Biotest
From Nature for Life

QUARTERLY STATEMENT
1 JANUARY TO 30 SEPTEMBER 2022

CONTENTS

BUSINESS PERFORMANCE

A. AT A GLANCE

The Biotest Group recorded revenue of € 360.8 million in the first nine months of financial year 2022. This represents a decline of -2.9 % compared to revenue of € 371.4 million in the same period of the previous year.

Compared to the previous year, EBIT at Group level declined to € -19.0 million in the first nine months of financial year 2022 (same period of the previous year: € -11.2 million).

Characterised by a worldwide higher demand for immunoglobulins, while the pandemic situation has remained difficult, Biotest was nevertheless still able to increase its sales significantly compared to the previous year, particularly of Intratect®, Biotest's standard immunoglobulin, due to a cautious and effective pricing policy.

The increase in revenue in the immunoglobulins and hyperimmunoglobulins product area could not fully compensate the decline in revenue in other product areas.

The continuous expansion of the company's own plasma collection network in Europe is one component of Biotest's strategy. This is intended to ensure a sufficient supply of human blood plasma, the most important raw material for Biotest's preparations. By the reporting date, 14 November 2022, seven new donation centres were opened.

In addition, Biotest acquired small quantities of US plasma from Grifols in the first nine months of 2022. These were used to produce clinical material for the Trimodulin study.

With support from the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung BMBF) and the Federal Ministry of Health (Bundesministerium für Gesundheit BMG) in the form of research grants totalling € 29 million, Biotest is continuing the development programme of the development product Trimodulin in moderate or severe COVID-19 disease. The first phase III study in patients with moderate or severe COVID-19 disease was submitted in May 2022. The submission of the phase III study with Trimodulin in patients with severe community-acquired pneumonia took place in October 2022.

Further progress was made in the Biotest Next Level expansion project. The dossier for IgG Next Generation was submitted to the drug regulatory authorities on 31 March 2022. The round of questions following the preliminary assessment report in the decentralised procedure was already concluded when the answers were submitted. The next step in the procedure is now the final assessment report. Approval and thus marketing authorisation for IgG Next Generation is expected by the end of 2022.

Following submission, Biotest was able to announce the signing of a licensing agreement for its novel immunoglobulin (IgG Next Generation) with the Saudi Arabian company Pharma Pharmaceutical Industries (PPI). Based on this agreement and with the help of Biotest's immunoglobulin expertise, PPI will be able to launch the first local polyvalent intravenous immunoglobulin in Saudi Arabia. The agreement is based on an upfront payment for the license, which will be based on three milestones from the signing of the contract, and a ten-year manufacturing and supply agreement. Biotest will manufacture the product at the new BNL fractionation plant. The market launch in the Kingdom of Saudi Arabia is expected by the end of 2023.

In addition to this submission, data was also submitted on Paste V, the precursor for Albiomin, which is produced at the new Biotest Next Level plant. Approval of the change notification in the EU was received in September 2022. The submission to the international authorities will take place by the end of 2022.

Biotest continues to work intensively on bringing the product candidates Trimodulin and Fibrinogen, which are currently in phase III, to marketing authorization as soon as possible.

The voluntary takeover offer published on 26 October 2021 for the shares of Biotest AG was effectively completed ("closing") on 25 April 2022. Following the closing of the public tender offer and the completion of the acquisition of Tiancheng (Germany) Pharmaceutical Holdings AG, Grifols now holds 96.20 % of the ordinary shares and 43.2 % of the preference shares and therefore 69.72 % of the share capital of Biotest AG. On 2 May 2022, Grifols, S.A. published pursuant to Section 23 para. 2 sentence 1 of the German Securities Acquisition and Takeover Act (Wertpapiererwerbs- und Übernahmegesetz, WpÜG) that Grifols, S.A. had acquired an additional 0.94 % of the voting rights in Biotest AG. Grifols, S.A. thus holds a total of 97.14 % of the voting rights in Biotest AG.

Earnings position

In the first nine months of the financial year 2022, the Biotest Group generated revenue of € 360.8 million after € 371.4 million in the same period of the previous year. The Therapy segment saw a decline in revenue of 3.6 % (€ 12.0 million). This resulted from the declining demand for drug therapies involving coagulation factors. Sales of merchandise in the segment Other Segments also declined by € 0.8 million compared to the same period of the previous year. The 6.1 % increase in sales in the Plasma & Services segment, on the other hand, was mainly due to higher toll manufacturing.

SALES BY SEGMENT

in € million	**Q1 - Q3 2022**	Q1 - Q3 2021	Change in %
Therapy	317.8	329.8	–3.6
Plasma & Services	38.5	36.3	6.1
Other Segments	4.5	5.3	–15.1
Biotest Group	**360.8**	**371.4**	**–2.9**

At the beginning of the financial year 2022, the sales regions were reorganised in order to optimise market preparation. Thereby, the country allocation to the regions was changed. At the level of the individual sales region, Biotest recorded revenue growth in the Central Europe and Intercontinental regions in the first nine months of 2022 compared to the same period of the previous year. This growth was more than offset by the stronger decline in sales in the regions Middle East, Africa and France as well as Eastern and Southern Europe, Central Asia, America. Sales fell particularly sharply (by 25.9 %) in the Eastern and Southern Europe, Central Asia, America region. This development is due, among other factors, to weaker sales in Turkey, Iraq and Russia compared to the same period of the previous year. In terms of absolute sales figures, the Central Europe region made the largest contribution, as in the previous year. The positive development in this sales region as well as in the Intercontinental region resulted, among other factors, from the increased prices and sales volumes of the product Intratect®.

SALES BY REGIONS

in € million	Q1 - Q3 2022	Q1 - Q3 2021*	Change in %
Central Europe	150.4	139.4	7.9
Eastern and Southern Europe, Central Asia, America*	71.1	95.9	-25.9
Intercontinental*	64.1	57.3	11.9
Middle East, Africa and France*	75.2	78.8	-4.6
Biotest Group	**360.8**	**371.4**	**-2.9**

* Previous year's figures have been adjusted according to the definition of the sales regions in 2022.

EBIT amounted to € -19.0 million in the first nine months of the financial year 2022 (same period of the previous year: € -11.2 million). This includes expenses for the Biotest Next Level project of € 63.9 million (same period of the previous year: € 57.5 million). The decline in EBIT compared to the same period of the previous year is mainly due to higher ramp-up costs for the newly built BNL plant (€ -5.9 million), higher BNL R&D costs (€ -0.5 million), higher BNL administrative costs (€ -0.5 million) and other costs (€ -1.2 million). In addition, the increased other operating expenses from impairment losses on financial assets measured at amortised cost in the amount of € 2.2 million had a negative effect compared to the same period of the previous year (same period of the previous year: other operating income in the amount of € 1.9 million). The € 1.8 million increase in administrative expenses in connection with higher recruitment and consulting costs also contributed to the deterioration in the operating result.

EBIT BY SEGMENT

in € million	Q1 - Q3 2022	Q1 - Q3 2021	Change in %
Therapy	–14.3	–16.2	11.7
Plasma & Services	–2.2	6.0	>-100
Other Segments	–2.5	–1.0	>-100
Biotest Group	**–19.0**	**–11.2**	**–69.6**

In the Therapy segment, EBIT remained in negative territory, but improved by € 1.9 million (11.7 %), mainly due to the lower cost of sales. However, this positive development could only partially compensate for the € 8.2 million decrease in EBIT in the Plasma & Services segment. The reasons for this included the higher cost of sales (by € 6.5 million) and the lower other operating income (by € 2.5 million). EBIT for Other Segments also remained negative and declined by around € 1.5 million compared to the same period of the previous year, which was partly due to higher cross-divisional administrative expenses.

Adjusted for the expenses for the Biotest Next Level expansion project, EBIT amounted to € 44.9 million in the first nine months of 2022 and was thus clearly positive, as in the previous year (same period of the previous year: € 46.3 million). The adjusted EBIT margin for the first nine months of the current financial year was 12.4 % after 12.5 % in the same period of the previous year.

ADJUSTED EBIT

in € million	Q1 - Q3 2022	Q1 - Q3 2021	Change in %
EBIT	–19.0	–11.2	-69.6
Expenses for Biotest Next Level*	63.9	57.5	11.1
ADJUSTED EBIT	**44.9**	**46.3**	**-3.0**

* Expenses for Biotest Next Level mainly include cost of sales of € 33.6 million (same period of the previous year: € 27.7 million) and research and development costs of € 29.8 million (same period of the previous year: € 29.3 million) for products that can only be manufactured in the new facility).

The financial result for the first nine months of the current financial year improved to € -11.9 million (same period of the previous year: € -16.5 million). This development is essentially due to income from value adjustments of the surrender claim against the trustee of shares in ADMA Biologics Inc. at fair value amounting to € 3.4 million (same period of the previous year: expenses of € -2.5 million).

In view of the influencing factors described above, the Biotest Group's earnings after taxes declined to € -34.2 million in the first three quarters of financial year 2022, compared to € -28.3 million in the same period of the previous year. This results in earnings per ordinary share of € -0.87 after € -0.73 for the same period of the previous year.

Asset position

The total assets of the Biotest Group decreased from € 1,104.2 million as of 31 December 2021 to € 1,079.3 million as of the reporting date 30 September 2022.

Non-current assets remained more or less unchanged, declining by € 0.3 million to € 581.8 million as of the balance sheet date compared to the balance sheet figure at the end of 2021 (31 December 2021: € 582.0 million). This decline is mainly due to a € 2.9 million reduction in deferred tax assets and a € 7.6 million reduction in property, plant and equipment. Conversely, other financial assets increased by € 7.9 million. This is mainly due to financing granted to third parties to support the establishment of new plasma collection centers.

Current assets decreased by € 24.7 million to € 497.5 million compared to the reporting date 31 December 2021 (€ 522.2 million). Trade receivables were down by € 13.9 million compared to the end of 2021 due to the balance sheet date. Cash and cash equivalents also declined by € 51.1 million to € 53.3 million in the first nine months of 2022. On the other hand, inventories increased by € 24.1 million and other financial assets by € 10.4 million. The increase is mainly due to an increase in cash deposits of € 4.9 million and the claim for return against the trustee in the amount of € 4.4 million.

On the liabilities side, equity amounted to € 343.8 million as of 30 September 2022 (31 December 2021: € 380.4 million). This decline is due to the negative result in the reporting period. The equity ratio was 31.9 % at the end of the first nine months of the current financial year (31 December 2021: 34.4 %). Debt increased by € 11.7 million to € 735.5 million as of 30 September 2022. Non-current liabilities increased by € 8.4 million to € 625.9 million since 31 December 2021, mainly due to an increase in non-current financial liabilities and pension provisions. Current liabilities increased by € 3.2 million to € 109.6 million as of 30 September 2022. This was mainly due to an increase of € 4.9 million in other provisions and € 7.3 million in current financial liabilities. This was offset by a € 8.6 million decline in trade payables.

Financial position

In the first nine months of 2022, the Biotest Group recorded an operating cash flow of € -16.8 million, primarily due to changes in working capital of € -13.7 million. Operating cash flow in the same period of the previous year amounted to € 3.3 million. Cash flow from investing activities amounted to € -24.8 million in the period from January to September 2022 (same period of the previous year: € -19.4 million). The increase is due, among other factors, to payments for investments in fixed assets. Cash flow from financing activities amounted to € -9.6 million in the first nine months of 2022 (previous year: € 24.1 million). Biotest is financed by a subordinated shareholder loan of € 290 million and financing of € 240 million concluded in 2019, of which € 125 million was drawn down as of 30 September 2022. As a result, credit lines of € 115 million are available as of 30 September 2022. The change in shareholdings has no direct impact on financing, as the takeover by Grifols S.A. represents a contractually permissible change of control.

B. RESEARCH AND DEVELOPMENT

At € 39.7 million (-2.2 %), the costs for research and development in the first nine months of financial year 2022 were below the comparable figure of the previous year of € 40.6 million. A complete list of all research and development projects is presented in the Annual Report 2021 (page 19).

Biotest was able to make further progress in the following research and development projects in the period from January to September 2022

RESEARCH & DEVELOPMENT PROGRESS IN THE FIRST NINE MONTHS OF 2022

Therapeutic area Clinical Immunology	
Cytotect	A phase III clinical trial (PreCyssion) to prevent transmission of the mother's CMV infection to the unborn child is currently in the treatment phase.
IgG Next Gen	Another study involving high-dose therapy in the dermatological field is currently being planned for Europe and the USA.
Therapeutic area Intensive Care Medicine	
Fibrinogen	The interim analysis in the phase III registration trial (AdFIrst study no. 995) was successful and confirmed the originally planned number of patients. Further interim analysis is planned as soon as 80% of the patients planned for the study can be evaluated.
Trimodulin (IgM Concentrate)	The submissions for the phase III trial in COVID-19 (TRICOVID, 1001) in the various countries are underway. Initial approvals have already been issued. The phase III study in sCAP (ESsCAPE, 996) in the countries selected has been submitted in October 2022.

In addition, Biotest is collecting "real world" data on its marketed products in three ongoing and other planned non-interventional studies (NIS). This serves the continued investigation of safety and efficacy in large patient populations and gaining further knowledge under everyday conditions, such as quality of life, course of treatment and application behaviour.

Research activities with regard to the treatment of a COVID-19 infection

In the phase II trial (ESsCOVID – Escape from severe COVID-19), Trimodulin significantly reduced both the clinical worsening and mortality in a subgroup of 96 COVID-19 patients who were still in an early systemic inflammatory phase compared to those patients who were treated with a placebo. The study results were presented to the Paul Ehrlich Institute (PEI) during a scientific advisory meeting, which recommended that the clinical development in a proposed phase III trial in COVID-19 (TRICOVID) be continued. This development is funded by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung BMBF) and the Federal Ministry of Health (Bundesministerium für Gesundheit BMG) with government grants totalling € 29 million. Of this amount, € 8.8 million was recognised in profit or loss in the first nine months of 2022. In addition, a second phase III study with Trimodulin has been submitted to the authorities in October 2022. In this study 996 (ESsCAPE), patients with severe community-acquired pneumonia are to be treated.

Pentaglobin® is successfully used for severe bacterial infections in combination with antibiotics. Furthermore, Biotest supports the investigation of the efficacy of Pentaglobin® in COVID-19 patients as part of academic-industrial collaborations (Investigator Initiated Studies). This is being done by the University Hospital of Bochum, Germany, in a large international register study. Initial evaluations suggest that Pentaglobin® can also lead to lower mortality in certain COVID-19 patients. Initial data was presented at the Symposium of the International Society of Intensive Care and Emergency Medicine (ISICEM).

C. MARKETING AND DISTRIBUTION

The first nine months of 2022 were characterised by high global demand for immunoglobulins (IgG) at a stable level and rising prices. Prices for Intratect® increased by more than 10 % in some countries. Some markets continue to report supply problems with immunoglobulins (IgG) and in many other countries there are still indications that product shortages could arise in the months ahead. Some regions are also reporting a similar situation with albumin, which is also reflected in a positive development of prices for Albumin of sometimes more than 10 %. The plasma volumes commercially collected in the USA and Europe were back at the level of 2019 for the first time in the first half of 2022 (source: Plasma Protein Therapeutics Association PPTA). However, the products obtained from this plasma will not be available until sometime next year due to the complex production process. The procurement costs for plasma are expected to remain high. The overall situation is also leading some countries (e.g. Saudi Arabia, Romania, the UK) to launch initiatives to improve self-sufficiency in the future.

Transplant activity remains down due to the impact of the corona pandemic, but is slowly recovering and moving towards pre-corona levels. Biotest expects transplant numbers to recover in the medium term and anticipates an increase in these life-saving interventions, which is already reflected in the positive sales signals for Cytotect, for example.

MARKETING & DISTRIBUTION PROGRESS IN THE FIRST NINE MONTHS OF 2022

Therapeutic area Clinical Immunology	
Cytotect® CP	New authorisation in Libya.
Hepatect®CP	Tenders were won in Algeria and Iraq. New authorisation in Libya.
Fovepta®	New market authorisation received in Saudi Arabia and new authorisation in Libya.
Intratect®	Volume increases in key markets such as Central Europe. Increase in list/reimbursement/sales prices in a number of countries, including Germany, Austria, Hungary, the UK and Spain. Special import license and initial sales of Intratect® 50 g/l and 100 g/l in France. New authorisations of Intratect® 5 % and Intratect® 10 % in Libya.
Zutectra®	New authorisation in Turkey.
Therapeutic area Haematology	
Haemoctin®	Extension of the FVIII contract for substantial volumes in Algeria. Significant increase in sales in Palestine and Vietnam. Increased convenience for patients by introducing a new transfer system in Germany and Switzerland. New authorisations for Haemoctin® 250, Haemoctin® 500 and Haemoctin® 1000 in Libya.
Haemonine®	Significant increase in sales in Germany. New authorisations of Haemonine® 500 and Haemonine® 1000 in Libya.
Therapeutic area Intensive Care Medicine	
Pentaglobin®	The increased use of Pentaglobin® in the treatment of COVID-19 patients with secondary bacterial infections generated additional sales, especially in Germany and Italy. New authorisation in Libya.
Albiomin®	Albiomin® 5 % and 20 %: New approval in Ghana and Albiomin® 20 % in Libya.

D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. REPORT ON CHANGES IN THE OUTLOOK

Due to developments during the year, the outlook for the Biotest Group has changed compared to the presentation in the 2021 Annual Report (pages 27 to 30). As presented there, the Board of Management is striving to maintain the sales level of 2021 in financial year 2022, but does not rule out sales being 5-10% lower. Excluding the possible effects of the Russian attacks on Ukraine, the Board of Management would have expected EBIT of € -20 million to € -25 million, taking accelerated R&D activities into account. The risks still seen on 24 March 2022 in connection with Corona and the war in Ukraine have not materialized to the extent expected and are no longer expected for the remaining weeks of the year, therefore an increase in the EBIT loss to € -40 million to € -60 million can be ruled out.

II. RISK REPORT

The risk situation for the Biotest Group has not changed that significantly compared to the situation presented in the Risk Report of the Annual Report 2021 (pages 30-41), with the exception of the risks presented below in connection with the gas supply and the high inflation rate.

This also applies to the assessment of risks in connection with pandemics/epidemics (page 41 in the Annual Report 2021) and plasma procurement. The high level of uncertainty regarding the further spread of the coronavirus will continue in the period after the reporting date. Any possible economic consequences cannot yet be conclusively assessed at the time of preparing this nine-month statement.

Furthermore, Russia's attacks on Ukraine have exacerbated the political and economic risks. For instance, there is a risk that sales in Eastern Europe will not materialise, business partners will experience difficulties in making payments, supply chains will be interrupted, and construction materials, spare parts, supplies and gas can only be purchased with considerable delays and significantly reduced volumes or at substantially higher prices. With regard to gas, there is a risk of significant undersupply or gas supply stops. High inflation rates could also have a significant impact on the asset, financial and earnings position of the Biotest Group. Even a production stoppage cannot be completely ruled out for the remaining weeks of 2022.

Beyond this, there are still no discernible risks that could jeopardise the continued existence of the Biotest Group.

III. OPPORTUNITIES REPORT

The opportunity situation of the Biotest Group has not changed significantly compared to the information presented in the Annual Report 2021 (pages 41 and 42).

E. SUPPLEMENTARY REPORT

On 11 November 2022 Biotest received marketing authorization for new intravenous immunoglobulin Yimmugo® (IgG Next Generation).

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

CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 30 September 2022

in € million	Q3 2022	Q3 2021	Q1 - Q3 2022	Q1 - Q3 2021
Revenue	107.7	113.6	360.8	371.4
Cost of sales	–84.1	–87.8	–280.1	–289.6
Gross profit	**23.6**	**25.7**	**80.7**	**81.7**
Other operating income	0.4	2.7	1.4	5.1
Marketing and distribution costs	–10.8	–10.5	–34.0	–34.2
Administrative expenses	–6.6	–6.3	–22.9	–21.1
Research and development costs	–15.3	–13.6	–39.7	–40.6
Other operating expenses	–1.2	–0.7	–4.4	–2.2
Operating profit	**–9.9**	**–2.6**	**–19.0**	**–11.2**
Financial income	5.5	0.7	12.9	4.9
Financial expenses	–8.5	–8.0	–24.8	–21.4
Financial result	**–3.0**	**–7.3**	**–11.9**	**–16.5**
Earnings before taxes	**–12.9**	**–9.9**	**–30.9**	**–27.7**
Income taxes	–1.4	–0.2	–3.3	–0.6
Earnings after taxes	**–14.3**	**–10.1**	**–34.2**	**–28.3**
Attributable to:				
Equity holders of the parent	–14.3	–10.1	–34.2	–28.3
Earnings per share in €	**-0,37**	**-0,26**	**-0,87**	**-0,73**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 September 2022

in € million	30 September 2022	31 December 2021
ASSETS		
Non-current assets		
Intangible assets	11.9	11.3
Property, plant and equipment	517.1	524.7
Right-of-use assets	26.7	25.3
Investments in joint ventures	4.8	4.5
Other assets	0.5	0.3
Other financial assets	13.5	5.6
Deferred tax assets	7.3	10.2
Total non-current assets	**581.8**	**582.0**
Current assets		
Inventories	268.7	244.6
Contract assets	34.5	39.1
Trade receivables	93.4	107.3
Current income tax assets	0.4	0.7
Other assets	23.7	12.9
Other financial assets	23.6	13.2
Cash and cash equivalents	53.3	104.4
Total current assets	**497.5**	**522.2**
Total assets	**1,079.3**	**1,104.2**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	118.5	184.4
Share of profit or loss attributable to equity holders of the parent	–34.1	–63.4
Equity attributable to equity holders of the parent	**343.8**	**380.4**
Total equity	**343.8**	**380.4**
Non-current liabilities		
Provisions for pensions and similar obligations	118.3	116.5
Other provisions	2.1	2.4
Financial liabilities	504.2	496.4
Other liabilities	0.1	–
Deferred tax liabilities	1.2	2.2
Total non-current liabilities	**625.9**	**617.5**
Current liabilities		
Other provisions	24.8	19.9
Current income tax liabilities	0.4	0.5
Financial liabilities	42.1	34.8
Trade payables	30.2	38.8
Other liabilities	11.9	12.4
Contract liabilities	0.2	–
Total current liabilities	**109.6**	**106.4**
Total liabilities	**735.5**	**723.8**
Total equity and liabilities	**1,079.3**	**1,104.2**

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 September 2022

in € million	Q1 - Q3 2022	Q1 - Q3 2021
Operating cash flow	8.8	12.2
Cash flow from changes in working capital	–13.7	1.8
Interest and taxes paid	–11.9	–10.7
Cash flow from operating activities	**–16.8**	**3.3**
Cash flow from investing activities	**–24.8**	**–19.4**
Cash flow from financing activities	**–9.6**	**24.1**
Cash changes in cash and cash equivalents	**–51.2**	**8.0**
Exchange rate-related changes in cash and cash equivalents	0.1	–0.1
Cash and cash equivalents on 1 January	104.4	71.3
Cash and cash equivalents on 30 September	**53.3**	**79.2**

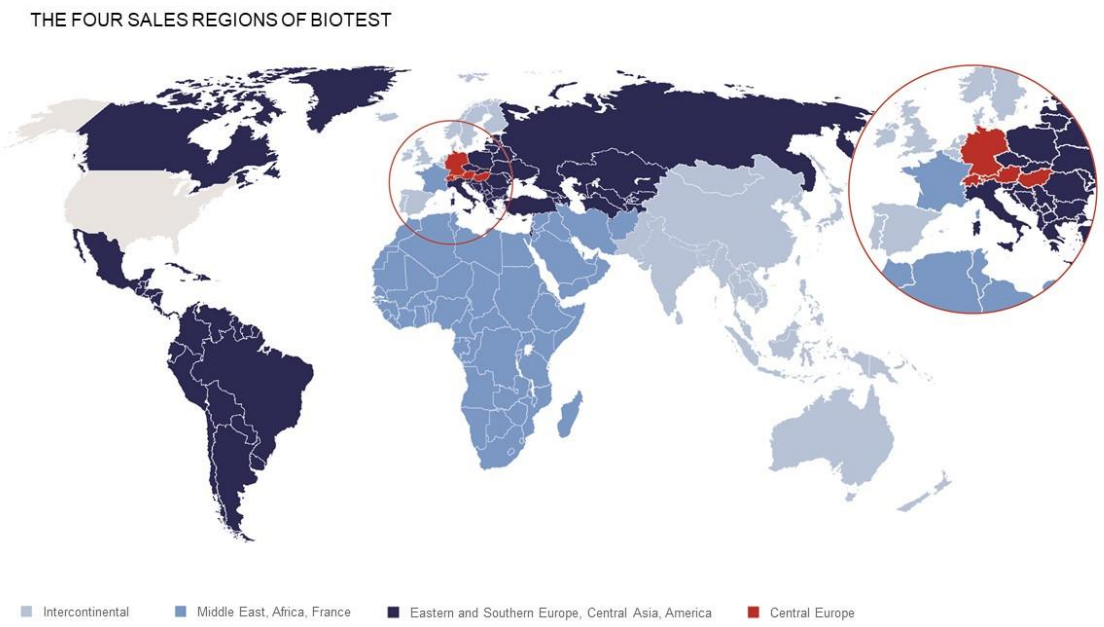
Dreieich, 14 November 2022

Biotest Aktiengesellschaft

Board of Management

Dr. Michael Ramroth	Dr. Georg Floß	Peter Janssen	Dr. Jörg Schüttrumpf
Chairman Board of Management	Member of the Board of Management	Member of the Board of Management	Member of the Board of Management

THE FOUR SALES REGIONS OF BIOTEST



FINANCIAL CALENDAR

23 March 2023
Annual Report 2022

04 May 2023
Three-month report

09 May 2023
Annual Shareholders' Meeting

10 August 2023
Half-year report

02 November 2023
Nine-month report

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This report contains forward-looking statements on overall economic development as well as on the state of business, earnings, financial and asset position of Biotest AG and its subsidiaries. These statements are based on current plannings, 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.

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