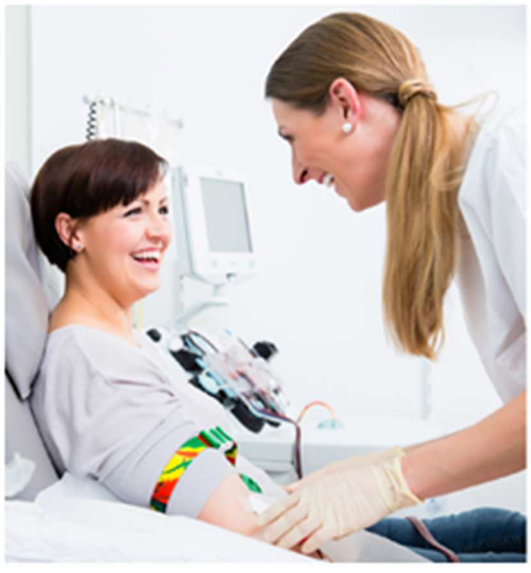
Biotest

From Nature for Life

HALF-YEAR REPORT 2024 BIOTEST AG



KEY FIGURES

BIOTEST GROUP		H1 2024	H1 2023	Change in %
Revenues	€ million	372.0	275.3	35.1
thereof:				
Germany	€ million	68.9	73.0	–5.6
Rest of World	€ million	303.1	202.3	49.8
thereof:				
European Union	€ million	134.4	139.1	–3.4
Rest of the World	€ million	139.3	121.3	14.8
Stateless	€ million	98.3	14.9	>100
EBITDA	€ million	100.1	37.5	>100
Depreciation and amortisation	€ million	21.7	17.7	22.6
Operating profit (EBIT)	€ million	78.4	19.8	>100
EBIT in % of revenues	*%*	*21.1*	7.2	
Earnings before taxes	€ million	59.4	1.2	>100
Earnings after taxes	€ million	39.1	1.7	>100
Earnings per share	€	0.98	0.03	>100
Financing				
Cash flow from operating activities	€ million	46.8	–74.8	>100
		30 June 2024	31 December 2023	
Equity	€ million	535.9	498.9	7.4
Equity ratio	*%*	*39.0*	*35.4*	
Balance sheet total	€ million	1,375.8	1,410.9	–2.5
Employees in FTEs	number	2,464	2,426	1.6

CONTENTS

DR. JÖRG SCHÜTTRUMPF
Chief Scientific Officer

AINHOA MENDIZABAL ZUBIAGA
Chief Financial Officer

PETER JANSSEN
Chief Executive Officer

Dear Shareholders,

On June 13, 2024, we achieved a historic success and a milestone in our efforts of recent years with the US approval of our immunoglobulin Yimmugo® by the responsible authority, the U.S. Food and Drug Administration (FDA). At the same time as the approval of Yimmugo®, our site in Dreieich, Germany, was also certified by the FDA. Following the approval of Yimmugo® in Europe, we now also have access to the world's largest single market for immunoglobulins, the USA. We immediately began ramping up our certified Biotest Next Level production facility at the Dreieich site and are aiming for a market launch in the USA in the first quarter of 2025. For this purpose, a binding term sheet for a future distribution agreement was concluded at the beginning of July, which provides for a minimum purchase volume of Yimmugo® over a period of seven years, corresponding to sales of more than USD 1 billion for Biotest AG.

This will be the first time that Biotest has launched an immunoglobulin from its production facility in Dreieich on the US market. Following this success, the approval of further products for the US market is planned. Following the successful completion of the phase III trial in acquired fibrinogen deficiency in February of this year, the application for marketing authorisation for Fibrinogen in the congenital and acquired fibrinogen deficiency indications is to be submitted to the FDA in the USA and in Europe before the end of this financial year. Yimmugo®, which is already present in the European markets of Germany, Austria and the UK, will be launched in the US market this year. This will gradually and significantly improve the capacity utilisation of Biotest Next Level and thus Biotest's profitability. In addition to the positive developments with Fibrinogen, we are also seeing progress with Trimodulin, another innovative new plasma protein, in the phase III trials in the indication severe community-acquired pneumonia (sCAP) and in the multinational CAP (community-acquired pneumonia) trial.

Biotest is continuing to expand its plasma collection centers in order to be able to meet the expected growth with a sufficient supply of blood plasma – the central raw material for Biotest products. In April, the twelfth collection center in Germany was opened in Wuppertal, which means that Biotest now has 38 collection centers in Europe (12 each in Hungary and Germany and 14 in the Czech Republic). Two more are to follow in Germany by the end of 2024. The aim is to further increase plasma collection at the company's own collection centers.

The collaboration between Biotest and our Spanish majority shareholder Grifols S.A. continued as planned in the first half of the year. This gives Biotest the opportunity to further develop its own new product developments using Grifols' organization and production network and thus make them available to patients even faster.

Despite a persistently challenging market environment, Biotest AG is on track to achieve its annual targets after six months of the 2024 financial year. In the first half of the year, the Biotest Group significantly increased sales from € 275 million to € 372 million. At the same time, Group EBIT increased significantly from € 20 million in the previous year to € 78 million. In addition to the positive sales and earnings effects from the growing day-to-day business, the technology transfer and licensing agreement with Grifols also had a positive impact. Biotest thus confirms the guidance for the full year 2024 issued in March, according to which Group sales are expected to increase by a high single-digit percentage compared with 2023 and an operating result (EBIT) in the range of € 80 to 100 million is to be achieved.

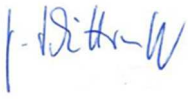
With its planned activities, Biotest will continue to contribute to improving patients' access to life-saving medicines. In the coming years, we expect the forthcoming approval of new products in more and more countries to boost growth and are aiming to increase sales to at least € 1 billion in the medium term, which will enable us to improve the margin and thus reduce debt.

With best regards,

Yours

Peter Janssen
Member of the
Board of Management

Ainhoa Mendizabal Zubiaga
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 2024

A. GROUP PRINCIPLES

I. THE GROUP'S BUSINESS MODEL

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

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

In operational terms, the company is divided into the following sales regions: European Union, Rest of the World, and Stateless. The European Union and Rest of the World regions cover the distribution of Biotest Group products. The Stateless region includes revenue from technology disclosure and development services for Grifols, S.A.

Until the 2023 financial year, the Biotest Group was managed according to the following segments: Therapy, Plasma & Services, and Other Segments. The new composition of the Board of Management and the review of the Biotest Group's reporting and management structure led to a change in operational business management during the 2023 financial year.

B. HUMAN RESOURCES

As of 30 June 2024, Biotest employed 2,464 full-time equivalents. This represents an increase of 1.6% compared to 2,426 full-time equivalents as of the end of the 2023 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 commercialisation and development of plasma proteins. In addition to continuously advancing its own research and development pipeline, the company's registration and marketing authorisation activities focus on the ongoing internationalisation and diversification of its portfolio. Moreover, the technology disclosure and development services ensure that Biotest's new product developments can be manufactured and marketed worldwide by making recourse to Grifols' organisation and production network. Biotest continues to expand its existing network of plasma collection centres every year. Plasma is also purchased.

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 new Biotest Next Level (BNL) production facility 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®, was approved in the German market and distribution commenced. At the end of June 2023, Biotest submitted the Biologics License Application (BLA) for the polyspecific immunoglobulin preparation Yimmugo® to the US Food and Drug Administration (FDA). The licence application covers the indication primary immunodeficiencies (PID). Yimmugo® received FDA approval in June 2024. This is the first product manufactured by Biotest in Dreieich to receive FDA approval. Biotest immediately started to ramp up production and will start shipping to the USA in the fourth quarter of 2024. The market launch is scheduled for the first quarter of 2025. The strategic partner for sales in the USA is Kedrion S.p.A., Barga, Italy, a global biopharmaceutical company. The strategic distribution agreement with Kedrion is expected to generate in excess of USD 1 billion in revenue for Biotest over a period of seven years. This is the largest commercial agreement that Biotest has entered into since it was founded.

Biotest is continuing to step up its efforts to rapidly develop the important development candidates Fibrinogen and Trimodulin, which will be produced in the new Biotest Next Level production facility, and to prepare them for marketing authorisation. Following the successful completion of the phase III trial in acquired fibrinogen deficiency in both completed indications, Fibrinogen is to be filed in the USA and the EU at the end of the year.

Following the acquisition by Grifols, S.A., as majority shareholder in April 2022, Biotest intends to expand future business opportunities in the subsequent years, and to improve the availability of plasma products to patients through closer collaboration with Grifols.

For example, measures such as technology disclosure and development services ensure that Biotest's new product developments can be manufactured and marketed worldwide by making recourse to Grifols' organisation and production network. In return, payments were agreed for the disclosed technology components as well as licence payments to be rendered at a later date based on the sales proceeds from the licensed products. In this context, Biotest recognised revenue from technology disclosure and development services for Grifols, S.A., in the amount of € 98.3 million in the first half of the 2024 financial year (prior-year period: € 14.9 million).

III. RESEARCH AND DEVELOPMENT (GENERAL)

As part of the corporate strategy, research and development, among other areas, form 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. At present, research activities are focussed on the new products Fibrinogen and Trimodulin, and are to be rapidly developed further and readied for marketing authorisation. Together with Yimmugo®, these form the core of the product portfolio intended for manufacture in the new Biotest Next Level production facility.

In addition, existing products are also being systematically developed to further enhance patient benefits or to achieve new indications and approvals in additional countries. In this context, 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 on 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 (Fibrinogen and Trimodulin) can be manufactured and distributed worldwide by making recourse to Grifols' organisation and production network. Kedrion S.p.A., Barga, Italy, was selected as the distribution partner for Yimmugo® in the USA.

A list of progress made on research and development projects in the first half of 2024 is presented in the section "Research and Development" of the economic and business report.

B. ECONOMIC REPORT

I. MACROECONOMIC CONDITIONS

According to the Kiel Institute for the World Economy (IfW), the 2024 year to date has been characterised by rather subdued growth in the global economy. While the US economy has lost momentum, the Eurozone has gained momentum, leading to a convergence of advanced economies. Production in emerging markets, primarily in China, also picked up, leading to a slight upturn in the first half of 2024 after a weak last quarter of 2023.

The moderate upturn in the global economy is expected to continue over the course of the forecast period, thanks to rising real wages in Europe, which are exerting a positive impact on consumer behaviour, and thanks to less restrictive monetary policy worldwide. Production is forecast to continue rising in the second half of 2024, according to the IfW's indicator for the global economic climate (calculated on the basis of sentiment indicators from 42 countries)[1]. Overall, the global economy is expected to grow by 3.2% both this year and next year.

In Germany, signs of an upturn in the first half of 2024 were evident, as a consequence of which the recession appears to be over. In particular, the leading indicator for gross domestic product points to further growth. Nevertheless, business and consumer sentiment remains at a low level. This is due to the now noticeable effects of tighter monetary policy, but above all to structural factors such as demographic change. For these reasons, the IfW expects gross domestic product in Germany to expand by 0.2% in 2024 and by 1.1% in 2025. Inflation in Germany has also levelled off since the beginning of the year, while the core rate remains high.[2]

Stagnation in the Eurozone has receded over the course of the year to date, according to the IfW. Thanks to rising real wages, consumption is also picking up again. Monetary policy easing is also gradually making itself felt. Accordingly, the IfW expects gross domestic product (GDP) to expand by 1.0% in 2024 (2023: 0.6%; 2024: 1.0%; 2025: 1.7%).[3] For 2025, a somewhat stronger economic recovery in the Eurozone is expected, with GDP growth of 1.7%. At the same time, inflation is forecast to fall to 2.3%. Following last year's low economic output, the IfW is forecasting a slight recovery in economic output in the UK in 2024 (2023: 0.1%, 2024: 0.9%, 2025: 1.4%). Higher growth is still expected for Asia (2023: 5.8%, 2024: 5.5%, 2025: 5.1%), while economic growth in Latin America will be weaker this year according to the IfW, but is expected to recover in 2025 (2023: 1.9%, 2024: 1.3%, 2025: 2.2%).[4]

Thanks to high medical demand worldwide for plasma protein products, the Biotest Group is exposed to global economic cycles to only a limited extent. This assessment by the management also applies under the current economic conditions. Nevertheless, effects on the operating business cannot be ruled out, particularly due to local crises, the wars in Ukraine and the Middle East, disruption to supply chains, and trends in exchange rates.

II. INDUSTRY-SPECIFIC CONDITIONS

A. IMMUNGLOBULINS AND ALBUMIN

The Biotest Group is active in global markets for immunoglobulins and albumin, which generated the strongest sales revenue 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 the positive trend in the overall market.

The long-term growth of the global albumin market is estimated in the mid-single-digit percentage range.[5] The Chinese market plays an important role in this context, with record strong growth continuing in 2023. Worldwide, Asian markets account for over 70% of global sales of human albumin, whereby China accounts for the largest share. The price trend for albumin was stable in 2023.[6]

For the immunoglobulin (IgG) market, sector experts expect the long-term target range to reflect annual global demand growth in the mid-single-digit percentage range.[7]

In the USA, the IgG volume in the twelve months to June 2023 grew in the upper single-digit percentage range year-on-year.[8] In Europe, the market volume for immunoglobulins achieved comparable growth over the same period.[9] For the full year of 2023, the German IVIG market, which is important for Biotest, grew at a low double-digit rate year-on-year.[10] 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 was on a positive trend

[1] Kiel Institute for the World Economy (2024), Kiel Economic Outlook, World Economy Summer 2024, p. 2
[2] Kiel Institute for the World Economy (2024), Kiel Economic Outlook, World Economy Summer 2024, p. 2
[3] Kiel Institute for the World Economy (2024), Kiel Economic Outlook, World Economy Summer 2024, p. 7
[4] Kiel Institute for the World Economy (2024), Kiel Economic Outlook, World Economy Summer 2024, p. 10
5 Markets and Markets (2020)
6 IQVIA (2023)
7 MRB (2021) supplemented by Biotest internal analyses.
8 PPTA North America Data Program (2023).
9 IQVIA (2023).
10 Biotest internal analysis based on Insight Health, IQVIA 2024

in 2023.[11] Compared to the first half of 2023, IVIG prices in the USA rose in the mid-single-digit percentage range in the first six months of 2024, while the US prices already published for the third quarter of 2024 show a stabilisation of the price level.[12]

In the second half of 2022 and first half of 2023, US plasma donations showed a significant upward trend and a recovery in the human blood plasma supply situation. Given the macroeconomic situation, plasma costs are nonetheless expected to remain high. The supply situation for immunoglobulins and albumin is continuing its recovery following the COVID-19 pandemic.

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. Further alternative therapies are expected to be approved in the coming years.

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 is growth in the low to mid-single-digit percentage range still expected due to increasingly established factor VIII therapies.[13] In many of these countries, haemophilia patients currently do not have access to coagulation factor therapy. While Europe and North and South America account for only around 29% of the world's population, they account for around 81% of the global factor VIII market volume.[14]

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 and the market penetration of this therapy to date has fallen short of expectations, 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 rates in the low single-digit percentage range are expected only in some emerging markets.[15] 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 revenue of 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 2023 period grew by around 6% compared to 2022.[16] From January to May 2024, on the other hand, a stabilisation of transplant figures compared to the same period of the previous year was observed.[17] Based on market observations, Biotest assumes that the number of transplantations will continue to stabilise.

For Biotest, this applies in particular to the products Cytotect®, Hepatect®, and Zutectra®. The former is generally used after stem cell and solid organ transplantations, and especially after heart and lung transplantations. Hepatect® and Zutectra® are utilised in the area of liver transplantation due to hepatitis B infection. While the number of liver transplants is growing at a mid-single-digit rate globally[18], the incidence of hepatitis B (HBV) is expected to decrease at the same time due to numerous efforts at both global and national level.[19] As a consequence, an increase in hepatitis B virus-related liver transplants in the low single-digit percentage range is anticipated.

The number of stem cell transplants, which is also relevant for Cytotect®, has been growing continuously over the last thirty years, with the period of the COVID-19 pandemic representing the only exception. Following the pandemic period, an initial recovery in the number of stem

11 IQVIA (2023), CMS.gov.
12 CMS.gov
13 MRB (2022)
14 WFH Report on the Annual Global Survey 2022.
15 IQVIA (2022), CMS.gov.
16 Eurotransplant 2024
17 Eurotransplant 2024
18 Transplant Observatory (2023)
19 WHO (2023)

cell transplants was already evident in 2021, and the positive long-term trend is expected to continue in the future.[20] By contrast, the entry into the market of innovative antiviral treatments is leading to greater pressure in Cytotect®'s established indications.

Medical demand in the sepsis area remains high. Approximately 47 to 50 million cases of sepsis occur annually, including up to 20 million in children under five years of age. These result in at least 11 million deaths per year worldwide.[21] Due to the ageing population and a continued lack of effective treatments for sepsis, sepsis cases are forecast to grow by about one per cent per year Germany, France, Italy, Spain, and the UK.[22] 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, thereby increasing the need for supportive care options.[23] This is leading to continued high demand for Pentaglobin®.

III. BUSINESS PERFORMANCE

A. AT A GLANCE

In the first half of the 2024 financial year, the Biotest Group generated revenue of € 372.0 million. This corresponds to growth of 35.1% compared to the revenue of € 275.3 million generated in the same period of the previous year. Product revenue grew by € 13.4 million, or 4.8%, to € 273.7 million. In addition, revenue from technology disclosure and development services for Grifols, S.A., as part of the technology transfer and licensing agreement amounted to € 98.3 million.

The new intravenous immunoglobulin Yimmugo® had a significant positive impact with revenue growing from € 16.0 million to € 25.6 million. Yimmugo® 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. Biotest has thereby expanded its immunoglobulin product portfolio to include an innovative product whose safety, efficacy, and tolerability have been proven in the authorisation studies. This new preparation offers patients and doctors an additional important treatment option and at the same time represents an important milestone on the path to a broader portfolio and greater product availability. Special products also contributed with € 5.9 million to the revenue growth.

Compared to the prior-year period, consolidated EBIT grew to € 78.4 million in the first six months of the 2024 financial year (prior-year period: € 19.8 million). This growth mainly reflected the earnings effect from technology disclosure and development services as part of the technology and licence agreement with Grifols, S.A., amounting to € 86.0 million (prior-year period: € 1.9 million).

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. Two further donor centres were opened in Germany in January and April 2024, respectively. As of the end of the first half of 2024, Biotest operates 38 donor centres in Germany, Hungary, and the Czech Republic. The opening of further plasma collection centres is planned for 2024. In addition, Biotest participates financially in the establishment of further collection centres with partners.

In September 2023, the US Food and Drug Administration (FDA) informed Biotest that it had accepted the Biologics License Application for Yimmugo® with the primary immunodeficiencies indication for review. The inspection of the Biotest Next Level facility by the FDA was conducted in December 2023. In mid-June 2024, the intravenous immunoglobulin Yimmugo® was approved in the USA by the US Food and Drug Administration (FDA) for the treatment of patients with primary immunodeficiencies (PID). At the same time as the approval of Yimmugo®, the site in Dreieich, Germany, was certified by the FDA.

With Fibrinogen and Trimodulin, two further new plasma proteins are in the advanced development stage. Biotest successfully completed the phase III clinical trial for the use of Fibrinogen in the acquired fibrinogen deficiency indication in February 2024, which represents an important milestone for the Biotest Next Level project at the site in Dreieich. The first applications for marketing authorisation are planned in important markets in Europe and the USA.

Biotest is also conducting a phase III trial with Trimodulin in the severe community-acquired pneumonia (sCAP) indication. In addition, the ongoing multinational TRICOVID trial was opened up to include patients with pneumonia caused by any type of pathogen and the first patient

20 EBMT Activity survey, Passweg et al. (2023)
21 Rudd et al. (2020)
22 Global Data (2024)
23 European Center for Disease Prevention and Control (2023), WHO (2023), UN environment program (2023)

was treated as part of this expansion in December 2023. Biotest is also pressing ahead with its research activities in relation to existing products in order to enhance patient care. We are striving for greater operational excellence in research and development as well as in procurement management and production. To this end, we will continue to focus on selected measures to make processes across all areas of the company even more efficient.

B. RESEARCH AND DEVELOPMENT

In the first half of the 2024 financial year, the Biotest Group's research and development costs amounted to € -29.3 million, slightly below the prior-year period (€ -30.7 million). Expenses as a percentage of revenue at 7.9% remained almost on the same level as the previous year (12.4%). The number of employees working in research and development (converted to full-time equivalents) remained stable with 225 full-time equivalents as of 30 June 2024, compared to 232 full-time equivalents as of 31 December 2023. The decrease in expenses is mainly the result of lower costs for Fibrinogen due to the termination of the 995 study in February 2024. An offsetting effect arose from the recognition of a grant from the German Federal Ministry of Education and Research (BMBF) in the first half of 2023, which reduced expenses. The BMBF grant expired in June 2023, as a consequence of which no expense-reducing effect arose in the 2024 financial year (previous year: € 4.2 million). At € 0.1 million, the research allowance in accordance with the German Research Allowance Act remained at the same level in the first half of the financial year (previous year: € 0.1 million). A complete list of all research and development projects is presented in the 2023 Annual Report (page 21).

Biotest made further progress in the following research and development projects in the January to June 2024 period:

RESEARCH & DEVELOPMENT PROGRESS IN THE FIRST SIX MONTHS OF 2024

Intensive Care Medicine therapeutic area	
Fibrinogen Concentrate	The results of the phase III registration trial for the treatment of acquired fibrinogen deficiency due to severe bleeding (AdFIrst study no. 995) show that the primary endpoint was achieved. The clinical study report is currently being prepared.
Trimodulin (IgM Concentrate)	a) TRICOVID study (in hospitalised and oxygen-dependent patients with community-acquired pneumonia (CAP) caused by any type of pathogen including SARS-CoV-2): the study is currently in the treatment phase. The study is currently being conducted in up to 14 countries. b) ESsCAPE study (patients with severe community-acquired pneumonia): In September 2023, the first patient was treated in an intensive care unit. The ESsCAPE study is currently being conducted in up to 20 countries worldwide.

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 other new products, Fibrinogen and Trimodulin. Alongside Yimmugo®, these form the core of the new product portfolio for manufacture in the new Biotest Next Level production plant.

In the phase III clinical trial relating to acquired fibrinogen deficiency, Biotest already achieved a significant milestone in February 2024. The AdFIrst phase III trial has reached its primary endpoint. In this study, the use of Fibrinogen in patients with acquired fibrinogen deficiency during major surgery was shown to be as effective as standard treatment in reducing blood loss. The clinical study report is currently being prepared. The results of Biotest's two clinical trials, the AdFIrst study and the completed phase I/III trial (no. 984) 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 aiming for marketing authorisation in Europe. Subsequent filing of an application in the USA is planned.

The phase III trial 996 (ESsCAPE) with Trimodulin in the severe community-acquired pneumonia indication is in the recruitment phase. This multinational phase III clinical trial will enrol around 590 adult patients. The ESsCAPE trial is being conducted in up to 20 countries worldwide and patients are being treated with either Trimodulin or a placebo as an adjunct therapy to standard treatment. The clinical design of this prospective, double-blind, placebo-controlled Phase III trial was developed on the basis of the promising results of the previous phase II clinical trial (CIGMA) with 160 sCAP patients requiring invasive mechanical ventilation. In the CIGMA trial, a subgroup of patients with signs of severe inflammation exhibited an encouraging reduction in mortality with Trimodulin treatment. In addition to clinical development for sCAP, Trimodulin is also being tested for the treatment of CAP (phase III trial TRICOVID; trials no. 1001). This community-acquired pneumonia (CAP) may have been caused by SARS-COV-2 as well as by other pathogens.

Biotest is currently conducting three non-interventional studies (NIS) on existing products. NIS is intended to help improve treatment options for shingles (herpes zoster). The study (VARIZOSTA study) will investigate the use of the herpes zoster virus-specific hyperimmunoglobulin

Varitect® CP (VZV-IgG) in complex herpes zoster, especially in patients with a high risk constellation for a severe course of the disease. Biotest is conducting an international, multi-centre observational study for Cytotect® (CMV-IgG) in patients after heart or lung transplantation. This study documents patients in whom a cytomegalovirus infection is suspected (prophylaxis) or has already developed (therapy). In 2023, Biotest expanded its NIS for the documentation of intravenous immunoglobulins (IVIG) from Intratect® 50 g/L and Intratect® 100 g/L to include the new IVIG Yimmugo®.

C. MARKETING AND DISTRIBUTION

The 2024 financial year saw a continuation of the trend of increasing plasma donations in the USA and Europe that has been evident since 2022. 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.

Clinical Immunology therapeutic area

The intravenous immunoglobulin Yimmugo®, which has been produced at the Biotest Next Level facility in Dreieich since November 2022, generated sales in Germany, Austria and the United Kingdom in the first half of 2024. In times of global shortage of immunoglobulin products, Yimmugo® offers an additional treatment option and thereby contributes to secure supplies for Biotest customers. Moreover, further marketing authorisations for Yimmugo® were obtained: in Norway and Hungary and, since June 2024, in the USA.

With the launch of Yimmugo® in Germany as a new immunoglobulin preparation in addition to Intratect®, Biotest is offering German practitioners an additional treatment option that many have already taken advantage of. Sales-supporting communication measures were deployed to advertise the fact that former Intratect® patients can also be treated with Yimmugo® in future. Intratect® recorded sales growth in all other countries. Biotest sells internationally the volumes of Intratect® that are released in Germany; the product is authorised in over 30 countries worldwide in addition to Germany.

The total revenue that Biotest generated from IgG preparations grew accordingly in the first six months of 2024.

The hyperimmuno-globulin portfolio with the key products Cytotect®, Hepatect®, and Zutectra® continued to face known challenges in the first six months of 2024, such as falling hepatitis B numbers and the increasing pressure of antiviral products as monotherapy.

However, stable and sometimes even higher revenue was achieved in this context, such as for Cytotect® in France, Spain, Saudi Arabia, and the UK. In the first half of the 2024 financial year, Cytotect® also received a further marketing authorisation in Thailand. This supports our strategy of expanding our global footprint and increasing future revenue. The market situation for hepatitis B hyperimmune globulins (Hepatect®, Zutectra®, and Fovepta®) remains difficult due to a diminishing level of hepatitis B cases in developed markets and strong competition from antiviral therapies, which was also evident in a slight decrease in revenue during the first half of the year. Initial sales were already generated in the new Zutectra® countries (Turkey, Taiwan) in the first half of 2024.

Intensive Care Medicine therapeutic area

Revenue generated with Pentaglobin® (IgM Preparation) continued on a decidedly positive trend in the first half of the 2024 financial year. Biotest achieved very positive revenue growth in various European and international markets, such as Germany, Colombia, Vietnam, and India. Pentaglobin® is a unique product for which no equivalent alternative exists on the market and which is experiencing growing demand. Biotest is working on options to increase production capacity, yield, and clinical support for this strategic product, such as with the PEPPER study, an investigator-sponsored study of Aachen University Hospital, in other words, a study initiated by Aachen University.

Demand for albumin remained high in the first six months of 2024 and sales are primarily limited by production capacity. This is also reflected in the fact that the average price for albumin rose slightly.

Haematology therapeutic area

In the coagulation factor product portfolio, factor VIII (Haemoctin®) and factor IX products (Haemonine®) remained under pressure in the first half of 2024 due to the intensively competitive situation with recombinant products, and constantly falling prices. This resulted in year-on-year lower revenue for Haemoctin®, whereas revenue generated from Haemonine® was stable.

MARKETING & DISTRIBUTION PROGRESS IN THE FIRST SIX MONTHS OF 2024

Clinical Immunology therapeutic area	
Yimmugo®	Expansion of distribution in Germany and Austria; marketing authorisation for the USA, Netherlands, Norway, and Hungary. First sales in UK; Mutual Recognition Procedure completed, expecting 5 further marketing authorisations.
Cytotect®	Distribution in Europe, Asia, South America, Africa, and the Middle East; positive revenue trend in various markets, especially in France, Spain and KSA. Marketing authorisation in Thailand.
Zutectra®	Commercialisation in Europe and Taiwan. Product launch and first sales in Turkey and Taiwan.
Hepatect®	Commercialisation in Europe, Africa, Asia, and the Middle East. New marketing authorisation in Bangladesh.
Varitect®	Commercialisation in Europe, South America, Asia, and the Middle East.
Intensive Care Medicine therapeutic area	
Pentaglobin®	Commercialisation in Central and South America, Asia, Europe, and the Middle East. Positive revenue growth in various countries such as Germany, Colombia, Vietnam, and India.
Albiomin®	Commercialisation in therapy in Europe, South America, China and Asia, Africa, and the Middle East including Israel; global commercialisation as excipient with focus on Europe.

IV. RESULTS OF OPERATIONS, NET ASSETS AND FINANCIAL POSITION

A. RESULTS OF OPERATIONS

In the first half of 2024, the Biotest Group generated revenue of € 372.0 million. This corresponds to growth of 35.1% compared to the revenue of € 275.3 million generated in the same period of the previous year.

Revenue from products and contract fractionation grew by € 13.4 million, or by 4.8%, to reach € 273.7 million. The new intravenous immunoglobulin Yimmugo®, which is produced in the new Biotest Next Level production facility at the Dreieich site, exerted a positive impact, with revenue growing from € 16.0 million to € 25.6 million The approval of Yimmugo®, also in the USA since June 2024, represents an important milestone on the way to a broader portfolio and greater product availability. The products Intratect® and Pentaglobin® also contributed to the increase in sales. Sales from contract fractionation and with Albiomin® and Haemoctin® declined slightly compared to the same period of the previous year.

In addition, revenue generated from technology disclosure and development services for Grifols, S.A., as part of the technology transfer and licensing agreement, amounted to € 98.3 million (previous year: € 14.9 million).

SALES BY SEGMENT

in € million	H1 2024	H1 2023	Change in %
European Union	134.4	139.1	–3.4
Rest of the World	139.3	121.3	14.8
Stateless	98.3	14.9	>100
Biotest Group	**372.0**	**275.3**	**35.1**

Due to the change in the segmentation structure, revenue is presented according to the various sales regions. Biotest reports in the three sales regions "European Union", "Rest of the World", and "Stateless". In the European Union region, revenue decreased by -3.4% to € 134.4 million in the first half of 2024 (previous year: € 139.1 million). This change reflects the lack of sales of the immunoglobulin preparation Intratect® following the sale of five Biotest subsidiaries in 2023 and lower additional revenue from contract fractionation, which was partly offset by higher revenue from the new immunoglobulin Yimmugo®. The Rest of the World region recorded 14.8% revenue growth to € 139.3 million in the first half of 2024, compared with € 121.3 million in the same period of the previous year. This growth mainly reflects higher revenue generated from Intratect®. Stateless revenue of € 98.3 million (previous year: € 14.9 million) relates to revenue generated from technology disclosure and development services for the parent company Grifols, S.A., Barcelona, Spain.

The cost of sales amounted to € 230.3 million in the first half of 2024 (prior-year period: € 202.8 million). An impairment loss of € 3.6 million was recognised in the cost of sales in relation to an asset under construction due to existing internal and external indications of impairment. The cost of sales ratio measured in relation to total revenue, adjusted for revenue generated from technology disclosure (€ 84.2 million) and development services (€ 14.1 million), amounted to 84.1% and was thereby higher than the level of 77.9% in the same period of the previous year.

Marketing and distribution costs rose slightly to € 26.2 million in the first six months of the 2024 financial year, compared with € 25.5 million in the same period of the previous year, due to a greater level of marketing activities for Yimmugo®.

The Biotest Group's administrative expenses amounted to € 18.4 million for the first half of 2024 and were thereby 10.2% higher than the previous year's level of € 16.7 million. This increase reflects higher insurance costs as well as auditing and legal advisory services, among other factors.

Research and development costs of € 29.3 million were incurred in the first six months of the current 2024 financial year, € 1.4 million below the previous year's level of € 30.7 million. The lower expenses mainly reflect lower costs for Fibrinogen due to the termination of the 995 study in February 2024. An offsetting effect arose from the recognition of a grant from the German Federal Ministry of Education and Research (BMBF) in the first half of 2023, which reduced expenses. The BMBF grant expired in June 2023, as a consequence of which no expense-reducing effect arose in the 2024 financial year (previous year: € 4.2 million). At € 0.1 million, the research allowance in accordance with the German Research Allowance Act remained at the same level in the first half of the financial year (previous year: € 0.1 million).

Other operating income decreased by € 13.3 million to € 11.4 million for the first six months of the 2024 financial year. Firstly, the significant reduction reflects the recognition of the disposal gain of € 23.1 million from the divestiture of five Biotest subsidiaries in the same period of the previous year. Secondly, offsetting effects arose from the € 5.0 million gain from the reversal of a valuation allowance previously applied to trade receivables, as well as from the € 4.1 million gain from the reversal of a financial liability in connection with plasma supply contracts.

In the first half of 2024, EBIT amounted to € 78.4 million and were thereby down on the previous year's level of € 19.8 million. This includes expenses of € 52.9 million for the ramp-up of production capacity and product development for the Biotest Next Level facility (prior-year period: € 43.8 million). The € 58.6 million growth in EBIT compared to the first half of 2023 is mainly due to the earnings effect from technology disclosure and development services for Grifols, S.A., amounting to € 86.0 million (prior-year period: € 1.9 million). As a consequence, the EBIT margin for the first six months of the current financial year amounted to 21.1%, compared with 7.2% in the same period of the previous year.

Adjusted EBIT presents the Biotest Group's operating performance excluding exceptional items. This metric is an alternative performance measure (APM) that is not defined in IFRS (International Financial Reporting Standards). The adjusted EBIT margin for the first six months of the current financial year amounted to 16.6%, compared with 14.8% in the same period of the previous year.

ADJUSTED EBIT

in € million	H1 2024	H1 2023	Change in %
EBIT	78.4	19.8	>100
Expenses for Biotest Next Level*	52.9	43.8	20.8
Earnings from development services	–1.8	–1.9	5.3
Earnings from technology disclosure	–84.2	–	>100
Disposal gain from sale of five subsidiaries	–	–23.1	>100
Adjusted EBIT	**45.3**	**38.6**	**17.4**

* The expenses for Biotest Next Level include cost of sales of € 31.3 million (prior-year period: € 19.8 million) and development costs of € 21.6 million (prior-year period: € 24.0 million). In order to ensure continuity and comparability, the expenses relating to the Biotest Next Level production facility and the Biotest Next Level research and development portfolio, are treated as special effects in the 2024 financial year, as in previous years.

KEY INCOME STATEMENT ITEMS OF THE BIOTEST GROUP

in € million	H1 2024	% of sales	H1 2023	% of sales
Revenue	372.0	100.0	275.3	100.0
Cost of sales	–230.3	61.9	–202.8	73.7
Marketing and distribution costs	–26.2	7.0	–25.5	9.3
Administrative expenses	–18.4	4.9	–16.7	6.1
Research and development costs	–29.3	7.9	–30.7	11.2
Other operating income and expenses	10.6	2.8	20.1	7.3
Financial income and expenses	–19.0	5.1	–18.6	6.8

The financial result amounted to € -19.0 million in the first half of 2024, compared with € -18.6 million in the same period of the previous year. The slight decrease is mainly due to a lower volume of forward exchange transactions and the resultant lower income compared to the previous year. The reduction is partly offset by the fact that, following the complete divestiture of the shares in ADMA Biologics Inc. in the 2023 financial year, expenses from fair value adjustments no longer exert a negative impact on the financial result.

For the Biotest Group, this leads to earnings before taxes (EBT) of € 59.4 million compared with € 1.2 million in the same period of the previous year.

In light of the aforementioned influencing factors, the Biotest Group's total earnings after taxes (EAT) grew to € 39.1 million in the first half of 2024 (prior-year period: € 1.7 million). This is equivalent to earnings per ordinary share of € 0.98 compared with € 0.03 in the first half of 2023.

KEY PERFORMANCE FIGURES OF THE BIOTEST GROUP

in € million	H1 2024	H1 2023	Change in %
EBIT	78.4	19.8	>100
EBT	59.4	1.2	>100
EAT	39.1	1.7	>100

B. NET ASSETS

The Biotest Group's total assets decreased from € 1,410.9 million as of the 31 December 2023 reporting date to € 1,375.8 million as of the 30 June 2024 reporting date.

Compared to the level at the end of 2023, non-current assets reduced to € 636.9 million (31 December 2023: € 654.4 million). The decrease in the first half of the year mainly reflected the € -14.1 million reduction in deferred tax assets in connection with the utilisation of loss carryforwards.

Current assets decreased by € -17.6 million compared to the end of 2023 and amounted to € 738.9 million as of 30 June 2024 (31 December 2023: € 756.5 million). This change reflects several effects that are partly mutually offsetting: the decrease is mainly due to the lower level of trade receivables of € -13.9 million, of contract assets of € -12.0 million, and of other assets of € -10.5 million. Furthermore, cash and cash equivalents decreased by €-41.8 million and amounted to € 66.3 million as of 30 June 2024 (31 December 2023: € 108.1 million). This is offset by the € 53.4 million higher level of inventories, which were further expanded to secure the sales planned for the coming months with the new BNL production facility.

Due to the positive result for the period, equity increased to € 535.9 million as of the 30 June 2024 reporting date (31 December 2023: € 498.9 million). The equity ratio thereby stood at 39.0% as of the end of the first half of 2024.

As of the 30 June 2024 reporting date, total debt had reduced by € -72.1 million to € 839.9 million (31 December 2023: € 912.0 million). Non-current liabilities have increased by € 12.0 million to € 538.7 million since 31 December 2023, primarily due to a higher level of other provisions. Current liabilities decreased by € -84.1 million to € 301.2 million as of the 30 June 2024 reporting date. This was mainly due to a decrease in current financial liabilities of € -65.5 million, which is attributable to the repayment of a loan tranche amounting to € -65.0 million of the secured loan with a total volume of € 240.0 million.

C. FINANCIAL POSITION

In the first six months of 2024, the Biotest Group recorded operating cash flow of € 46.8 million, primarily due to the positive EBIT, which was partially offset by working capital changes amounting to € -36.0 million. The working capital changes mainly reflect a higher level of inventories and a decrease in trade payables. Cash inflows from trade receivables could not offset this effect. In the same period of the previous year, operating cash flow amounted to € -74.8 million.

Cash flow from investing activities in the period from January to June 2024 amounted to € -14.5 million (previous year: € 19.4 million), which is mainly attributable to payments for capital expenditure. The prior-year period was significantly influenced by payments received from the sale of shares in five Biotest subsidiaries.

Cash flow from financing activities in the first half of 2024 amounted to € -74.2 million and was thereby below the previous year's level of € -2.5 million. Cash outflows from financing activities were mainly incurred for the repayment of a loan tranche in the amount of € -65.0 million, cash deposits for guarantees issued to banks, and the repayment portion of lease liabilities in accordance with IFRS 16.

Biotest is financed by a subordinated shareholder loan in the nominal amount of € 290 million, which was extended on 15 March 2024 until 2 January 2030. In addition, there is external financing concluded in 2019 with a volume of € 240 million, which was partially repaid due to the maturity of a loan tranche on 2 April 2024 and therefore had a balance of € 160 million as at 30 June 2024. To cover further financing requirements, Biotest AG and Grifols Worldwide Operations Limited, Dublin, Ireland, a wholly owned subsidiary of Grifols, S.A., concluded a financing agreement in the amount of € 147 million on 7 March 2023, which had not been utilised by 30 June 2024. As a result, credit lines amounting to € 147 million were unused as at 30 June 2024. Please refer to our comments in section D Supplementary report.

D. OVERALL ASSESSMENT OF THE COMPANY'S BUSINESS SITUATION

Despite the challenging development in individual markets and the simultaneous focus on future projects, the Biotest Group can look back on a positive first half of 2024 and recorded an increase in sales of 35.1% to € 372.0 million and an improvement in EBIT of € 58.6 million to € 78.4 million. Both were influenced to a large extent by the effects of the technology disclosure and the provision of development services for Grifols, S.A., as well as sales of the new intravenous immunoglobulin Yimmugo® and special products.

The Group continues to focus on ramping up the Biotest Next Level production facilities in Dreieich. Since November 2022, the first Biotest Next Level preparation Yimmugo® has been manufactured there, which also received marketing authorisation for the USA in June 2024, together with FDA certification of the production facilities. In addition, Biotest is stepping up its efforts to rapidly develop the development candidates Fibrinogen and Trimodulin and obtain authorisation for them. The aim is to submit Fibrinogen to the authorities in the indications of congenital and acquired fibrinogen deficiency in the EU and the USA at the end of this financial year. For further research activities, please refer to Chapter A.IV Research and development (General) in the 2023 Annual Report and to the Business performance chapter, Section B Research and development of this half-year report.

Due to the improved earnings, net assets and financial position as well as the expansion of production to include Biotest Next Level, the Management Board considers the economic situation of the Biotest Group to be positive overall.

C. OUTLOOK, RISK AND OPPORTUNITIES REPORT

I. OUTLOOK REPORT

A. TRENDS IN THE MARKET ENVIRONMENT

Target markets

According to current forecasts, global demand for immunoglobulins (IgG) is set to grow annually in the mid-single-digit percentage range over the coming years.[24] The prices of these preparations are beginning to stabilise at a high level and may even rise slightly due to the further increase in demand, depending on the market.[25]

[24] MRB (2021) supplemented by Biotest internal analyses.
[25] IQVIA (June 2023), www.cms.gov supplemented by Biotest internal analyses.

The long-term growth rate of the global albumin market is forecast to amount to around 6% per year.[26]

Up to 2027, the global market is projected to diminish at a single-digit negative percentage rate per year in terms of plasmatic factor VIII preparations.[27]

B. EXPECTED DEVELOPMENT OF THE BIOTEST GROUP

Expected business and results of operations of the Biotest Group

For the 2024 financial year, the Board of Management is aiming for upper single-digit percentage revenue growth compared to 2023, including revenue from technology disclosure and development services for Grifols, S.A. This revenue growth is enabled by the ramp-up of the Yimmugo® production facility within Biotest Next Level. It remains the case that the Board of Management does not rule out negative revenue trends due to potential reductions in demand owing to the economic situation and country-specific savings in the healthcare sector.

Accordingly, the Board of Management expects an operating result (EBIT) in a range between € 80 million and € 100 million for 2024. As a consequence, the Board of Management anticipates a slight improvement in return on capital employed (ROCE) in 2024 compared to the 2023 financial year, and a positive cash flow from operating activities significantly above the previous year's level.

Expected financial and net assets position of the Biotest Group

The Biotest Group aims to maintain a balanced financing structure in terms of its ratio of debt to equity, as well as of 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 products within the new production facility. Moreover, Biotest has expanded its network of plasma collection centres to ensure the requisite plasma supplies for the new Biotest Next Level production facility, among other objectives. For the 2024 financial year, the Biotest Group plans to invest at the same level as in the previous year. The major share of capital expenditure will go towards the expansion and maintenance of production facilities and infrastructure measures at the Dreieich site in Germany. Furthermore, some of the investments are also attributable to the expansion of existing plasma centres and the establishment of new plasma centres in Europe, as well as further developments in the areas of digitalisation and sustainability.

Financing in 2024 has been mainly provided by shareholder loans and further 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 cash inflows in connection with 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 2023 (pages 31-42), 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 exert an adverse effect on the Biotest Group's financial position and performance.

Apart from this, it remains the case that no discernible risks exist that could jeopardise the Biotest Group as a going concern.

[26] Markets and Markets (2020) supplemented by Biotest internal analyses.
[27] MRB (2022).

III. OPPORTUNITIES REPORT

The opportunity situation of the Biotest Group has changed compared to the presentation in the opportunity report of the 2023 Annual Report due to the intensified cooperation with Grifols, S.A. and the binding term sheet regarding a new cooperation with Kedrion S.p.A., Barga, Italy.

The intensified cooperation with Grifols has increased the opportunities to jointly generate higher sales revenues with higher production capacities and a stronger market presence. Biotest would participate in this through additional product sales and possibly license fees.

The planned increase in productivity and doubling of production capacity as part of the Biotest Next Level project will result in a variety of opportunities that will take the Biotest Group to a new level, with the possibility of approval and distribution of these new products in the global environment as well as in the important and attractive US market. Here, Biotest has signed a binding term sheet for a long-term agreement with Kedrion S.p.A., Barga, Italy, for the marketing and distribution of the immunoglobulin Yimmugo® in the United States after the US Food and Drug Administration (FDA) approved the Biologics License Application (BLA) on 13 June 2024.

D. SUPPLEMENTARY REPORT

As at 30 June 2024, Biotest AG was in discussions with the financing partners of the existing external loan to extend the financing. For this reason, the repayment of € 160.0 million originally due on 2 July 2024 was postponed by one month to 2 August 2024. The repayment was made on 2 August 2024 using mainly the loan from Grifols Worldwide Operations Limited, Dublin, Ireland, a wholly owned subsidiary of Grifols, S.A., in the amount of € 147 million.

No further 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 2024

in € million	Q2 2024	Q2 2023	H1 2024	H1 2023
Revenue	156.8	158.0	372.0	275.3
Cost of sales	–105.7	–110.3	–230.3	–202.8
Gross profit	**51.1**	**47.8**	**141.7**	**72.5**
Other operating income	10.7	24.2	11.4	24.7
Marketing and distribution costs	–13.1	–13.2	–26.2	–25.5
Administrative expenses	–8.3	–7.1	–18.4	–16.7
Research and development costs	–14.2	–19.9	–29.3	–30.7
Other operating expenses	–0.6	–2.9	–0.8	–4.6
Operating profit	**25.6**	**28.9**	**78.4**	**19.8**
Financial income	1.7	3.4	3.5	7.0
Financial expenses	–10.0	–12.7	–22.5	–25.6
Financial result	**–8.3**	**–9.3**	**–19.0**	**–18.6**
Earnings before taxes	**17.3**	**19.6**	**59.4**	**1.2**
Income taxes	–7.6	2.5	–20.3	0.6
Earnings after taxes	**9.7**	**22.2**	**39.1**	**1.7**
Attributable to:				
Equity holders of the parent	9.7	22.2	39.1	1.7
Earnings per share in €	**0.24**	**0.55**	**0.98**	**0.03**

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME

of the Biotest Group for the period from 1 January to 30 June 2024

in € million	H1 2024	H1 2023
Profit (Loss)	**39.1**	**1.8**
Exchange difference on translation of foreign operations	–0.5	0.7
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	**–0.5**	**0.7**
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	**–0.5**	**0.7**
Total comprehensive income, net of tax	**38.6**	**2.5**
Attributable to:		
Equity holders of the parent	**38.6**	**2.5**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

of the Biotest Group as of 30 June 2024

in € million	30 June 2024	31 December 2023
ASSETS		
Non-current assets		
Intangible assets	15.0	15.0
Property, plant and equipment	520.1	522.4
Right-of-use assets	55.3	56.0
Investments in joint ventures	11.3	11.3
Other assets	0.1	0.1
Other financial assets	16.3	16.7
Deferred tax assets	18.8	32.9
Total non-current assets	**636.9**	**654.4**
Current assets		
Inventories	472.5	419.1
Contract assets	39.6	51.6
Trade receivables	131.3	145.2
Current income tax assets	0.1	–
Other assets	10.7	21.2
Other financial assets	18.4	11.3
Cash and cash equivalents	66.3	108.1
Total current assets	**738.9**	**756.5**
Total assets	**1,375.8**	**1,410.9**
EQUITY AND LIABILITIES		
Equity		
Subscribed capital	39.6	39.6
Share premium	219.8	219.8
Retained earnings	237.4	112.5
Share of profit or loss attributable to equity holders of the parent	39.1	127.0
Equity attributable to equity holders of the parent	**535.9**	**498.9**
Total equity	**535.9**	**498.9**
Non-current liabilities		
Provisions for pensions and similar obligations	93.9	91.1
Other provisions	14.0	4.8
Financial liabilities	429.7	429.7
Other liabilities	–	–
Deferred tax liabilities	1.1	1.1
Total non-current liabilities	**538.7**	**526.7**
Current liabilities		
Other provisions	16.5	23.1
Current income tax liabilities	1.1	0.9
Financial liabilities	194.6	260.1
Trade payables	69.4	78.1
Other liabilities	17.2	22.9
Contract liabilities	2.4	0.2
Total current liabilities	**301.2**	**385.3**
Total liabilities	**839.9**	**912.0**
Total equity and liabilities	**1,375.8**	**1,410.9**

CONSOLIDATED CASH FLOW STATEMENT

of the Biotest Group for the period from 1 January to 30 June 2024

in € million	H1 2024	H1 2023
Operating cash flow before changes in working capital	102.5	18.5
Cash flow from changes in working capital	–36.0	–81.6
Interest and taxes paid	–19.7	–11.7
Cash flow from operating activities total	**46.8**	**–74.8**
Cash flow from investing activities total	**–14.5**	**19.4**
Cash flow from financing activities total	**–74.2**	**–2.5**
Cash changes in cash and cash equivalents	**–41.9**	**–57.9**
Exchange rate-related changes in cash and cash equivalents	0.1	–
Cash and cash equivalents on 1 January	108.1	116.6
Consolidation group related changes to cash	–	–0.4
Cash and cash equivalents on 30 June	**66.3**	**58.3**

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY

of the Biotest Group for the period from 1 January to 30 June 2024

in € million	Subscribed capital	Share premium	Retained earnings	Remeasurement of defined benefit obligations	Translation reserve	Total equity
As of 1 January 2023	39.6	219.8	123.2	–9.5	–2.0	371.1
Reclassification to income statement	–	–	–0.3	–	0.3	–
Other comprehensive income after tax	–	–	–	–2.0	2.8	0.8
Profit (loss)	–	–	127.0	–	–	127.0
Total comprehensive income	–	–	126.7	–2.0	3.1	127.8
Dividend payments	–	–	–	–	–	–
As of 31 December 2023	39.6	219.8	249.9	–11.5	1.1	498.9
As of 1 January 2024	39.6	219.8	249.9	–11.5	1.1	498.9
Reclassification to income statement	–	–	–	–	–	–
Other comprehensive income after tax	–	–	–	–	–0.5	–0.5
Profit (loss)	–	–	39.1	–	–	39.1
Total comprehensive income	–	–	39.1	–	–0.5	38.6
Dividend payments	–	–	–1.6	–	–	–1.6
As of 30 June 2024	39.6	219.8	287.4	–11.5	0.6	535.9

SELECTED DISCLOSURES

METHOD OF PREPARATION

These interim consolidated financial statements as of 30 June 2024 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 2024 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 2024.

The accounting policies applied are the same as those used in the last financial statements. In the 2024 financial year, a change of accounting estimates by cost of sales was made by allocating raw material costs to end products differently.

These interim consolidated financial statements were approved for publication by the Board of Management on 30 July 2024.

SCOPE OF CONSOLIDATION

The consolidated financial statements of Biotest AG include three (previous year: three) domestic and eight (previous year: eight) 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. Since that date, this subsidiary has been fully consolidated.

Biotest France SAS, Paris, France, Biotest (UK) Ltd., Birmingham, UK, Biotest Italia S.r.l., Milan, Italy, Biotest Farmacêutica Ltda., São Paulo, Brazil, and Biotest Medical S.L.U., Barcelona, Spain, were sold to units of the Grifols Group in the first half of 2023 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 2023 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 2024	31 December 2023
Shareholder loan	333.1	329.5
Financial liabilities to third parties	208.3	272.3
Lease liabilities	57.5	57.8
Financial liabilities	**598.9**	**659.6**
Cash and cash equivalents	66.3	108.1
	66.3	**108.1**
Net debt	**532.6**	**551.5**

The decrease in net debt compared to the previous year is mainly due to the reduction in financial liabilities to third parties. This effect was partially offset by the decrease in cash and cash equivalents. A loan concluded in 2019 with a total volume of € 240.0 million and a maturity date in 2024 had a nominal value of € 160 million as at 30 June 2024.

SEGMENT REPORTING
of the Biotest Group for the period from 1 January to 30 June 2024

			Revenue
in € million	H1 2024	H1 2023	Change in %
European Union	134.4	139.1	-3.4
Rest of the World	139.3	121.3	14.8
Stateless	98.3	14.9	>100
Biotest Group	**372.0**	**275.3**	**35.1**

in € million							Segments	
Categories	European Union		Rest of the World		Stateless		Total	
	H1 2024	H1 2023*	H1 2024	H1 2023	H1 2024	H1 2023	H1 2024	H1 2023
Type of products and services								
Sale of Biotest products	134.4	139.1	117.7	97.6	–	–	252.1	236.7
Toll manufacturing	–	–	21.6	23.7	–	–	21.6	23.7
Technology disclosure and development services	–	–	–	–	98.3	14.9	98.3	14.9
	134.4	**139.1**	**139.3**	**121.3**	**98.3**	**14.9**	**372.0**	**275.3**
Timing of revenue recognition								
Goods transferred at a point in time	134.4	139.1	117.7	97.6	84.2	–	336.3	236.7
Services transferred over a period of time	–	–	21.6	23.7	14.1	14.9	35.7	38.6
	134.4	**139.1**	**139.3**	**121.3**	**98.3**	**14.9**	**372.0**	**275.3**

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

QUARTERLY COMPARISON
by business segment

			Revenue		
in € million	Q2 2024	Q1 2024	Q4 2023	Q3 2023	Q2 2023
European Union	75.7	58.7	67.2	54.1	74.0
Rest of the World	60.0	79.3	62.3	50.5	69.1
Stateless	21.1	77.2	54.7	120.5	14.9
Biotest Group	**156.8**	**215.2**	**184.2**	**225.1**	**158.0**

OTHER DISCLOSURES

Schedule of assets – net presentation

in € million	Carrying amount as of 31 December 2023	Capital expenditure	Disposals net	Depreciation and amortisation	Currency translation differences	Carrying amount as of 30 June 2024
Intangible assets	15.0	0.4	–	–0.4	–	15.0
Property, plant & equipment	522.4	16.2	–0.9	–18.1	0.5	520.1
Right of use assets	56.0	3.5	–1.2	–3.2	0.2	55.3
Total	**593.4**	**20.1**	**–2.1**	**–21.7**	**0.7**	**590.4**

Employees

by operating functions

Full-time equivalents	30 June 2024	31 December 2023	Change in %
Production	1,890	1,828	3.4
Administration	207	223	–7.2
Distribution	142	143	–0.7
Research and development	225	232	–3.0
Biotest Group	**2,464**	**2,426**	**1.6**

Financial instruments as of 30 June 2024

in € million	Carrying amount	Fair value
Assets		
Trade receivables	131.3	131.3
Other financial assets	34.7	34.3
Cash and cash equivalents	66.3	66.3
Equity and liabilities		
Trade payables	69.4	69.4
Financial liabilities		
Subordinated shareholder loans	333.1	362.9
Secured loans from financial institutions	162.8	165.7
Unsecured promissory note loans	–	–
Other financial liabilities	70.4	71.0
Derivatives without hedging relationship	0.5	0.5

FAIR VALUE HIERARCHY

According to IFRS 13.72, the financial instruments measured at fair value on the statement of financial position 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.

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 allocated to hierarchy level 2. The fair value of the pension funds is allocated 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 analysed by currency. The fair value is assigned to hierarchy level 2.

CONTINGENT ASSETS AND CONTINGENT LIABILITIES

A contingent asset is a potential asset that derives from past events and whose existence will not be confirmed until the occurrence or non-occurrence of one or more uncertain future events that do not lie entirely within the company's scope of control.

Contingent liabilities are potential obligations that originate from past events and whose existence will not be confirmed until the occurrence or non-occurrence of one or more uncertain future events that do not lie entirely within the company's scope of control. Contingent liabilities may also be based on current obligations that derive from past events but are not recognised in the financial statements, either because an outflow of resources with a loss of economic benefits is not likely or because the amount of the obligation cannot be estimated sufficiently reliably.

A contingent liability of € 5.1 million exists in the context of an ongoing antitrust case in Romania.

Cash of € 13.9 million (previous year: € 10.4 million) was deposited with banks as collateral.

Contingent liabilities of € 0.5 million (previous year: € 1.8 million) exist from collateral for liabilities of affiliated companies.

As in the previous year, no contingent assets existed as of the reporting date.

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 an original maturity of the shareholder loans until January 2025, which were extended on 15 March 2024 until 2 January 2030. The carrying amount of the loans with accrued interest as of 30 June 2024 is € 333.1 million. The interest expense from the shareholder loans amounted to € 3.6 million in the first half of 2024.

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

In the first half of the 2024 financial year, Biotest generated revenue of € 98.3 million from technology disclosure and development services for Grifols, S.A., Barcelona, Spain, as part of the technology transfer and licensing agreement.

Moreover, Biotest generated revenue of € 34.6 million with its sister company Grifols UK Ltd., Cambridge, UK, in the first half of 2024. Biotest's receivables due from Grifols UK Ltd., Cambridge, UK, amounted to € 6.0 million as of 30 June 2024.

In the first half of the 2024 financial year, Biotest and its sister companies Biotest Farmacêutica Ltda., São Paulo, Brazil, Biotest Italia S.r.l., Trezzano sul Naviglio, Italy, Biotest Medical S.L.U., Barcelona, Spain, Biotest (UK) Ltd., Birmingham, UK, Grifols Portugal – Produtos Farmacêuticos e Hospitalares, Lda., Rio de Mouro, Portugal, Grifols Nordic AB, Stockholm, Sweden, Grifols Movaco, S.A., Parets del Vallès (Barcelona), Spain, Grifols France S.A.R.L., Paris, France, Grifols Italia S.p.A., Vicopisano, Italy, and Grifols Asia Pacific Pte. Ltd., Singapore, generated revenue amounting to a total of € 26.9 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 2024, Biotest generated revenue of € 3.2 million from toll manufacturing with BioDarou P.J.S. Co. Biotest's receivables and contract assets from BioDarou P.J.S. Co. amounted to € 7.4 million as of 30 June 2024. The accumulated allowances for receivables and contract assets amounted to € 0.1 million as of 30 June 2024.

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

EVENTS AFTER THE REPORTING DATE

Please refer to our comments in section D Supplementary report.

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 net assets, financial position, and results of operations, 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.

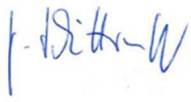
Dreieich, 30 July 2024

Biotest Aktiengesellschaft

Board of Management

Peter Janssen
Member of the
Board of Management

Ainhoa Mendizabal Zubiaga
Member of the
Board of Management



Dr. Jörg Schüttrumpf
Member of the
Board of Management

FINANCIAL CALENDAR

5 November 2024
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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