase in noncurrent assets is mainly attributable to the first-time application of IFRS 16 Leases and the associated capitalisation of rights of use in the amount of  $\notin$  21.4 million. On the other hand, current assets decreased by  $\notin$  19.0 million compared with the 31 December 2018 reporting date. This change is based on several effects: Inventories increased by  $\notin$  27.7 million to secure the sales planned for the coming months, while trade receivables decreased by  $\notin$  24.5 million in line with the decline in sales. Other assets also decreased from  $\notin$  22.9 million to  $\notin$  12.9 million, in particular due to a decrease in tax receivables. Cash and cash equivalents decreased by  $\notin$  18.5 million in the first quarter of 2019.

Under equity and liabilities, equity amounted to  $\notin$  493.9 million as of 31 March 2019 (31 December 2018:  $\notin$  495.2 million). As a result, the equity ratio reached 47.3%. Debt increased slightly to  $\notin$  550.7 million (31 December 2018:  $\notin$  547.1 million). Non-current debt increased by  $\notin$  21.6 million, mainly due to the recognition of lease liabilities corresponding to the capitalisation of rights of use in accordance with IFRS 16 Leases. Current debt decreased by  $\notin$  17.8 million to  $\notin$  107.8 million as of 31 March 2019. This was due in particular to the decline in trade payables.

#### **Cash Flow**

The Biotest Group reported operating cash flow from continuing operations of € 7.9 million in the first three months of 2019, which was mainly caused by negative EBIT of € –9.9 million. In the same period of the previous year, operating cash flow amounted to -32.3 million. Cash flow from investing activities for continuing operations amounted to € –9.7 million in the in the period from January to March 2019 (same period of the previous year: € –10.9 million), which was mainly caused by payments for investments in fixed assets. Cash flow from financing activities for continuing operations was € –0.9 million in the first three months of 2019 (same period of the previous year: € 65.0 million). This was mainly due to payments for the repayment portion of lease liabilities following the introduction of IFRS 16.

#### 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 31 March 2019: Assets of  $\notin$  21.4 million are disclosed as rightof-use assets, which mainly relate to right-of-use buildings. At the same time, financial liabilities increased by  $\notin$  21.6 million. In addition, the assets from finance leases with a carrying amount of  $\notin$  3.1 million previously recognized under IAS 17 are reclassified from property, plant and equipment to right-of-use assets.

In the income statement, the Group's operating result improved by  $\notin$  0.2 million, while interest expenses rose by  $\notin$  0.4 million.

### **B. RESEARCH AND DEVELOPMENT**

Compared to the same quarter of the previous year, the costs of research and development increased by 17.6 % to € 14.0 million in the first three months of the business year 2019 (same period of the previous year: € 11.9 million). This was mainly due to higher expenses for the production of hospital materials for the IgG Next Generation and Trimodulin projects. A complete list of all research and development projects is provided 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 March 2019:

# RESEARCH & DEVELOPMENT PROGRESS IN THE FIRST THREE MONTHS OF 2019

Therapeutic area Haematology		
Fibrinogen	Phase III clinical trials on congenital and acquired fibri- nogen deficiency are proceeding according to plan.	
Therapeutic	area Clinical Immunology	
lgG Next Generation	Phase III study in PID (Primary immune deficiencies), recruitment of adults and children has been comple- ted. The treatment phase is underway (1 year). Phase III study in ITP (Immune thrombocytopenia). Study completed. Evaluation underway.	
Therapeutic	area Intensive Care Medicine	
Trimodulin	Coordination with the U.S. Food and Drug Administra- tion (FDA) continues. Phase III study and paediatric de- velopment plan in preparation.	

### C. MARKETING AND DISTRIBUTION

The first quarter of 2019 was characterised by rising global demand for immunoglobulins (IVIGs) and at the same time rising prices.

At the annual meeting of the European Society for Blood and Marrow Transplantation in March 2019 in Frankfurt/Main, Biotest presented the new communication campaign for Cyototect and other specialty products. The new campaign aims to support the market penetration of the specialty portfolio in the various sales regions.

#### MARKETING & DISTRIBUTION PROGRESS IN THE FIRST THREE MONTHS OF 2019

Haemoctin® SDH

Therapeutic area Clinical Immunology			
Intratect <sup>®</sup>	January 2019: Extension of approved indications in 22 European countries to include the neurological indica- tions chronic inflammatory demyelinating polyneuro- pathy (CIDP) and multifocal motor neuropathy (MMN) as well as an extension in secondary immunodeficien- cies (SID) February 2019: New approval for Intratect 10 %, 50 ml in Pakistan		
Cytotect CP	February 2019: national approval of Cytotect CP received in Slovenia		
Zutectra	Approval of Zutectra in Iran		
Therapeutic a	irea Haematology		
Haemoctin <sup>®</sup>	March 2019: Approval granted in 13 European coun- tries for the half solvent volume of the Factor VIII drug		

### 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  $\notin$  -15 to -35 million could then be expected, while EBIT of  $\notin$  -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).

#### **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

There were no events after the balance sheet date that had a significant influence on the earnings, asset or financial position.

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.

Biotest also received an additional insurance compensation payment of  $\notin$  5.5 million in April.

The talks mentioned in the 2018 Annual Report (page 37) to raise further debt capital were continued. The key points are currently being negotiated with several banks and financing institutions. The risk assessment remains unchanged.

# CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 March 2019

in € million	Q1 2019	Q1 2018
Revenue	77.5	88.0
Cost of sales		-57.8
Gross profit	19.5	30.2
Other operating income	4.5	0.9
Marketing and distribution costs	-11.1	-12.4
Administrative expenses		-8.6
Research and development costs		-11.9
Other operating expenses	-0.9	-1.0
Change in impairments on financial assets measured at amortised cost	-0.4	-0.2
Operating profit		-3.0
Fair value adjustments on financial instruments measured at fair value	9.9	2.2
Financial income	2.1	2.0
Financial expenses	-3.1	-11.9
Financial result	9.0	-7.7
Earnings before taxes	-0.9	-10.7
Income taxes	-0.3	2.6
Earnings after taxes from continuing operations	-1.2	-8.1
Earnings after taxes from discontinued operations		35.1
Earnings after taxes (total)	-1.2	27.0
Attributable to:		
Equity holders of the parent	-1.2	27.0
thereof from continuing operations		-8.1
thereof from discontinued operations	0.0	35.1
Non-controlling interests		-
thereof from continuing operations		_
thereof from discontinued operations		
Earnings per ordinary share in €	-0.04	0.67
thereof from continuing operations	-0.04	-0.22
thereof from discontinued operations		0.89

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 March 2019

in€million	31 March 2019	31 December 2018
ASSETS		
Non-current assets		
Intangible assets	17.0	16.4
Property, plant and equipment		512.7
Right-of-Use assets	24.5	
Investments in joint ventures		1.9
Other assets	0.1	0.2
Other financial assets	7.7	7.4
Deferred tax assets	8.7	8.6
Total non-current assets	568.5	547.2
Current assets		
Inventories	236.0	208.3
Contract assets		30.5
Trade receivables	94.2	118.7
Current income tax assets	0.5	0.4
Other assets		
Other financial assets		46.3
Cash and cash equivalents	43.4	61.9
	469.9	489.0
Assets held for sale		6.1
Total current assets	476.1	495.1
Total equity and liabilities	1,044.6	1,042.3
EQUITY AND LIABILITIES		
Equity		
Subscribed Capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	52.9	53.9
Share of profit or loss attributable to equity holders of the parent	181.6	181.7
Equity attributable to equity holders of the parent	493.9	495.0
Non-controlling interests	_	0.2
Total equity	493.9	495.2
Non-current liabilities		
Provisions for pensions and similar obligations	89.0	88.9
Other provisions	0.9	1.2
Financial liabilities	350.3	328.7
Other liabilities	0.1	-
Deferred tax liabilities	2.6	2.7
Total non-current liabilities	442.9	421.5
Current liabilities		
Other provisions	22.7	22.6
Current income tax liabilities	3.0	2.8
Financial liabilities	2.4	0.7
Contract liabilities	3.4	2.5
Trade payables	50.6	73.4
······································	25.7	23.6
Other liabilities	107.8	125.6
Other liabilities Total liabilities Total liabilities		<u> </u>

# CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 March 2019

in € million	Q1 2019	Q1 2018
Operating cash flow before changes in working capital	-3.0	-0.2
Cash flow from changes in working capital		-24.5
Interest and taxes paid		-7.6
Cash flow from operating activities from continuing operations		-32.3
Cash flow from operating activities from discontinued operations		0.5
Cash flow from operating activities total		-31.8
Cash flow from investing activities from continuing operations		-10.9
Cash flow from investing activities from discontinued operations		-
Cash flow from investing activities total		-10.9
Cash flow from financing activities from continuing operations		65.0
Cash flow from financing activities from discontinued operations		-
Cash flow from financing activities total		65.0
Cash changes in cash and cash equivalents		22.3
Exchange rate-related changes in cash and cash equivalents	_	-1.9
Cash and cash equivalents on 1 January	61.9	22.3
Cash and cash equivalents on 31 March	43.4	42.7
thereof from discontinued operations		_
thereof from continuing operations	43.4	42.7

Dreieich, 7 May 2019 Biotest Aktiengesellschaft Board of Management

Mr. Kanno,

Dr Michael Ramroth Chairman of the Board of Management

OGD\_  $\langle$ ()

Dr Georg Floß Member of the Board of Management

## THE FOUR SALES REGIONS OF BIOTEST



# FINANCIAL CALENDAR

# ACKNOWLEDGEMENTS

**14 AUGUST 2019** Half-year report for 2019

**14 NOVEMBER 2019** Nine-month report for 2019

# PUBLISHER

Biotest AG Landsteinerstr. 5 63303 Dreieich Germany www.biotest.com

### **IR Contact**

Dr Monika Buttkereit Phone: +49 (0) 6103 801 4406 Fax: +49 (0) 6103 801 347 investor\_relations@biotest.de

### **PR Contact**

Dirk Neumüller Phone: +49 (0) 6103 801 269 pr@biotest.com

### CONCEPT AND DESIGN

Scheufele Hesse Eigler Kommunikationsagentur GmbH, Frankfurt am Main, Germany

### EDITORIAL OFFICE AND PROJECT MANAGEMENT

cometis AG, Wiesbaden, Germany

#### PHOTOGRAPHY

Simone Kiefer, Dreieich, Germany

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.



BIOTEST AG | Landsteinerstr. 5, 63303 Dreieich, Germany, www.biotest.com