Biotest
From Nature for Life

# QUARTERLY STATEMENT AS OF 31 MARCH 2023

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# BUSINESS PERFORMANCE

## A. AT A GLANCE

The Biotest Group recorded revenue of € 117.2 million in the first quarter of the 2023 financial year. This represents an increase of 1.2 % compared to revenue of € 115.9 million in the same period of the previous year.

The increase in sales is mainly driven by the new intravenous immunoglobulin Yimmugo®, which was successfully launched in November 2022. Biotest is now producing this as the first commercial preparation in an innovative manufacturing process in the new Biotest Next Level production facility at the Dreieich site. Biotest thereby expanded its immunoglobulin product portfolio with an innovative product whose safety, efficacy and tolerability have been proven in pivotal trials, and which offers patients and doctors a further important treatment option. At the same time, the marketing authorisation of Yimmugo® represents an important milestone on the path to a broader portfolio and greater product availability. Revenue of approximately € 3.5 million was generated with the newly approved immunoglobulin Yimmugo® in the first quarter of 2023. Despite limited availability of the immunoglobulin preparation Intratect®, the reduction in revenue was partly offset by stronger revenue growth in the Intensive Care Medicine portfolio, particularly by human albumin.

Compared to the previous year, EBIT at Group level deteriorated to € -9.1 million in the first three months of the 2023 financial year (prior-year period: € -5.0 million). The main reasons for this development were higher cost of sales due to higher plasma prices as well as higher marketing and distribution costs.

One component of Biotest's strategy is the continuous expansion of the company's own plasma collection network in Europe. This is intended to ensure a sufficient supply of human blood plasma, the most important raw material for Biotest's preparations. A total of seven new donation centres were opened in the Czech Republic in the previous year. The opening of additional plasma collection centres is planned for 2023. For example, one additional donation centres were opened in each of Germany and Hungary in April 2023, after the balance sheet date.

In addition, Biotest participates financially in the establishment of further collection centres with partners.

Biotest is stepping up its efforts to rapidly develop the product candidates Fibrinogen and Trimodulin, which are currently in late Clinical Phase III and will be produced in the new Biotest Next Level facility, and to prepare them for marketing authorisation. Biotest is developing Fibrinogen not only for congenital but also for acquired fibrinogen deficiency. For example, in March 2023, an interim analysis of the Phase III AdFIrst in acquired fibrinogen deficiency confirmed the number of patients originally planned for the study. Biotest is also continuing to advance the development of Trimodulin in hospitalised COVID-19 patients. In addition, Biotest has access to research grants totalling € 29 million from the German Federal Ministry of Education and Research (BMBF) and the German Federal Ministry of Health (BMG). Moreover, a second Phase III trial with Trimodulin in the severe community-acquired pneumonia indication was launched. Since November 2022, the authorities in the different countries have been granting the first trial authorisations and the ethics commissions have been granting the subsequent authorisations that are required.

Due to the presentation in millions of euros, rounding differences of +/- one decimal place may arise when summing the amounts stated below.

### Results of operations

In the first three months of 2023, the Biotest Group generated revenue of € 117.2 million compared with € 115.9 million in the same period of the previous year. Revenue in the Therapy Segment was slightly higher than in the same quarter of the previous year and reflected higher revenue with the new immunoglobulin Yimmugo® and higher revenue of human albumin, mainly in Israel, partly offset by lower revenue of the immunoglobulin preparation Intratect®. Revenue in the Plasma & Services Segment of € 11.3 million was 3.9 % higher than in the first quarter of the previous year due to a higher level of toll manufacturing. In addition, revenue in the Other Segments in the first quarter of 2023 amounted to € 1.7 million, compared with € 1.3 million in the first quarter of the previous year. This increase was mainly due to a higher level of revenue from merchandise.

REVENUE BY SEGMENT

| in € million | Q1 2023 | Q1 2022 | Change in % |
|---|---|---|---|
| Therapy | 104.2 | 103.7 | 0.5 |
| Plasma & Services | 11.3 | 10.9 | 3.9 |
| Other Segments | 1.7 | 1.3 | 31.5 |
| **Biotest Group** | **117.2** | **115.9** | **1.2** |

The sales regions were restructured at the beginning of the 2023 financial year. This entailed an adaptation of the assignment of countries to regions. At the sales region level, Biotest recorded year-on-year revenue growth in the Central Europe as well as Middle East, Africa and France regions in the first quarter of 2023. This growth was partially offset by the lower level of revenue generated in the Eastern and Southern Europe, Central Asia, Americas and Other regions. Revenue in the Middle East, Africa and France region posted strong growth (of 25.2 %). This growth mainly reflected year-on-year higher revenue generated in Saudi Arabia, Jordan and Oman. In terms of absolute revenue figures, the Central Europe region continued to make the largest contribution.

REVENUE BY REGION

| in € million | Q1 2023 | Q1 2022* | Change in % |
|---|---|---|---|
| Central Europe | 51.0 | 50.7 | 0.5 |
| East and South Europe, Central Asia, America* | 30.9 | 32.4 | -4.8 |
| Middle East, Africa and France* | 22.5 | 18.0 | 25.2 |
| Other* | 12.9 | 14.8 | -12.8 |
| **Biotest Group** | **117.2** | **115.9** | **1.2** |

*Previous year's figures have been adjusted according to the definition of the sales regions in 2023.

EBIT for the first quarter of 2023 amounted to € -9.1 million, significantly lower than the prior-year figure (prior-year period: € -5.0 million). This includes expenses of € 22.2 million for the ramp-up of production capacity in the Biotest Next Level facility (prior-year period: € 20.3 million). The decrease in EBIT compared with the first quarter of 2022 is mainly due to the increase in cost of sales by € -1.5 million or 3.2 %. This development is due to the fact that plasma prices were significantly higher. At the same time, marketing and distribution costs increased by € 1.4 million due to higher marketing costs for the launch of Yimmugo® as well as higher transportation costs. Administrative expenses also increased by € 1.0 million compared with the first quarter of 2022. Research and development costs, which decreased by € 0.2 million to € 10.8 million, only slightly influenced the improvement in EBIT. This includes the expense reducing research allowance under the Research Allowance Act and the BMBF grant totalling € 1.7 million (prior-year period: € 2.2 million). As a consequence, the EBIT margin for the first three months of the current financial year amounted to -7.8 %, compared with -4.3 % in the same period of the previous year.

In the Therapy Segment, EBIT remained in negative territory, deteriorating significantly by € -3.6 million due to the higher cost of sales as well as marketing and distribution costs expenses. This development was reinforced by the € -1.0 million decrease in EBIT in the Plasma & Services Segment. EBIT for Other Segments also remained negative but improved by around € 0.4 million year-on-year, due in part to higher cross-segmental administrative costs.

EBIT BY SEGMENT

| in € million | Q1 2023 | Q1 2022 | Change in % |
|---|---|---|---|
| Therapy | –6.5 | –2.9 | >-100% |
| Plasma & Services | –1.7 | –0.7 | >-100% |
| Other Segments | –1.0 | –1.4 | 29.2 |
| **Biotest Group** | **–9.1** | **–5.0** | **-84.3** |

The financial result for the first quarter of the current year deteriorated by € -5.7 million to € -9.3 million (prior-year period: € -3.7 million). This decrease is mainly due to the € 2.3 million increase in interest expenses. In the first quarter of 2023, the expenses from value adjustments applied to the surrender claim against the trustee of shares in ADMA Biologics Inc. at fair value in the amount of € 1.0 million also had a negative effect on the financial result (prior-year period: income of € 1.3 million).

In view of the influencing factors described here, the Biotest Group's result after taxes for the first quarter of 2023 decreased to € -20.4 million compared with € -4.9 million in the same quarter of the previous year. This results in earnings per ordinary share of € -0.53 compared with € -0.13 in the same period of the previous year.

## Net assets

Total assets of the Biotest Group decreased slightly from € 1,203.0 million as of December 31, 2022 to € 1,190.2 million as of 31 March 2023. Non-current assets increased by € 9.1 million to € 592.7 million as of the balance sheet date compared to the balance sheet value

at the end of 2022 (31 December 2022: € 583.6 million). The increase in the first quarter mainly arose from the capitalisation of development costs of € 4.4 million and additions to rights of use for buildings in the amount of € 4.3 million. Current assets decreased by € -22.0 million compared with the 31 December 2022. This reduction mainly reflects the decrease in cash and cash equivalents of € -48.7 million and in trade receivables of € -4.1 million. In contrast, inventories increased by € 33.8 million. Contract assets also rose by € 6.3 million to € 39.4 million as of 31 March 2023.

On the equity and liabilities side of the balance sheet, equity amounted to € 351.1 million as of 31 March 2023 (31 December 2022: € 371.1 million). The decrease reflects the negative result in the reporting period. The equity ratio amounted to 29.5 % at the end of the first three months of the 2023 financial year (31 December 2022: 30.8 %). Total Liabilities have increased by € 7.2 million to € 839.1 million over the course of the year to date. Non-current liabilities rose by € 7.9 million to € 709.6 million since 31 December 2022, mainly due to an increase of non-current financial liabilities. Current liabilities decreased by € -0.7 million to € 129.5 million as of the 31 March 2023. This was mainly due to a decrease in trade payables of € -6.4 million, which was partly offset by an increase in other provisions of €4.9 million and in financial liabilities of € 0.7 million.

### Financial Position

The Biotest Group recorded € -37.3 million of operating cash flow in the first three months of 2023, primarily due to changes of working capital of € -24.3 million. Operating cash flow amounted to € 20.0 million in the same period of the previous year. Cash flow from investing activities amounted to € -10.2 million in the period from January to March 2023 (prior-year period: € -7.7 million). The increase is due to capital expenditure payments, among other factors. Cash flow from financing activities amounted to at € -1.3 million in the first three months of 2023 (prior-year period: € -1.5 million). Biotest is financed by a subordinated shareholder loan of € 290 million and a € 240 million financing facility concluded in 2019, of which € 225 million has been drawn as of 31 March 2023. To cover further financing requirements in 2023, Biotest AG and Grifols Worldwide Operations Limited, Dublin, Ireland, a wholly owned subsidiary of Grifols, S.A., concluded a € 147 million financing agreement on 7 March 2023. As a consequence, credit lines of € 162 million are available as of 31 March 2023.

## B. RESEARCH AND DEVELOPMENT

At € 10.8 million, costs for research and development in the first three months of financial year 2023 were slightly below the comparable value for the previous year of € 11.0 million. The lower costs mainly reflect from the capitalisation of development costs in the amount of € 4.4 million (prior-year period: € 0.0 million) and a research allowance of € 1.7 million in accordance with the German Research Allowance Act (prior-year period € 2.2 million), which reduced research and development costs. A complete list of all research and development projects is presented in the 2022 Annual Report (page 19).

Biotest made further progress in the following research and development projects in the January to March 2023 period:

RESEARCH & DEVELOPMENT PROGRESS
IN THE FIRST THREE MONTHS OF 2023

| | |
|---|---|
| **Intensive Care Medicine therapeutic area** | |
| Fibrinogen Concentrate | The final interim analysis was successfully completed for the pivotal Phase III trial for the treatment of acquired fibrinogen deficiency due to major bleeding (AdFIrst Study No. 995). This confirmed the originally planned number of patients. |
| Trimodulin (IgM Concentrate) | Start of two Phase III trials planned for 2023:<br>a) TRICOVID trial (hospitalised COVID-19 patients): submissions in various countries are underway, and initial authorisations have been granted. First patient treated in December 2022.<br>b) ESsCAPE study (patients with severe community-acquired pneumonia): submissions in selected countries have been issued, and authorisations are underway. |
| Clinical immunology therapeutic area | |
| BT097 (Cytotect® CP Biotest): | The Phase III registration trial (PreCyssion; study no. 997) is in the treatment phase. |

### Research activities in relation to innovative plasma protein products

The focus of research and development projects is on plasma proteins. Research activities are currently concentrating on the further new products Fibrinogen Concentrate and Trimodulin. Along with Yimmugo®, these form the core for the manufacture of the new product portfolio in the new Biotest Next Level production plant.

In the Phase III trial relating to acquired fibrinogen deficiency, Biotest achieved a significant milestone in March 2023. For ex-ample, the last interim analysis of the Phase III AdFIrst (Adjusted Fibrinogen Replacement Strategy) trial with Fibrinogen, which is used in patients with acquired fibrinogen deficiency, was successful. The number of patients originally planned for the trial was confirmed. The AdFIrst

study is a prospective, randomised, active-controlled, multicentre Phase III trial and investigates the efficacy and safety of Biotest's human Fibrinogen Concentrate BT524 in patients experiencing high blood loss during planned spine or abdominal surgery. The efficacy and tolerability of Fibrinogen will be assessed in the AdFIrst study in comparison to standard therapy consisting of blood plasma preparations (fresh frozen plasma and cryoprecipitate). The aim of the final interim analysis was to verify that the trial could achieve a positive outcome and to confirm the final sample size. The AdFIrst trial will now continue as planned without modification until the full enrolment of 200 evaluable patients. The decision follows the recommendation of an independent statistician and is based on the successful completion of the planned final interim analysis after 160 treated patients were evaluable and analysed. Biotest expects recruitment to be completed in 2023. The results of Biotest's two clinical trials, the AdFIrst study and the completed Phase I/III trial in patients with congenital fibrinogen deficiency, will serve as the basis for the marketing authorisation of Fibrinogen Concentrate BT524 for the treatment of patients with congenital and acquired fibrinogen deficiency. Biotest is seeking marketing authorisation in Europe and subsequently in the USA.

In addition, a second Phase III trial 996 (ESsCAPE) with Trimodulin in the severe community-acquired pneumonia indication is currently underway. The submissions to regulators in the various countries have been realised. The US and European authorities have given their approval, and the approvals by the ethics commissions are still awaited. Moreover, the Phase III trial in COVID-19 (TRICOVID, 1001) has already been submitted and approved in several countries. Further submissions are currently underway. The first patient was treated in December 2022.

A Phase III clinical trial of Cytotect® CP in pregnant women for the prevention of CMV infection of the unborn child is currently in the treatment phase. This Phase III clinical trial is investigating the efficacy and safety of Biotest's CMV hyperimmunoglobulin (CMVIG) Cytotect® CP for the treatment of pregnant women with a primary CMV infection in order to prevent CMV transmission to the foetus.

In addition, in January 2023, the first patient was enrolled in Biotest's prospective, multicentre, observational trial on the use of CMV hyperimmunoglobulins after heart and lung transplantation. The non-interventional trial will be conducted in 20 transplant centres in Austria, Belgium, Croatia, Germany, Italy, Spain, and the UK, and is expected to enrol a total of approximately 500 patients. The aims of the large-scale trial are to provide detailed data on the use of Cytotect® CP and clinical outcomes in the management of cytomegalovirus after heart or lung transplantation.

## C. MARKETING AND DISTRIBUTION

Demand for immunoglobulins (IgG) remains at a stable high level and is growing globally. In the second half of 2022, the number of plasma donations in the USA increased sharply, in some cases surpassing 2019 levels.[1] As a consequence, signs of an improvement in the supply situation of immunoglobulins are evident, especially in high-priced markets. However, due to the lengthy production of plasma proteins (around 9-12 months), in the coming months the product volumes obtained from the additional plasma will only reach the global markets with a delay. Due to price regulation for pharmaceuticals, the higher production costs for plasma products resulting from the macroeconomic situation can only be passed on to the markets in the form of price increases to a limited extent.

After the transplant situation in the 2022 financial year increasingly recovered from the lingering coronavirus situation[2] and at the same time was characterised by increasing competition from antiviral therapies, Biotest expects a progressive normalisation of transplant activities in hospitals for the current 2023 year.

The return of numerous hospitals to normal operations over the course of 2022/2023 and the associated resumption of planned operations have led to higher demand for albumin, which in some cases could not be covered by stocks. This has temporarily led to rising prices, especially in important markets such as China. With the increase in US plasma collections, the supply situation is also expected to normalise for albumin.

[1] PPTA (2023)
[2] Eurotransplant (April 2023)

MARKETING & DISTRIBUTION PROGRESS
IN THE FIRST THREE MONTHS OF 2023

| | |
|---|---|
| **Clinical immunology therapeutic area** | |
| Yimmugo® | Expansion of marketing in Germany |
| Cytotect® | New authorisation in several European countries. Positive revenue trend in various markets, especially in Croatia. |
| Zutectra® | Product launch in Turkey and Taiwan |
| Hepatect® | Positive revenue trend in Germany and various international markets |
| Varitect® | Positive revenue growth for Varitect® |
| **Intensive Care Medicine therapeutic area** | |
| Pentaglobin® | Rising price trend |
| Albiomin® | Market authorisation obtained in France |

# D. OUTLOOK, RISK AND OPPORTUNITIES REPORT

## I. REPORT ON CHANGES IN THE OUTLOOK

Biotest AG, Dreieich, Germany and Grifols S.A., Barcelona, Spain are close to signing technology transfer and licensing agreements. These agreements ensure that Biotest's new product developments will be manufactured and commercialised worldwide by using the organisation and facilities of Grifols. It also allows Grifols to optimize its own processes and reduce in-house developments. A payment for the transferred technology and later recurring royalty payments depending on net sales of the licensed products were agreed as consideration. The payment for the technology will have a positive effect on the EBIT of Biotest in a triple-digit million range in 2023.

For this reason, the Board of Management raises its EBIT guidance for 2023 from a range between € -15 million to € -20 million to a level potentially exceeding € 100 million. A more precise specification depends on the revenue and earnings recognition of the final project milestones.

## II. RISK REPORT

The Biotest Group's risk situation has not changed significantly since its presentation in the 2022 Annual Report (pages 30 to 42).

Above and beyond this, no discernible risks exist that could jeopardise the Biotest Group as a going concern.

## III. OPPORTUNITIES REPORT

The Biotest Group's opportunities situation has not changed significantly since its presentation in the 2022 Annual Report (pages 42 to 43).

# E. SUPPLEMENTARY REPORT

As part of an optimization of global sales activities, Biotest concluded share purchase agreements with Grifols to acquire Biotest's subsidiaries in Brazil, Italy and Spain in a first step on May 2, 2023.

In April 2023 Biotest opened one additional plasma collection center in Germany and in Hungary. Biotest is therefore continuing the planned expansion of its own plasma collection centers in Europe.

No events occurred after the balance sheet date that could have a significant impact on the Group's financial position and performance.

# CONSOLIDATED STATEMENT OF INCOME

of the Biotest Group for the period from 1 January to 31 March 2023

| in € million | Q1 2023 | Q1 2022 |
|---|---|---|
| Revenue | 117.2 | 115.9 |
| Cost of sales | –92.5 | –89.7 |
| **Gross profit** | **24.7** | **26.2** |
| | | |
| Other operating income | 0.5 | 0.2 |
| Marketing and distribution costs | –12.2 | –10.9 |
| Administrative expenses | –9.6 | –8.6 |
| Research and development costs | –10.8 | –11.0 |
| Other operating expenses | –1.7 | –0.9 |
| **Operating profit** | **–9.1** | **–5.0** |
| | | |
| Financial income | 3.6 | 4.4 |
| Financial expenses | –13.0 | –8.0 |
| **Financial result** | **–9.3** | **–3.7** |
| | | |
| **Loss before taxes** | **–18.5** | **–8.6** |
| | | |
| Income taxes | –1.9 | 3.7 |
| **Loss** | **–20.4** | **–4.9** |
| | | |
| Attributable to: | | |
| **Equity holders of the parent** | –20.4 | –4.9 |
| | | |
| **Earnings per share in €** | **–0.53** | **–0.13** |

# CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 31 March 2023

| in € million | 31 March 2023 | 31 December 2022 |
|---|---|---|
| **ASSETS** | | |
| **Non-current assets** | | |
| Intangible assets | 20.7 | 16.4 |
| Property, plant and equipment | 519.1 | 520.3 |
| Right-of-use assets from leases | 30.5 | 27.5 |
| Investments in joint ventures | 5.1 | 5.1 |
| Other assets | 0.3 | 0.3 |
| Other financial assets | 15.2 | 13.3 |
| Deferred tax assets | 1.9 | 0.7 |
| **Total non-current assets** | **592.7** | **583.6** |
| **Current assets** | | |
| Inventories | 327.6 | 293.8 |
| Contract assets | 41.5 | 35.2 |
| Trade receivables | 120.4 | 124.5 |
| Current income tax assets | 0.6 | 0.6 |
| Other assets | 20.5 | 21.7 |
| Other financial assets | 18.9 | 27.0 |
| Cash and cash equivalents | 68.0 | 116.6 |
| **Total current assets** | **597.4** | **619.4** |
| **Total assets** | **1,190.2** | **1,203.0** |
| **EQUITY AND LIABILITIES** | | |
| **Equity** | | |
| Subscribed capital | 39.6 | 39.6 |
| Share premium | 219.8 | 219.8 |
| Retained earnings | 112.1 | 143.4 |
| Share of profit or loss attributable to equity holders of the parent | –20.4 | –31.7 |
| **Equity attributable to equity holders of the parent** | **351.1** | **371.1** |
| **Total equity** | **351.1** | **371.1** |
| **Non-current liabilities** | | |
| Provisions for pensions and similar obligations | 85.6 | 85.8 |
| Other provisions | 2.0 | 1.9 |
| Financial liabilities | 618.9 | 612.8 |
| Other liabilities | 0.0 | 0.0 |
| Deferred tax liabilities | 3.1 | 1.2 |
| **Total non-current liabilities** | **709.6** | **701.7** |
| **Current liabilities** | | |
| Other provisions | 31.2 | 26.3 |
| Current income tax liabilities | 0.3 | 0.3 |
| Financial liabilities | 32.0 | 31.3 |
| Trade payables | 44.7 | 51.1 |
| Other liabilities | 21.1 | 21.0 |
| Contract liabilities | 0.2 | 0.2 |
| **Total current liabilities** | **129.5** | **130.2** |
| **Total liabilities** | **839.1** | **831.9** |
| **Total equity and liabilities** | **1,190.2** | **1,203.0** |

# CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 31 March 2023

| in € million | Q1 2023 | Q1 2022 |
|---|---|---|
| Operating cash flow before changes in working capital | –1.5 | 5.0 |
| Cash flow from changes in working capital | –24.3 | 20.4 |
| Interest and taxes paid | –11.5 | –5.4 |
| **Cash flow from the operating activities** | **–37.3** | **20.0** |
| **Cash flow from the investing activities** | **–10.2** | **–7.7** |
| **Cash flow from the financing activities** | **–1.3** | **–1.5** |
| **Cash changes in cash and cash equivalents** | **–48.8** | **10.8** |
| Exchange rate-related changes in cash and cash equivalents | 0.2 | 0.1 |
| Cash and cash equivalents on 1 January | 116.6 | 104.4 |
| **Cash and cash equivalents on 31 March** | **68.0** | **115.3** |

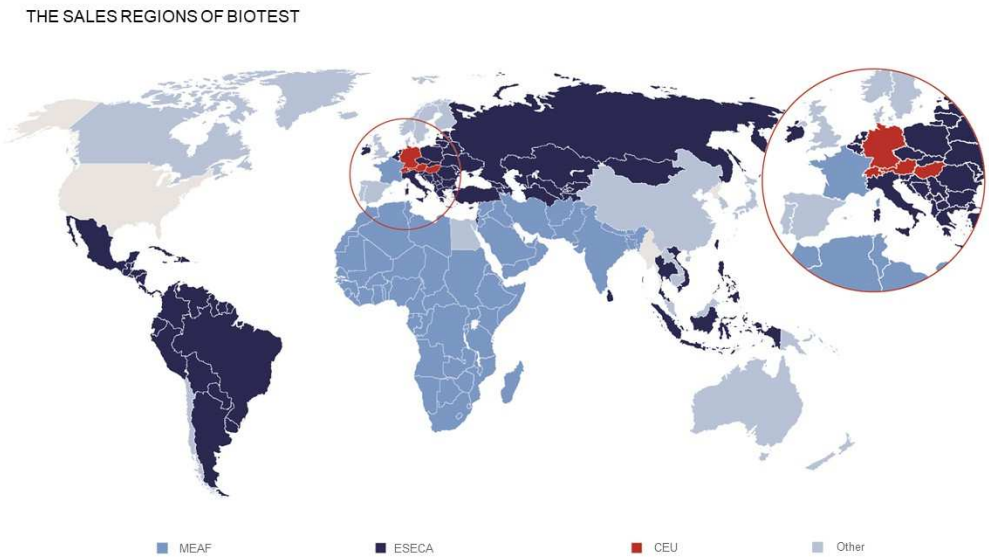
Dreieich, 9 May 2023

Biotest Aktiengesellschaft

Board of Management

| Dr. Michael Ramroth | Ainhoa Mendizabal Zubiaga | Peter Janssen | Dr. Jörg Schüttrumpf |
|---|---|---|---|
| Chairman of the 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

**10 AUGUST 2023**
Half-year report

**2 NOVEMBER 2023**
Nine-month report

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This report contains forward-looking statements about macreconomic trends as well as the business position, results of operations, financial position and net assets of Biotest AG and its subsidiaries. These statements are based on the company's current plans, estimates, forecasts and expectations and are thereby subject to risks and uncertain factors that could lead actual developments to diverge significantly from expected developments. The forward-looking statements are only valid at the time of publication of this annual report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

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