

HALF-YEAR REPORT 2023 BIOTEST AG



KEY FIGURES

BIOTEST GROUP		H1 2023	H1 2022	Change in %
Revenues	€ million	275.3	253.1	8.8
thereof:				
Germany	€ million	73.0	76.0	-3.9
Rest of World	€ million	202.3	177.1	14.2
thereof:				
Therapy	€ million	248.1	220.6	12.5
Plasma & Services	€ million	23.8	29.4	-19.0
Other Segments	€ million	3.4	3.1	9.7
EBITDA	€ million	37.5	8.8	>100
Depreciation and amortisation	€ million	17.7	17.9	-1.1
Operating profit (EBIT)	€ million	19.8	-9.1	>100
EBIT in % of revenues	%	7.2	-3.6	-
Earnings before taxes	€ million	1.2	-18.0	>100
Earnings after taxes	€ million	1.7	-19.9	>100
Earnings per share	€	0.03	-0.50	>100
Financing				
Cash flow from operating activities	€ million	-74.8	1.9	>-100
		30 June 2023	31 December 2022	
Equity	€ million	373.6	371.1	0.7
Equity ratio	%	30.8	30.8	-
Balance sheet total	€ million	1,214.1	1,203.0	0.9
Employees in FTEs	number	2,307	2,228	3.5

CONTENTS

3 FOREWORD	17 RISK REPORT
5 INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 2021	17 OPPORTUNITIES REPORT
5 GROUP PRINCIPLES	18 SUPPLEMENTARY REPORT
5 BUSINESS MODEL OF THE GROUP	19 CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS AS OF 30 JUNE 2023
5 GROUP STRATEGY	19 CONSOLIDATED STATEMENT OF INCOME
6 RESEARCH AND DEVELOPMENT (GENERAL)	20 CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
7 ECONOMIC REPORT	21 CONSOLIDATED STATEMENT OF FINANCIAL POSITION
7 MACROECONOMIC CONDITIONS	22 CONSOLIDATED CASH FLOW STATEMENT
8 INDUSTRY-SPECIFIC CONDITIONS	23 CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
9 BUSINESS PERFORMANCE	24 SELECTED DISCLOSURES
12 RESULTS OF OPERATIONS, NET ASSETS AND FINANCIAL POSITION	31 FINANCIAL CALENDAR
16 OUTLOOK, RISK AND OPPORTUNITIES REPORT	32 ACKNOWLEDGEMENTS
16 OUTLOOK REPORT	



AINHOA MENDIZABAL ZUBIAGA
Chief Financial Officer

PETER JANSSEN
Chief Operations Officer

DR. JÖRG SCHÜTTRUMPF
Chief Scientific Officer

DR. MICHAEL RAMROTH
Chairman of the
Board of Management

Dear Shareholders,

In the first half of 2023, we further improved the conditions to develop the Biotest Group's business successfully over the long term. We paved the way for closer collaboration with our partner Grifols and thereby laid important foundations to expand our production capacities and enhance the marketing of our plasma protein products internationally. The focus is particularly on the accelerated further development of Fibrinogen and Trimodulin. To deepen the partnership between Biotest and Grifols, several contracts were signed that will significantly expand business opportunities for Biotest over the coming years. In order to efficiently implement this closer collaboration, Biotest has divested its interests in its subsidiaries in Spain, Brazil, Italy, the UK and France to Grifols.

Biotest and Grifols will join forces in core markets to ensure more secure supplies of plasma proteins and to share the strong research pipeline. The agreements that have been reached enable the two companies to collaborate in the areas of research and development, production and sales while maintaining their independence. This will enable Biotest and Grifols to offer their complementary product portfolios in significantly more countries. Both parties will also exchange their knowledge as part of the technology transfer and licensing agreement. Biotest's new product developments can be manufactured and marketed worldwide by utilising Grifols' organisation and production network. In return, the companies have agreed a payment for the technology that is transferred as well as subsequent royalty payments based on sales revenues from the licensed products. Given this, in April we raised our EBIT guidance for 2023 from a range between € -20 million and € -15 million to a level potentially in excess of € 100 million.

We are satisfied with our business performance during the first half of 2023. We succeeded in overcoming the challenges in our markets and grew our revenue by 8.8 % to € 275.3 million. Our new immunoglobulin Yimmugo® made a significant contribution to this revenue growth. In addition, we recognised initial revenue of € 14.9 million from development services rendered for Grifols as part of the technology transfer and licensing agreement, which had a positive impact on the revenue growth. EBIT amounted to € 19.8 million and reflected

not only expenses for the ramp-up of production capacities in the Biotest Next Level facility as well as significantly higher plasma prices, but also income from the divestiture of five Biotest subsidiaries in the amount of € 23.1 million.

Plasma supplies remain central to Biotest's business. In the spring, a further plasma collection centre was opened in Germany and a further in Hungary, so that we now have a total of 36 plasma collection stations in Europe. For the second half of the year, we are planning to open more donation centres to ensure supplies of this important raw material. In addition, in the further course of the year Biotest will continue its intensified efforts to rapidly develop the product candidates Fibrinogen and Trimodulin, which are in late Clinical Phase III and are to be manufactured in the new Biotest Next Level production facility, and to make them ready for regulatory approval. We reached an important milestone in this context in March 2023, when the interim analysis of the Phase III AdFirst study in acquired fibrinogen deficiency confirmed the originally planned number of patients for the study. We also made further progress with our hyperimmunoglobulin preparation Cytotect® CP. With five new approvals in Europe, we further expanded the presence of Biotest's CMV hyperimmunoglobulin in Europe in the first half of the year.

We look forward to the current financial year with great confidence and we will continue to drive our business activities forward as part of our close partnership with Grifols. Biotest will thereby gain greater impact and become increasingly internationally oriented in order to address the great potentials on offer in our target markets worldwide. This is also illustrated by our product Yimmugo®, which is manufactured in an innovative production process in our new Biotest Next Level facility. For example, Biotest submitted the Biologics License Application (BLA) for the polyspecific immunoglobulin preparation Yimmugo® (IgG Next Generation) to the US Food and Drug Administration (FDA) on 30 June 2023 – the first ever product manufactured by Biotest in Dreieich. The marketing authorisation application covers the primary immunodeficiency (PGD) indication. Approval is not anticipated until mid-2024, at the earliest. With the activities that are planned, Biotest will continue to contribute to improving access to life-saving medicines for patients.

Kind regards,



Dr. Michael Ramroth
Chairman of the
Board of Management



Ainhoa Mendizabal Zubiaga
Member of the
Board of Management



Peter Janssen
Member of the
Board of Management



Dr. Jörg Schüttrumpf
Member of the
Board of Management

INTERIM MANAGEMENT REPORT FOR THE BIOTEST GROUP AS OF 30 JUNE 2023

A. GROUP PRINCIPLES

I. BUSINESS MODEL OF THE GROUP

The Biotest Group, headquartered in Dreieich, Germany, is an international supplier of biological medicines. Currently marketed products as well as new developments are obtained from human blood plasma or manufactured using biotechnology methods. The main therapeutic areas are Clinical Immunology, Haematology and Intensive Care Medicine.

The Biotest Group is engaged in research and development in all three therapeutic areas. Biotest covers all the material steps of the value chain, such as preclinical and clinical development of the preparations, plasma collection, production, worldwide distribution and sales.

A. THE BIOTEST GROUP'S OPERATING SEGMENTS

The Company's operations are divided into the following operating segments: Therapy, Plasma & Services, and Other Segments. The Therapy Segment includes products, development projects and related contracts, such as the technology transfer agreement assigned to the three aforementioned therapeutic areas. Plasma sales, toll manufacturing and know-how transfer are combined in the Plasma & Services Segment. Biotest reports on its merchandise business and cross-divisional costs not allocated to the Therapy or Plasma & Services segments within Other Segments.

B. HUMAN RESOURCES

As of 30 June 2023, Biotest employed 2,307 full-time equivalents. This represents a rise of 3.4% compared to 2,228 full-time equivalents as of the end of the 2022 financial year. The increase is mainly due to the personnel requirements in the new plasma centres and in production.

II. GROUP STRATEGY

The core element of Biotest's strategy is a clear focus on the distribution and development of plasma proteins. In addition to continuously advancing its own research and development pipeline, plasma collection, production and quality assurance the Company's registration and marketing authorisation activities are focused on the ongoing internationalisation and diversification of its portfolio. The Company's existing expertise, particularly in the areas of plasma collection and fractionation, is also leveraged in order to offer free capacities in toll manufacturing on the market.

The Biotest Group has been expanding its capacities at the Company's headquarters in Dreieich since 2013 in order to participate in future global market growth. The Biotest Next Level (BNL) project will expand the product portfolio and double fractionation capacities. In the future, five rather than three product lines will be obtained from the raw material plasma, while at the same time increasing yields. This is intended to further strengthen the Company's profitability and thereby its competitiveness in markets worldwide in order to lay the foundation for the Group's further profitable growth. In November 2022, the first Biotest Next Level preparation Yimmugo® (IgG Next Generation) was approved in the German market and distribution commenced. At the End of June 2023, Biotest submitted the Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for the polyspecific immunoglobulin preparation Yimmugo (IgG Next Generation). This is Biotest's second product for which an application for authorisation has been submitted to the FDA. The marketing authorisation application covers the indication primary immunodeficiencies (PID). Once the marketing authorisation has been received, Biotest plans to expand the indication to include chronic primary immune thrombocytopenia (ITP).

Following the acquisition by Grifols, S.A. as majority shareholder in April 2022, Biotest has expanded business opportunities and improved the availability of plasma products to patients through a closer collaboration with Grifols.

For this purpose, several contracts were signed to expand the partnership between Grifols and Biotest. The various agreements will enable both companies, while maintaining their independence, to work together in the areas of research and development, manufacturing and sales and distribution, enabling them to offer their complementary product portfolios in many more countries, share knowledge and provide patients with better access to life-saving plasma medicines. Grifols and Biotest will join forces in core markets in order to strengthen their combined position in leveraging greater plasma supply security, manufacturing capabilities and a strong research pipeline and in order to thereby help ensure availability of plasma products well into the future.

Among other measures, a technology transfer agreement and a licensing agreement will ensure that Biotest's new product developments can be manufactured and distributed worldwide by using Grifols' organisation and production network. In return, a payment was agreed for the technology transfer as well as licence payments to be made at a later date based on the sales proceeds from the licensed products. In this context, Biotest recognised the first revenue from development services rendered to Grifols, S.A. in the amount of € 14.9 million in the second quarter of the financial year 2023.

In order to implement closer collaboration, Biotest has now sold the shares of the Biotest subsidiaries in Spain, Brazil, Italy, the UK and France to Grifols. The Biotest and Grifols subsidiaries will operate as two companies with only one joint managing director. In Germany, the joint committee for the coordination of sales activities chaired by Biotest has started work.

Further details are provided in the Research and Development (General) section and in the Opportunities Report section.

III. RESEARCH AND DEVELOPMENT (GENERAL)

As part of the corporate strategy, research and development, among other areas, forms the basis for the Biotest Group's future growth. The ongoing development of existing products and the development of new products enables considerable potential to be tapped in this area.

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

Following the approval of Yimmugo® in November 2022, Biotest continued to intensify its efforts in the first half of 2023 to rapidly develop the late-stage product candidates, Fibrinogen and Trimodulin and bring them to regulatory approval.

In addition, existing products are also systematically developed to further enhance patient benefits or to achieve new indications and approvals in additional countries. For example, Cytotect® is currently in clinical development for a further indication: prevention of cytomegalovirus (CMV) infection of the unborn child in pregnant women with primary CMV infection of the mother. In addition, Biotest will collect further data for its marketed products in three ongoing and further planned non-interventional trials (NIS). The non-interventional trials serve to continue the investigation of safety and efficacy in large patient populations and to gain further knowledge under everyday conditions, such as concerning quality of life, treatment course and application behaviour.

A technology transfer and licensing agreement signed with Grifols will also ensure that Biotest's new product developments (Yimmugo®, Fibrinogen and Trimodulin) can be manufactured and distributed worldwide by using Grifols' organisation and production network.

A list of the progress of the research and development projects carried out in the first half of 2023 is shown in the "Research and development" section of the economic and business report.

In the first half of 2023, the Biotest Group's research and development costs amounted to € 30.7 million (prior-year period: € 24.4 million) and are attributable to plasma proteins. These expenses amounted to 12.4 % of revenue compared with 9.6 % in the same period of the previous year. The focus of research and development is in particular the accelerated further development of Fibrinogen and Trimodulin.

B. ECONOMIC REPORT

I. MACROECONOMIC CONDITIONS

Important overall conditions that contributed significantly to the weakening of the global economy in the previous year have recently improved significantly, according to the Kiel Institute for the World Economy (IfW). Energy prices have fallen again, for example, and China has increased the chances for steady growth by abandoning its zero-Covid policy. In addition, supply chain constraints are no longer exerting an unusually strong impact on economic activity. It is especially these factors that have helped the global economy to regain its footing, according to the IfW.¹

The IfW regards tight monetary policy, which has led to significantly higher financing costs and which in turn has inhibited the propensity to spend, as a restraining factor. Moreover, fiscal policy is tending to be restrictive. In 2022, global production continued to expand at a rate 3.3 %, still within the medium-term trend range. For 2023 and 2024, the IfW economists forecast moderate global production growth of 2.8 % and 3.0 % respectively, with signs of a sustainable recovery continuing to be lacking.²

For the German economy, the IfW forecasts gross domestic product 0.3 % lower in 2023 due to the weak winter half-year. Growth of 1.8 % is expected for 2024.³

After significantly weaker US GDP growth in 2022 compared to 2021, the IfW continues to forecast subdued economic performance (2022: 2.1 %; 2023: 1.3 %; 2024: 0.8 %). For the Eurozone as a whole, the IfW expects the economy to gradually pick up again after the recent period of weakness (2022: 3.5 %; 2023: 0.6 %; 2024: 1.7 %), while the outlook for Asia looks much better (2022: 4.4 %; 2023: 5.7 %; 2024: 5.2 %). After a noticeable recovery last year, the UK is expected to experience much weaker economic output growth in the current year (2022: 4.1 %; 2023: 0.4 %; 2024: 1.2 %). For Latin America, economic forecasts envisage a further slowdown in growth momentum in 2023 after moderate growth in the previous year (2022: 3.7 %; 2023: 1.6 %; 2024: 1.1 %).⁴

Due to high medical demand worldwide for plasma protein products, the Biotest Group is dependent on global economic cycles to only a minor extent. This assessment by the management also applies under the current economic conditions. Nevertheless, impacts on the operating business, especially due to local crises, geopolitical developments, supply chain disruptions, restrictive financial policy as well as changes in exchange rates, cannot be ruled out.

¹ Kiel Institute for the World Economy (2023), Economic reports from Kiel, World economy in summer 2023, p. 2.

² Ibid. p. 2.

³ Kiel Institute for the World Economy (2023), Economic reports from Kiel, German economy in summer 2023, p. 2.

⁴ Kiel Institute for the World Economy (2023), Economic reports from Kiel, World economy in summer 2023, pages 8, 9, 21 and 23.

II. INDUSTRY-SPECIFIC CONDITIONS

A. IMMUNOGLOBULINS AND ALBUMIN

The Biotest Group is active in global markets for immunoglobulins and albumin, which generated the strongest sales revenues of the product range in the past financial year. Established markets in Europe as well as further regions of the world are continuing to contribute to this positive trend.

The long-term growth of the global albumin market is forecast to amount to around 6 % per year.⁵ For the immunoglobulin (IgG) market, sector experts expect the long-term target range to reflect an annual global increase in demand in the mid-single-digit percentage range.⁶ In the USA, IgG volumes grew at a mid-single-digit rate over the course of 2022.⁷ In Europe, the market volume for immunoglobulins reached a year-on-year growth rate of around 4 % over the full course of 2022. In the first half of 2023, the German market, which is important for Biotest, grew at a low double-digit rate year-on-year.⁸ This trend in Europe is based on slightly higher price levels compared to the rest of the world. The supply situation in low-price markets remains tight.

As a consequence of the COVID-19 pandemic and associated restrictions for people, plasma donations in the USA were down significantly in 2020 and 2021. This led to a product shortage of immunoglobulins and albumin that continues up to the present. In the second half of 2022 and first quarter of 2023, US plasma donations showed a significant upward trend and a recovery in the human blood plasma supply situation. Owing to long production cycles, the supply situation for plasma products is not expected to recover until during the course of the first half of 2023. Given the macroeconomic situation, plasma costs are expected to remain high. Collected plasma volumes in the EU countries Germany, Austria, Czech Republic and Hungary, which are significant for Biotest, stood at a slightly higher level in 2022 than in 2019 (before the pandemic).⁹

Prices for intravenous immunoglobulins (IVIg) in the EU immunoglobulins market are significantly below the price level in the USA on average, while globally the average price is developing slightly positively.¹⁰ Albumin prices also recorded an upward trend.¹¹

B. HAEMOPHILIA

The treatment of haemophilia A is increasingly characterised by non-factor replacement therapies in addition to the use of recombinant Factor VIII preparations. Numerous alternative treatments make competition more intense and keep price pressure high in the overall market.

New therapeutic options are restraining the growth of the Factor VIII market, particularly in the USA, Europe and other developed markets. Only in emerging markets growth in the low to mid single-digit percentage range is still expected due to increasingly established Factor VIII therapies.¹² In many of these countries, haemophilia patients have only access that is slowly beginning to coagulation factor therapy. While Europe, North and South America account for only around 27 % of the world's population, these regions account for around 76 % of the global Factor VIII market volume.¹³

In August 2022, the first gene therapy for the treatment of haemophilia A received marketing authorisation from the EMA (European Medicines Agency). This therapy promises to eliminate the need for traditional treatments for several years. Although the population of suitable patients is limited, this will place further pressure on developed Factor VIII markets and further strengthen the importance of markets outside the USA and Europe. Up to 2027, the global market is projected to diminish at a single-digit negative percentage rate in terms of volumes of plasmatic Factor VIII preparations. The volume decrease is expected to be particularly significant in the USA, the largest market for haemophilia preparations, and in the European market, which is important for Biotest. Volume growth in the low single-digit percentage range is

⁵ Markets and Markets (2020).

⁶ MRB (2021).

⁷ PPTA North America Data Program (2023).

⁸ IQVIA (2023).

⁹ PPTA (2023).

¹⁰ IQVIA (2022), CMS.gov.

¹¹ IQVIA (2022).

¹² MRB (2022).

¹³ WFH Report on the Annual Global Survey 2021.

expected only in some emerging markets.¹⁴ The simultaneous decrease in prices for plasmatic Factor VIII preparations in developed markets and the shift of the market to lower-priced emerging markets led to a negative trend in sales revenues generated with plasmatic Factor VIII products.

C. SPECIAL PRODUCTS

The Biotest Group has products in its special portfolio that are used in various transplantations.

Due to the extensive lifting of coronavirus protection measures, the number of transplants reported to Eurotransplant during the January to June 2023 period grew by around 15 %.¹⁵ Based on market observations, Biotest assumes that the number of transplantations will continue to stabilise.

For Biotest, this concerns in particular the products Cytotect, generally in the area of organ transplantation and especially in heart and lung transplantation, as well as Hepatect and Zutectra in the area of liver transplantation due to hepatitis B infection. While the number of liver transplants globally is increasing at a mid-single-digit rate¹⁶, the incidence of hepatitis B (HBV) is expected to decline at the same time due to numerous efforts at the global and national level.¹⁷ Therefore, an increase in hepatitis B virus-related liver transplants in the low single-digit percentage range is expected.

The number of stem cell transplants, which is also relevant for Cytotect, has been continuously developing positively over the last 30 years, with the period of the COVID-19 pandemic as the only exception. A first recovery in the number of stem cell transplants from this could already be observed in 2021, and the positive long-term trend is expected to continue in the future.¹⁸ The market entry of innovative antiviral treatments, on the other hand, is increasing the pressure in Cytotect's established indications.

The medical need in the sepsis area remains high. Approximately 47 to 50 million cases of sepsis occur annually, including up to 20 million in children under 5 years of age. These result in at least 11 million deaths per year worldwide.¹⁹ Due to the ageing population and as effective treatments for sepsis continue to be lacking, sepsis cases are projected to grow by about one per cent per year in the EU4 + UK.²⁰ At the same time, the incidence of multidrug-resistant infections, ranked by the WHO as one of the "top 10 global public health threats", is rising, increasing the need for supportive care options.²¹ This results in a continued high demand for Pentaglobin.

III. BUSINESS PERFORMANCE

A. AT A GLANCE

The Biotest Group recorded revenue of € 275.3 million in the first half of the 2023 financial year. This represents an increase of 8.8 % compared to revenue of € 253.1 million in the same period of the previous year.

The revenue growth is significantly due to the new intravenous immunoglobulin Yimmugo®, which was successfully launched in November 2022 and is now the first commercial preparation to be produced in an innovative manufacturing process in the new Biotest Next Level production facility at the Dreieich site in Germany. In the first half of 2023, Biotest generated revenue of € 9.6 million with Yimmugo®. In addition, revenue with Grifols, S.A. from the further development of Yimmugo®, Fibrinogen and Trimodulin from January 2023 to June 2023 in the amount of € 14.9 million under the technology transfer and licensing agreement contributed to revenue growth. The agreement be-

¹⁴ IQVIA (2022), CMS.gov.

¹⁵ Eurotransplant (2023).

¹⁶ Transplant Observatory (2023)

¹⁷ WHO (2023)

¹⁸ EBMT Activity survey, Passweg et. al (2023)

¹⁹ Rudd et.al (2020)

²⁰ GlobalData (2021)

²¹ European Center for Disease Prevention and Control (2023), WHO (2023), UN environment program (2023)

tween Biotest AG and Grifols, S.A. was signed on 31 May 2023 with effect from 1 January 2023. Despite limited availability of the immunoglobulin preparation Intratect®, the reduction in revenue relating to this product was offset by stronger revenue growth in the Intensive Care Medicine portfolio, by human albumin.

Compared to the prior-year period, consolidated EBIT grew to € 19.8 million in the first six months of the 2023 financial year (prior-year period: € -9.1 million). This growth mainly reflects the € 23.1 million gain on the divestiture of five Biotest subsidiaries to Grifols.

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. In the first half of 2023, Biotest opened two more plasma collection centres and has thereby successfully continued the planned expansion of its own donor centres. In April, Biotest opened the 12th plasma collection centre in Hungary, in Budapest. In addition, the 10th plasma collection centre in Germany was also officially opened in Münster, Westphalia, in April 2023. Plasma donors can donate plasma there six days a week, from Monday to Saturday. 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. In March 2023, an interim analysis of the phase III AdFirst trial in acquired fibrinogen deficiency confirmed the number of patients originally planned for the trial.

Biotest continues to advance the development of Trimodulin in hospitalised COVID-19 patients, with patient enrolment lagging behind expectations. Research grants from the German Federal Ministry of Education and Research (BMBF) and the German Federal Ministry of Health (BMG) support this project. Moreover, a second phase III trial with Trimodulin in the severe community-acquired pneumonia indication was launched. The majority of study approvals by the authorities in the various countries have been granted. The subsequent necessary approvals by the ethics committees are still pending.

In addition, the product Cytotect® CP Biotest has received approvals in three other European markets – Slovakia, the Czech Republic and Romania – within the first four months. With these new authorisations, Biotest's hyperimmunoglobulin now has approvals in 28 countries, most of them in Europe. This enabled Biotest to further expand the presence of Biotest's CMV hyperimmune globulin in Europe and reaffirm its commitment to providing life-saving treatments to patients in need. Biotest's hyperimmune globulin is an immunoglobulin against human cytomegalovirus used for the prophylaxis of clinical manifestations of CMV infections in patients receiving immunosuppressive therapy. This particularly concerns patients after solid organ or stem cell transplantation, where CMV infection can cause serious or even life-threatening complications.

At the end of June 2023, Biotest submitted the Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for the polyspecific immunoglobulin preparation Yimmugo (IgG Next Generation). This is Biotest's first product manufactured by Biotest in Dreieich for which an application for authorisation has been submitted to the FDA. The marketing authorisation application covers the indication primary immunodeficiencies (PGD). Once the authorisation has been received, Biotest plans to expand the indication to include chronic primary immune thrombocytopenia (ITP).

In the first half of 2023, there were personnel changes on the Management Board and the Supervisory Board of Biotest AG. The Supervisory Board of Biotest AG appointed Ms. Ainhoa Mendizabal Zubiaga to the Company's Board of Management as Chief Financial Officer (CFO) with effect as of 15 February 2023. At the Annual General Meeting of Biotest AG, Mr. Raimon Grifols Roura was elected to the Supervisory Board as a shareholder representative with a large majority, as proposed by the Supervisory Board. Mr. Raimon Grifols Roura, as Chief Corporate Officer, is a member of the Board of Directors of Grifols, S.A., Barcelona, Spain, the Company's major shareholder. As substitute member for Mr. Raimon Grifols Roura, Mr. Javier Lluell Colera was also elected by a large majority. Mr. Javier Lluell Colera is Deputy Chief Financial Officer of Grifols, S.A.

B. RESEARCH AND DEVELOPMENT

At € -30.7 million, costs for research and development in the first six months of financial year 2023 were significantly (9.6 %) above the comparable level for the previous year of € -24.4 million. The increase in expenses was mainly due to the progress of the research and development projects Fibrinogen and Trimodulin. The increase was partially offset by the recognition of a research allowance in accordance with the Research Allowance Act (Forschungszulagengesetz) and a grant from the Federal Ministry of Education and Research in the amount of € 4.3 million (previous year € 6.6 million). 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 June 2023 period:

RESEARCH & DEVELOPMENT PROGRESS IN THE FIRST SIX 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)	Two phase III trials: a) TRICOVID trial (hospitalised COVID-19 patients): Submissions to authorities and ethics committees are complete and approvals to conduct the study have been obtained in various countries. First patient treated in December 2022. The study is in the treatment phase. b) ESsCAPE study (patients with severe community-acquired pneumonia): submissions in selected countries have been issued, and authorisations are underway. The first approvals to conduct studies in the USA and individual European countries have been granted. The study is in the recruitment phase.
Clinical Immunology therapeutic area	
BT 097 (Cytotect® CP Biotest)	The phase III registration trial (PreCysson; trial no. 997) is in the treatment phase.

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

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 new products Fibrinogen and Trimodulin. Alongside 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; the final 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. 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 for the treatment of patients with congenital and acquired fibrinogen deficiency. Biotest is seeking marketing authorisation in Europe and subsequently in the USA.

Moreover, the phase III trial in COVID-19 (TRICOVID, 1001) has already been submitted and approved in several countries. Further authorisation procedures are currently underway. The first patient was treated in December 2022. The study is in the treatment phase. 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 granted

approvals. In addition, the approvals of the respective ethics committees have been obtained in the USA and in some European countries and the first trial centres have been activated. Approval procedures are still ongoing in other countries.

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 CMV after heart or lung transplantation.

C. MARKETING AND DISTRIBUTION

Biotest observed that the growth trend in plasma donations which was evident in the USA and Europe in 2022 continued during the first half of 2023.²² Nonetheless, demand for immunoglobulins (IgG) and albumin remains at a stable high level and is growing globally, which is also reflected in the stable price trend.

The return of many hospitals to normal operations and associated resumption of planned surgeries led to higher demand for albumin in the first half of 2023. 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. Demand for albumin in Asia is high, while the situation in the MEAF (Middle East Africa France) region has also improved significantly. Biotest successfully expanded its albumin business with revenue growing worldwide and the start of the partnership with Grifols in China.

MARKETING & DISTRIBUTION PROGRESS IN THE FIRST SIX MONTHS OF 2023

Clinical Immunology therapeutic area	
Yimmugo®	Expansion of distribution 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 in some markets

IV. RESULTS OF OPERATIONS, NET ASSETS AND FINANCIAL POSITION

A. RESULTS OF OPERATIONS

In the first half of 2023, the Biotest Group generated revenue of € 275.3 million compared with € 253.1 million in the prior-year period. Revenue in the Therapy Segment was higher year-on-year and reflected revenue from the new immunoglobulin Yimmugo® amounting to € 9.6 million as well as revenue from human albumin that was € 13.1 million higher year-on-year, which was partly reduced by a lower level of revenue from Intratect®. In addition, revenue of € 14.9 million from development services rendered for Grifols, S.A., Barcelona, Spain, under the technology transfer and licensing agreement contributed to the revenue growth. At € 23.8 million, revenue in the Plasma & Services Segment was 19.0 % lower year-on-year due to a lower level of toll manufacturing. In addition, revenue in the Other Segments area increased

²² Source: PPTA 2023

to € 3.4 million compared with € 3.1 million in the same period of the previous year. This growth is due to a higher level of revenue generated with merchandise.

SALES BY SEGMENT

in € million	H1 2023	H1 2022	Change in %
Therapy	248.1	220.6	12.5
Plasma & Services	23.8	29.4	-19.0
Other Segments	3.4	3.1	9.7
Biotest Group	275.3	253.1	8.8

At the beginning of the 2023 financial year, the sales regions were restructured. This entailed an adaptation of the assignment of countries to regions. At sales region level, Biotest recorded year-on-year revenue growth in Central Europe as well as in the Middle East, Africa and France in the first half of 2023. This growth was partly offset by the lower level of revenue generated in the Eastern and Southern Europe, Central Asia, America and Other regions. Revenue in the Middle East, Africa and France region posted strong growth (of 14.7 %). This growth mainly reflected year-on-year higher revenue generated in Saudi Arabia, Jordan and Oman. The Central Europe region continued to make the largest contribution when measured in terms of absolute revenue figures. Stateless revenue of € 14.9 million relates to revenue generated with the parent company Grifols, S.A., Barcelona, Spain.

REVENUE BY REGION

in € million	H1 2023	H1 2022*	Change in %
Central Europe	111.0	104.7	6.0
Eastern and Southern Europe, Central Asia, America*	62.2	66.8	-6.9
Middle East, Africa and France*	56.2	49.0	14.7
Other	31.0	32.6	-4.9
Stateless	14.9	-	-
Biotest Group	275.3	253.1	8.8

*The prior-year figures have been adjusted in line with the definition of the sales regions in 2023.

The cost of sales amounted to € 202.8 million in the first half of 2023 (prior-year period: € 196.0 million). The cost of sales ratio measured in relation to total revenue, adjusted for revenue from development services (€ 14.9 million), was 77.9 % and thereby at the same level as the previous year's period of 77.4 %.

Marketing and distribution costs of € 25.5 million for the first six months of the 2023 financial year were higher than the previous year's level of € 23.3 million, due to higher marketing costs for the launch of Yimmugo® and increased transport costs.

The Biotest Group's administrative expenses for the first half of 2023 of € 16.7 million were up 2.4 % year-on-year (prior-year period: € 16.3 million). The increase is due to a higher level of insurance costs and consultancy services in connection with the sale of the Biotest subsidiaries to Grifols, S.A., Barcelona, Spain, among other factors.

In the first six months of the 2023 financial year, research and development costs of € 30.7 million were incurred, € 6.3 million above the previous year's level (€ 24.4 million). Of this amount, € 13.0 million is attributable to the further development services relating to Yimmugo, Trimodulin and Fibrinogen. This includes the expense-reducing research allowance under the Research Allowance Act and the BMBF (Federal Ministry of Education and Research) grant totalling € 4.3 million (prior-year period: € 6.6 million).

The increase in other operating income is mainly due to the € 23.1 million (prior-year period: € 0.0 million) gain on the divestiture of interests in the subsidiaries Biotest France SAS, Paris, France, Biotest (UK) Ltd., Birmingham, UK, Biotest Italia S.r.l., Milan, Italy, Biotest Farmacêutia Ltda., São Paulo, Brazil and Biotest Medial S.L.U., Barcelona, Spain to Grifols, S.A., Barcelona, Spain.

EBIT in the first half of 2023 amounted to € 19.8 million and was thereby up year-on-year (prior-year period: € -9.1 million). This includes expenses of € 43.8 million for the ramp-up of production capacity in the Biotest Next Level facility (prior-year period: € 41.5 million). The increase in EBIT of € 28.9 million compared to the first half of 2022 is mainly due to the gain on the disposal of five Biotest subsidiaries to Grifols, S.A., Spain in the amount of € 23.1 million and the € 1.9 million margin from the charging-on of development services. As a consequence, the EBIT margin for the first six months of the current financial year amounted to 7.2 %, compared with -3.6 % in the same

period of the previous year. Adjusted EBIT describes the operating performance of the Biotest Group excluding exceptional items. In the previous year, the one-off effects related to expenses from the Biotest Next Level expansion project. With the market launch of Yimmugo® in November 2022, the Biotest management considers the project to be completed and the expenses for Biotest Next Level are no longer recognised as a exceptional item. This project has been completed. In the 2023 financial year, the exceptional items relate to the revenue from development services charged to Grifols, S.A., Barcelona, Spain, and the gain on the disposal of five Biotest subsidiaries. This metric is an alternative performance measure (APM) that is not defined in IFRS (International Financial Reporting Standards).

ADJUSTED EBIT			
in € million	H1 2023	H1 2022	Change in %
EBIT	19.8	-9.1	>100
Expenses for Biotest Next Level	-	41.5	-100.0
Earnings from development services	-1.9	-	-
Disposal gain	-23.1	-	-
adjusted EBIT	-5.2	32.4	>100
adjusted EBIT margin	-4.2%	12.8%	-

KEY INCOME STATEMENT ITEMS OF THE BIOTST GROUP

in € million	H1 2023	% of sales	H1 2022	% of sales
Revenue	275.3	100.0	253.1	100.0
Cost of sales	-202.8	77.4	-196.0	78.3
Marketing and distribution costs	-25.5	9.2	-23.3	9.2
Administrative expenses	-16.7	6.4	-16.3	5.7
Research and development costs	-30.7	9.6	-24.4	10.5
Other operating income and expenses	20.1	0.9	-2.2	0.4
Financial income and expenses	-18.6	3.5	-8.9	3.6

The adjusted EBIT margin for the first six months of the current financial year amounted to -4.2 %, compared with 12.8 % in the same period of the previous year.

EBIT BY SEGMENT

in € million	H1 2023	H1 2022	Change in %
Therapy	23.6	-6.8	>100
Plasma & Services	-2.1	-0.5	>-100
Other Segments	-1.7	-1.8	6
Biotest Group	19.8	-9.1	>100

In the Therapy Segment, EBIT was in positive territory and increased significantly by € 30.4 million, which is mainly due to the gains on disposal of the Biotest subsidiaries amounting to € 23.1 million. This positive change contrasts with the € 1.6 million reduction in EBIT in the Plasma & Services Segment, which amounted to € -2.1 million in the first half of 2023 (prior-year period: € -0.5 million).

In the Other Segments area, EBIT improved by € 0.1 million year-on-year to € -1.7 million. This was partly due to lower cross-divisional administrative expenses.

In the first half of 2023, the financial result amounted to € -18.6 million, compared with € -8.9 million in the same period of the previous year. This decrease is mainly due to the € 5.9 million increase in interest expenses. In the first half 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 € 0.9 million also had a negative effect on the financial result (prior-year period: income of € 1.8 million).

For the Biotest Group, this leads to earnings before taxes (EBT) of € 1.2 million compared with € -18.0 million in the same period of the previous year.

In view of the influencing factors described above, the Biotest Group's total earnings after taxes (EAT) in the first half of 2023 thereby increased to € 1.7 million (prior-year period: € -19.9 million). This is equivalent to earnings per ordinary share of € 0.03 compared with € -0.50 in the first half of 2022.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	H1 2023	H1 2022	Change in %
EBIT	19.8	-9.1	>100
EBT	1.2	-18.0	>100
EAT	1.7	-19.9	>100

B. NET ASSETS

The Biotest Group's total assets increased slightly from € 1,203.0 million as of the 31 December 2022 reporting date to € 1,214.1 million as of the 30 June 2023 reporting date.

Compared to the level at the end of 2022, non-current assets increased to € 593.4 million (31 December 2022: € 583.6 million). The increase in the first half arose mainly from € 9.5 million of additions to rights of use from leases.

Current assets increased slightly by € 1.3 million compared to the end of 2022 and amounted to € 620.7 million as of 30 June 2023 (31 December 2022: € 619.4 million). This change is based on several effects that partly offset each other: inventories were further expanded to secure the sales revenues planned over the coming months with the new BNL production facility, and increased by € 47.3 million. Contract assets also rose by € 8.9 million and trade receivables by € 24.8 million. By contrast, other financial assets decreased by € -14.4 million. This was mainly due to the divestiture of the entire remaining shares in ADMA Biologics Inc. within the first six months of 2023. Furthermore, cash and cash equivalents decreased by € -58.3 million and amounted to € 58.3 million as of 30 June 2023 (31 December 2022: € 116.4 million).

Due to the positive result for the period, equity increased to € 373.5 million as of the 30 June 2023 reporting date (31 December 2022: € 371.1 million). The equity ratio thereby stood at 30.8 % as of the end of the first half of 2023.

As of the 30 June 2023 reporting date, total debt had risen by € 8.7 million to € 840.6 million (31 December 2022: € 831.9 million). Non-current liabilities have increased by € 16.1 million to € 717.8 million since 31 December 2022, primarily due to a higher level of non-current financial liabilities. Current liabilities decreased by € 7.4 million to € 122.8 million as of the 30 June 2023 reporting date. This was mainly due to a decrease in trade payables of € 10.5 million, which was partly offset by an increase in trade payables of € 3.4 million.

C. FINANCIAL POSITION

The Biotest Group recorded € -74.8 million of operating cash flow in the first six months of 2023, primarily due to working capital changes of € -81.6 million. The working capital changes mainly reflect a higher level of inventories, trade receivables and the impact on working capital of changes in the scope of consolidation in connection with the divestiture of five subsidiaries. The proceeds from the sale of the shares in ADMA Biologics Inc. during the first six months of 2023 exerted an opposite effect. In the same period of the previous year, operating cash flow amounted to € 1.9 million.

Cash flow from investing activities in the period from January to June 2023 amounted to € 19.4 million (previous year: € -15.5 million), reflecting, among other items, € 35.0 million of payments received from the divestiture of the interests in the Biotest subsidiaries in Spain, Brazil, Italy, UK and France to Grifols, S.A., Barcelona, Spain, which were partially offset by payments for capital expenditure. Cash flow from financing activities in the first half of 2023 amounted to € -2.5 million and was thereby above the previous year's level of € -5.8 million. The cash outflows from financing activities were mainly for the repayment portion of the lease liabilities in accordance with IFRS 16. 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 30 June 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, which had not been drawn yet as of 30 June 2023. As a consequence, credit lines of € 162 million were available as of 30 June 2023.

D. OVERALL ASSESSMENT OF THE COMPANY'S BUSINESS SITUATION

The effects of high inflation rates and higher prices for the important raw material plasma, could assume an adverse trend for the Biotest Group and thereby have a significant adverse effect on the Biotest Group's financial position and performance. Biotest management still does not expect any major disruptions due to Russia's attack on Ukraine.

Due to the various partnership agreements signed between Biotest and Grifols, in April 2023 the Board of Management raised the EBIT forecast for 2023 from a range between € -20 and -15 million to a level that could potentially exceed € 100 million. Further specification depends on the revenue and earnings realisation in relation to the final project milestones.

For further research activities, please see section A.IV Research and Development (General) in the 2022 Annual Report as well as the following section B of this half-year report.

C. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. OUTLOOK REPORT

A. TRENDS IN THE MARKET ENVIRONMENT

Target markets

According to current studies, global demand for immunoglobulins (IgG) will continue to grow annually in the mid-single-digit percentage range over the next few years.²³ The prices of these preparations are beginning to stabilise at a high level and may potentially even slightly increase, depending on the market, due to further demand growth.²⁴

The long-term growth of the global albumin market is forecast to amount to around 6 % per year.²⁵

Growth of between -5 % and 1 % per year is forecast for the global market for plasmatic Factor VIII preparations up to 2024.²⁶

B. EXPECTED DEVELOPMENT OF THE BIOTEST GROUP

Expected business and results of operations of the Biotest Group

Biotest AG, Dreieich, Germany and Grifols, S.A., Barcelona, Spain have signed various agreements, including relating to technology transfer and licensing agreement. These agreements ensure that Biotest's new product developments can be manufactured and distributed worldwide by making recourse to Grifols' organisation and production network. This also enables Grifols to optimise its own processes and reduce in-house developments. In return, a payment was agreed for the transferred technology as well as recurring licence payments to be made at a later date based on sales generated by the licensed products. Revenues from the technology transfer and the development services will probably have a positive effect on earnings before interest and taxes (EBIT) in a three-digit figure in millions of euros in the second half of 2023.

For this reason, in April 2023, the Board of Management raised the EBIT forecast for 2023 from a range between € -20 and € -15 million to a level that could potentially exceed € 100 million. Further specification depends on the revenue and earnings realisation in relation to the final project milestones.

²³ MRB (2021) supplemented by Biotest internal analyses.

²⁴ IQVIA (June 2023), www.cms.gov supplemented by Biotest internal analyses.

²⁵ Markets and Markets (2020) supplemented by Biotest internal analyses.

²⁶ MRB (2019), Biotest internal analysis.

For the 2023 financial year, the Board of Management aims for revenue growth in the mid-single-digit percentage range compared with 2022, excluding revenue under the technology transfer and licensing agreement. This revenue growth is enabled by the start-up of the Yimmugo® production facility within Biotest Next Level. However, the Board of Management does not rule out negative sales developments as a consequence of potential cyclically induced declines in demand and country-specific savings in the healthcare sector.

Expected financial and net assets position of the Biotest Group

The Biotest Group aims to maintain a balanced financing structure with regard to the ratio of debt to equity as well as short-term to long-term credit financing. The Group has used and will continue to use the majority of the cash and cash equivalents received in recent years for the Biotest Next Level project in order to secure the ramp-up of the new production facility and to ensure the requisite raw material supplies of plasma. For the 2023 financial year, capital expenditure by the Biotest Group in a volume of approximately € 35 million to € 40 million is planned. Around one tenth of the capital expenditure reflects further investments for the expansion of existing plasma centres and the establishment of new centres in Europe. The major share of capital expenditure is to be devoted to the expansion and maintenance of production facilities and infrastructure measures at the Dreieich site in Germany. Financing in 2023 has been mainly provided by shareholder loans and other external financing sources. These financing sources, which are available to Biotest on both a short-term and long-term basis, the contractual financing commitment from Grifols Worldwide Operations Limited, Dublin, Ireland, as well as the technology transfer and licensing agreement, secure the emerging financing requirements for the ramp-up of the Biotest Next Level project as well as further R&D activities.

II. RISK REPORT

The risk situation of the Biotest Group has not changed significantly compared to the presentation in the Risk Report in the Annual Report 2022 (pages 30-42), except for the risks previously presented in connection with the effects of the Russia-Ukraine war and the high inflation rate. High inflation rates could have an adverse effect on the Biotest Group's financial position and performance.

Apart from this, there are still no discernible risks that could jeopardise the continued existence of the Biotest Group as a going concern.

III. OPPORTUNITIES REPORT

Opportunities for the Biotest Group have changed significantly compared to the presentation in the Opportunities Report in the Annual Report 2022 due to the strengthening of the partnership with Grifols, S.A.

On 28 April 2023, the Supervisory Board approved the conclusion of several agreements by the Board of Management to further expand the cooperation between Grifols, S.A. and Biotest AG in research & development, manufacturing, production and marketing & distribution. For example, a technology transfer agreement and a licensing agreement will ensure that Biotest's new product developments can be manufactured and distributed worldwide by using Grifols' organisation and production network. In return, a payment was agreed for the technology transfer as well as licence payments to be made at a later date based on the sales proceeds from the licensed products. The payment for the technology will have a positive effect on earnings before interest and taxes (EBIT) in the three-digit range in millions of euros in the second half of the financial year 2023.

The intensified collaboration with Grifols has enhanced the chances of jointly generating higher revenues for the new products Yimmugo®, Trimodulin and Fibrinogen with the higher production capacities and a stronger market presence. Biotest would participate in these through additional product sales and, potentially, licence payments.

D. SUPPLEMENTARY REPORT

No events occurred after the balance sheet date that 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 30 June 2023

in € million	Q2 2023	Q2 2022	H1 2023	H1 2022
Revenue	158.0	137.2	275.3	253.1
Cost of sales	-110.3	-106.4	-202.8	-196.0
Gross profit	47.8	30.8	72.5	57.1
Other operating income	24.2	0.8	24.7	1.0
Marketing and distribution costs	-13.2	-12.4	-25.5	-23.3
Administrative expenses	-7.1	-7.6	-16.7	-16.3
Research and development costs	-19.9	-13.5	-30.7	-24.4
Other operating expenses	-2.9	-2.3	-4.6	-3.2
Operating profit	28.9	-4.2	19.8	-9.1
Financial income	3.4	3.0	7.0	7.3
Financial expenses	-12.7	-8.2	-25.6	-16.2
Financial result	-9.3	-5.2	-18.6	-8.9
Earnings before taxes	19.6	-9.4	1.2	-18.0
Income taxes	2.5	-5.6	0.6	-1.9
Earnings after taxes	22.2	-15.0	1.7	-19.9
Attributable to:				
Equity holders of the parent	22.2	-15.0	1.7	-19.9
Earnings per share in €	0.55	-0.39	0.03	-0.50

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 June 2023

in € million	H1 2023	H1 2022
Profit (Loss)	1.8	-19.9
Exchange difference on translation of foreign operations	0.7	-1.0
Reclassification of foreign currency translation differences recognised in the statement of income	0.3	-
Reclassification of the deconsolidation effect to the income statement	-0.3	-
Other comprehensive income, net of tax reclassified to profit or loss in subsequent periods	0.7	-1.0
Remeasurement of defined benefit plans	-	-
resulting income tax effect	-	-
Other comprehensive income, net of tax, not to be reclassified to profit or loss in subsequent periods	-	-
Other comprehensive income, net of tax	0.7	-1.0
Total comprehensive income, net of tax	2.5	-20.9
Attributable to:		
Equity holders of the parent	2.5	-20.9

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 June 2023

in € million	30 June 2023	31 December 2022
ASSETS		
Non-current assets		
Intangible assets	15.5	16.4
Property, plant and equipment	518.7	520.3
Right-of-use assets	37.0	27.5
Investments in joint ventures	5.1	5.1
Other assets	0.2	0.3
Other financial assets	15.9	13.3
Deferred tax assets	1.0	0.7
Total non-current assets	593.4	583.6
Current assets		
Inventories	341.1	293.8
Contract assets	44.1	35.2
Trade receivables	149.3	124.5
Current income tax assets	–	0.6
Other assets	15.3	21.7
Other financial assets	12.6	27.0
Cash and cash equivalents	58.3	116.6
Total current assets	620.7	619.4
Total assets	1,214.1	1,203.0
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	112.4	143.4
Share of profit or loss attributable to equity holders of the parent	1.7	–31.7
Equity attributable to equity holders of the parent	373.5	371.1
Total equity	373.5	371.1
Non-current liabilities		
Provisions for pensions and similar obligations	86.2	85.8
Other provisions	2.1	1.9
Financial liabilities	628.5	612.8
Other liabilities	–	–
Deferred tax liabilities	1.0	1.2
Total non-current liabilities	717.8	701.7
Current liabilities		
Other provisions	15.8	26.3
Current income tax liabilities	0.4	0.3
Financial liabilities	33.6	31.3
Trade payables	54.5	51.1
Other liabilities	18.3	21.0
Contract liabilities	0.2	0.2
Total current liabilities	122.8	130.2
Total liabilities	840.6	831.9
Total equity and liabilities	1,214.1	1,203.0

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 June 2023

in € million	H1 2023	H1 2022
Operating cash flow before changes in working capital	18.5	9.2
Cash flow from changes in working capital	-81.6	1.2
Interest and taxes paid	-11.7	-8.5
Cash flow from operating activities total	-74.8	1.9
Cash flow from investing activities total	19.4	-15.5
Cash flow from financing activities total	-2.5	-5.8
Cash changes in cash and cash equivalents	-57.9	-19.4
Exchange rate-related changes in cash and cash equivalents	-	-
Cash and cash equivalents on 1 January	116.6	104.4
Consolidation group related changes to cash	-0.4	-
Cash and cash equivalents on 30 June	58.3	85.0

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 June 2023

in € million	Subscribed capital	Share-premium	Retained earnings	Remeasurement of defined benefit obligations	Translation reserve	Total equity
As of 1 January 2022	–	–	155.7	–32.7	–2.0	121.0
Reclassification to income statement	–	–	–	–	–	–
Other comprehensive income after tax	–	–	–	23.2	–	23.2
Profit (loss)	–	–	–31.7	–	–	–31.7
Total comprehensive income	–	–	–31.7	23.2	–	–8.5
Dividend payments	–	–	–0.8	–	–	–0.8
As of 31 December 2022	39.6	219.8	123.2	–9.5	–2.0	371.1
As of 1 January 2023	39.6	219.8	123.2	–9.5	–2.0	–
Reclassification to income statement	–	–	–0.4	0.1	0.3	–
Other comprehensive income after tax	–	–	–	–	0.7	0.7
Profit (loss)	–	–	1.8	–	–	1.8
Total comprehensive income	–	–	1.8	–	0.7	2.5
Dividend payments	–	–	–	–	–	–
As of 30 June 2023	39.6	219.8	124.6	–9.4	–1.0	373.6

SELECTED DISCLOSURES

METHOD OF PREPARATION

These interim considered financial statements as of 30 June 2023 of Biotest AG and its subsidiaries have been prepared in accordance with the International Financial Reporting Standards (IFRS) that are mandatory in the European Union. Accordingly, these interim consolidated financial statements as of 30 June 2023 have been prepared in accordance with IAS 34 "Interim Financial Reporting" and contain condensed reporting compared to the consolidated financial statements. IFRS include the International Financial Reporting Standards (IFRS), the International Accounting Standards (IAS) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IC) and the Standing Interpretation Committee (SIC). The Biotest Group's accounting policies are based on IFRS whose application is mandatory for financial years beginning on 1 January 2023.

The accounting policies applied are the same as those used in the last financial statements.

These interim consolidated financial statements were approved for publication by the Board of Management on 10 August 2023.

SCOPE OF CONSOLIDATION

The consolidated financial statements of Biotest AG include three (previous year: three) domestic and seven (previous year: eleven) foreign companies in which Biotest AG directly or indirectly holds the majority of voting rights.

On 30 May 2023, the Biotest Group founded a 100% subsidiary Biotest Lux S.à.r.l, Luxembourg, Luxembourg. This subsidiary has been fully consolidated since then.

Biotest France SAS, Paris, France, Biotest (UK) Ltd, Birmingham, UK, Biotest Italia S.r.l., Milan, Italy, Biotest Farmacêutia Ltda, Saõ Paulo, Brazil and Biotest Medial S.L.U, Barcelona, Spain were sold to entities of the Grifols Group in the past quarter as part of the integration into the Grifols Group.

BioDarou P.J.S. Co., based in Tehran, Iran, is included in the consolidated financial statements at equity as a joint venture.

An overview of the participating interest of Biotest AG as defined by Section 313 (2) HGB is provided in the 2022 Annual Report, section F 9 List of shareholdings.

Grifols Biotest Holdings GmbH, Frankfurt am Main, Germany (until 25 April 2022 operating as Tiancheng (Germany) Pharmaceutical Holdings AG ("Tiancheng"), Munich, Germany), holds a majority interest in the voting rights of Biotest AG. The Biotest Group is included in the consolidated financial statements of Grifols, S.A., Barcelona, Spain, which, as the Group's ultimate parent company, also prepares the consolidated financial statements for the largest group of consolidated companies.

NET DEBT

in € million	30 June 2023	31 December 2022
Shareholder loan	325.7	322.0
Financial liabilities to third parties	269.7	266.0
Lease liabilities	38.7	29.0
Financial liabilities	634.1	617.0
Cash and cash equivalents	58.3	116.6
	58.3	116.6
Net debt	575.8	500.4

The year-on-year increase in net debt is mainly attributable to the lower level of cash and cash equivalents. A loan concluded in 2019 for a total volume of € 240.0 million with a maturity in 2024 was drawn down in an amount of € 225 million as of 30 June 2022. No further drawings were made in the first half of the year.

SEGMENT REPORTING

of the Biotest Group for the period from 1 January to 30 June 2023

in € million	Revenue			EBIT		
	H1 2023	H1 2022	Change in %	H1 2023	H1 2022	Change in %
Therapy	248.1	220.6	12.5	23.6	-6.8	>100
Plasma & Services	23.8	29.4	-19.0	-2.1	-0.5	>-100
Other Segments	3.4	3.1	9.7	-1.7	-1.8	5.6
Biotest Group	275.3	253.1	8.8	19.8	-9.1	>100

in € million	Revenue based on customer's geographical location		
	H1 2023	H1 2022*	Change in %
Central Europe	111.0	104.7	6.0
Eastern and Southern Europe, Central Asia, America*	62.2	66.8	-6.9
Intercontinental*	56.2	49.0	14.7
Middle East, Africa and France*	31.0	32.6	-4.9
Stateless	14.9	-	-
Biotest Group	275.3	253.1	8.8

*The prior-year figures have been adjusted in line with the definition of the sales regions in 2023.

RECONCILIATION OF TOTAL SEGMENT RESULTS TO EARNINGS AFTER TAXES OF THE BIOTEST GROUP

in € million	H1 2023	H1 2022
Operating profit (EBIT)	19.8	-9.1
Financial income and expenses	-18.6	-8.9
Earnings before taxes (EBT)	1.2	-18.0
Income taxes	0.6	-1.9
Earnings after taxes (EAT)	1.7	-19.9

in € million	Segments							
	Therapy		Plasma & Services		Other Segments		Total	
Categories	H1 2023	H1 2022*	H1 2023	H1 2022	H1 2023	H1 2022	H1 2023	H1 2022
Type of products and services								
Sale of Biotest products	233.2	220.6	-	-	-	-	233.2	220.6
Toll manufacturing and know-how transfer	-	-	23.8	29.4	-	-	23.8	29.4
Development services	14.9	-	-	-	-	-	14.9	-
Sale of merchandise	-	-	-	-	3.4	3.1	3.4	3.1
	248.1	220.6	23.8	29.4	3.4	3.1	275.3	253.1
Geographical markets								
Central Europe	93.3	90.9	14.3	10.7	3.4	3.1	111.0	104.7
Eastern and Southern Europe, Central Asia, America*	62.1	56.6	0.1	1.3	-	-	62.2	57.9
Middle East, Africa and France*	46.8	42.5	9.4	-	-	-	56.2	42.5
Other	31.0	30.6	-	17.4	-	-	31.0	48.0
Stateless	14.9	-	-	-	-	-	14.9	-
	248.1	220.6	23.8	29.4	3.4	3.1	275.3	253.1
Timing of revenue recognition								
Goods transferred at a point in time	248.1	220.6	-	-	3.4	3.1	251.5	223.7
Services transferred over a period of time	-	-	23.8	29.4	-	-	23.8	29.4
	248.1	220.6	23.8	29.4	3.4	3.1	275.3	253.1

*The prior-year figures have been adjusted in line with the definition of the sales regions in 2023.

QUARTERLY COMPARISON

by business segment

in € million	Revenue				
	Q2 2023	Q1 2023	Q4 2022	Q3 2022	Q2 2022
Therapy	143.8	104.2	141.7	97.2	117.0
Plasma & Services	12.5	11.3	11.9	9.1	18.4
Other Segments	1.7	1.8	1.6	1.4	1.8
Biotest Group	158.0	117.3	155.2	107.7	137.2

in € million	EBIT				
	Q2 2023	Q1 2023	Q4 2022	Q3 2022	Q2 2022
Therapy	23.5	-6.5	5.6	-7.5	-3.9
Plasma & Services	-2.1	-1.7	-3.7	-1.7	0.2
Other Segments	-1.7	-1.0	0.4	-0.7	-0.4
Biotest Group	19.7	-9.2	2.3	-9.9	-4.1

OTHER DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2022	Changes scope of consolidation net	Capital expenditure	Disposals net	Depreciation and amortisation	Currency translation differences	Carrying amount as of 30 June 2023
Intangible assets	16.4	16.4	0.9	-0.1	-0.5	-	16.7
Property, plant & equipment	520.3	520.3	13.6	-1.0	-14.6	0.7	519.0
Right of use assets	27.5	25.3	13.2	-0.8	-2.6	0.4	37.7
Total	564.2	562.0	27.7	-1.9	-17.7	1.1	573.4

Employees

by operating functions

Full-time equivalents	30 June 2023	31 December 2022	Change in %
Production	1,724	1,574	9.6
Administration	214	242	-11.4
Distribution	146	189	-22.4
Research and development	222	223	-0.5
Biotest Group	2,307	2,228	3.6

Financial instruments as of 30 June 2023

in € million	Carrying amount	Fair value
Assets		
Trade receivables	149.3	149.3
Other financial assets	28.5	27.4
Cash and cash equivalents	58.3	58.3
Equity and liabilities		
Trade payables	54.5	54.5
Financial liabilities		
Subordinated shareholder loans	325.7	353.5
Secured loans from financial institutions	224.2	239.6
Unsecured promissory note loans	2.0	2.1
Other financial liabilities	71.0	69.8
Derivatives without hedging relationship	0.4	0.4

FAIR VALUE HIERARCHY

According to IFRS 13.72, the financial instruments measured at fair value on the balance sheet are to be classified in a three-level hierarchy of fair value measurement. The level in each case reflects the market proximity of the data included in the determination of the fair value. The levels of the fair value hierarchy are described below:

Level 1: Quoted market prices for identical assets or liabilities in active markets,

Level 2: Information other than quoted market prices that is observable directly (e.g. prices) or indirectly (e.g. derived from prices) and

Level 3: Information for assets and liabilities that is not based on observable market data.

For assets and liabilities that are recognised in the financial statements on a recurring basis, the Group determines whether transfers have occurred between levels in the hierarchy by reviewing the classification (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

In order to comply with the fair value disclosure requirements, the Group has identified groups of assets and liabilities based on their nature, characteristics and risks as well as the levels of the fair value hierarchy explained above.

In accordance with IFRS 7.29, it was assumed that the fair value of current financial instruments corresponds to the carrying amount, unless stated otherwise.

Trade receivables (both sold and unsold) and other assets mainly have remaining terms of less than one year. For this reason, the carrying amounts at the reporting date correspond approximately to the fair values. In the case of other non-current receivables and financial investments held to maturity, which consequently have remaining terms of more than one year, the fair values correspond to the present values of the payments associated with the assets, taking into consideration the respective current interest rate parameters, which reflect market- and partner-related changes in conditions and expectations.

For the financial (non-derivative) assets measured at fair value, the fair value is determined by reference to the share price of ADMA Biologics Inc. and in the previous year (as of 30 June 2022) still including a discount. The discount was estimated based on the size of the share block, the trading volume, the profitability of the company and the urgency of the sale. The estimates are derived from historical empirical data. In the previous year (as of 30 June 2022), the fair value was assigned to hierarchy level 3.

Since 27 September 2022, the trustee has sold 2,395,580 shares of ADMA Biologics Inc. in small quantities spread over four months. In each case, the current daily price of the shares was achieved and a discount no longer had to be applied for the size of the share package. As publicly quoted prices are thereby available on an active market, the valuation of the shares in ADMA Biologics Inc. was reclassified from hierarchy level 3 to hierarchy level 1 on 31 December 2022.

Derivative financial assets and liabilities (foreign exchange transactions and embedded derivatives) are measured on a mark-to-market basis using quoted foreign exchange rates and yield curves available in the market. The fair value is assigned to hierarchy level 2.

The fair value of the pension funds recognised in other financial assets is assigned to hierarchy level 1.

Trade accounts payable and other liabilities generally have remaining terms to maturity of less than one year. For this reason, here, too, the carrying amounts also approximate the corresponding fair values.

The fair values of liabilities to financial institutions, liabilities to the shareholder and other financial liabilities are determined as the present values of the payments associated with the liabilities on the basis of the relevant yield curve and the credit spread curve broken down by currency. The fair value is assigned to hierarchy level 2.

CONTINGENT ASSETS AND CONTINGENT LIABILITIES

A contingent asset is a possible asset that arises from past events and whose existence will be confirmed only by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the entity. There are no contingent assets in the first half of 2023.

Contingent liabilities are possible obligations that arise from past events and whose existence has yet to be confirmed by the occurrence or non-occurrence of one or more uncertain future events not wholly within the control of the entity. Contingent liabilities may also arise from present obligations that result from past events but are not recognised either because the outflow of resources embodying economic benefits is not probable or the amount of the obligation cannot be measured with sufficient reliability.

There is a contingent liability of € 5.1 million in connection with ongoing antitrust proceedings in Romania.

Cash deposits of € 11.8 million (previous year: € 12.5 million) were made with banks as collateral.

There are contingent liabilities of € 1.5 million (previous year: € 1.7 million) from collateral for liabilities of affiliated companies.

There are contingent liabilities for price moratoriums and mandatory discounts in the single-digit millions (previous year: € 0.0 million).

RELATED PARTY DISCLOSURES

Grifols Biotest Holdings GmbH, Munich, Germany, a directly controlled subsidiary of Grifols, S.A., Barcelona, Spain, holds a majority interest (97.14 % of the voting ordinary shares of Biotest AG) in Biotest AG.

Grifols Biotest Holdings GmbH, Munich, Germany, grants Biotest subordinated shareholder loans in the total amount of € 290.0 million with the maturity of the shareholder loans until January 2025. The carrying amount of the loans with accrued interest as of 30 June 2023 is € 325.7 million. The interest expense from the shareholder loans amounted to € 3.7 million in the first half of 2023.

In the first half of 2023, Biotest Pharma GmbH, Dreieich, did not deliver any goods to Anhui Tonrol Pharmaceutical Co., Ltd., Anhui, People's Republic of China. As of 30 June 2023, Biotest Pharma GmbH had receivables due from Anhui Tonrol Pharmaceutical Co., Ltd. amounting to € 0.0 million.

The following relationships exist with individual companies of the Grifols Group:

Biotest purchased € 3.2 million of goods from Grifols Worldwide Operations Ltd. in Dublin, Ireland, in the first half of 2023. As of 30 June 2023, Biotest has no liabilities to Grifols Worldwide Operations Ltd.

In the first half of the financial year 2023, Biotest generated revenues from development services to Grifols, S.A., Barcelona, Spain under the technology transfer agreement in the amount of € 14.9 million.

The Biotest Group also has reportable relationships with the joint venture BioDarou P.J.S. Co., Tehran/Iran.

In the first six months of 2023, Biotest generated revenue of € 2.3 million from toll manufacturing with BioDarou P.J.S. Co. Biotest's receivables and contract assets from BioDarou P.J.S. Co. amounted to € 7.8 million as of 30 June 2023. The accumulated allowances for receivables and contract assets amounted to € 0.1 million as of 30 June 2023.

Apart from these business relationships, no material transactions with related parties arose in the reporting period.

EVENTS AFTER THE REPORTING DATE

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

INFORMATION IN ACCORDANCE WITH SECTION 115 (5) OF THE WpHG

These interim consolidated financial statements and the interim Group management report have not been reviewed by an auditor.

RESPONSIBILITY STATEMENT

Declaration in accordance with section 37y No. 1 of the German Securities Code (WpHG) in conjunction with Sections 297 (2) Sentence 3 and 315 (1) Sentence 6 of the German Commercial Code (HGB)

To the best of our knowledge, and in accordance with the applicable reporting principles for interim financial reporting, the interim consolidated financial statements give a true and fair view of the Group's financial position and performance, and the interim Group management report includes a fair review of the development and performance of the business and the position of the Group, together with a description of the principal opportunities and risks associated with the expected development of the Group for the remaining months of the financial year.

Dreieich, 10 August 2023

Biotest Aktiengesellschaft

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Chairman of the
Board of Management



Ainhoa Mendizabal Zubiaga
Member of the
Board of Management



Peter Janssen
Member of the
Board of Management



Dr. Jörg Schüttrumpf
Member of the
Board of Management

FINANCIAL CALENDAR

2 November 2023

Nine-month report

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This report contains forward-looking statements about macroeconomic trends as well as the business position, financial position and financial performance 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 half-year report. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

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