



> BIOTEST GROUP

FY 2023 Results, March 28, 2024



# Welcome to the Full Year 2023 Presentation

# Leadership Team



**Peter Janssen**  
Chief Executive Officer

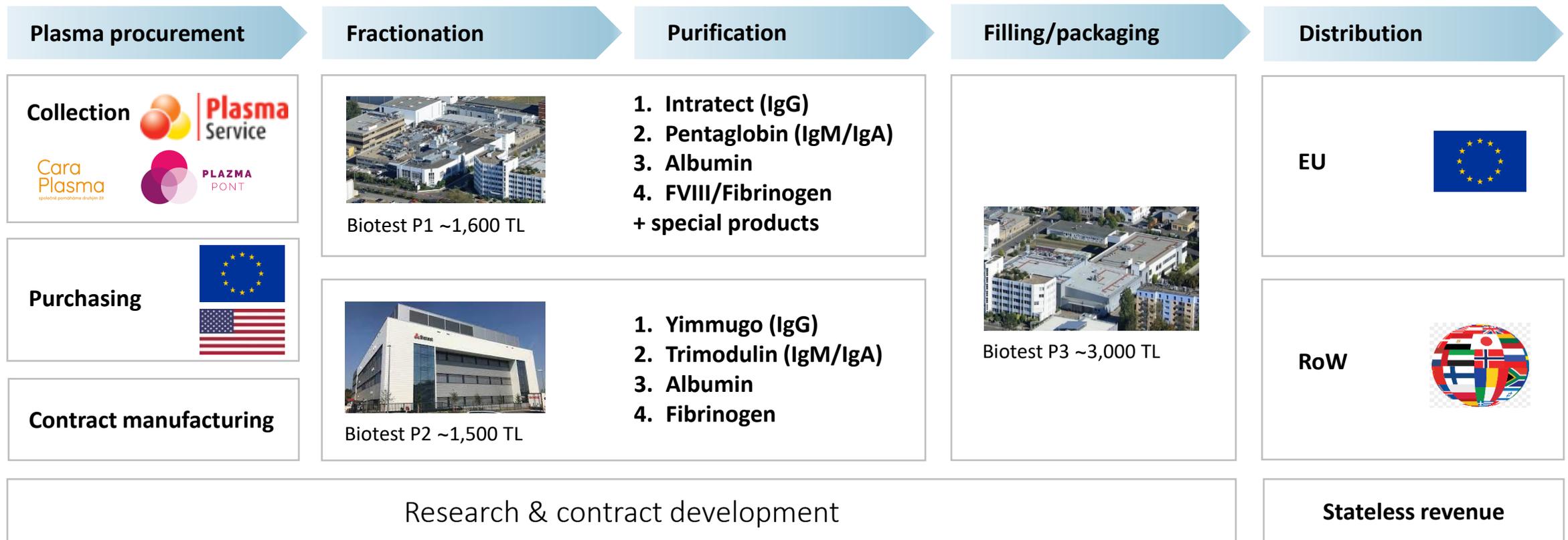


**Ainhoa Mendizabal Zubiaga**  
Chief Financial Officer



**Dr. Jörg Schüttrumpf**  
Chief Scientific Officer

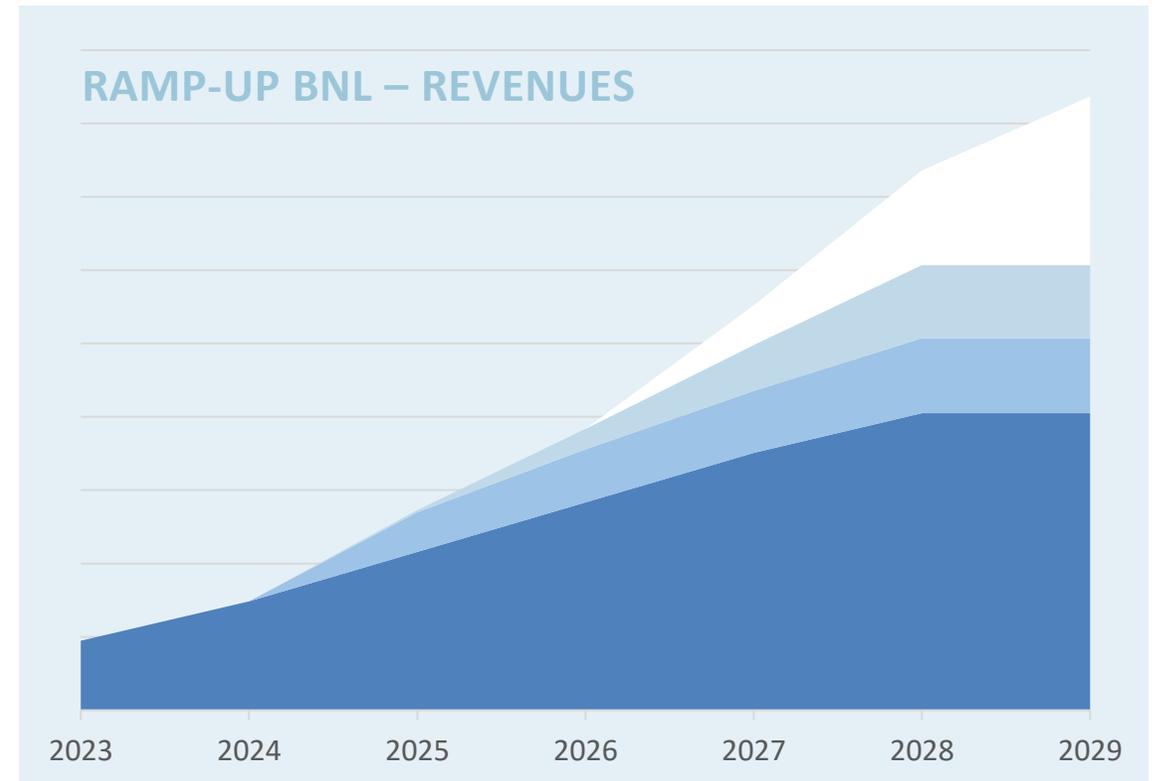
# Operational Model of Biotest



## BNL Target

- > Capacity expansion
- > New products
- > New markets
- > Increase in profitability

<b>Today</b>	<b>2027</b>
<b>0,3 TL</b>	<b>1,5 TL</b>
<b>1 product</b>	<b>4 products</b>





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# Biotest Group – Highlights FY 2023

# Biotest Group – Highlights FY 2023

## 1 BIOTEST NEXT LEVEL

- **Expansion of capacities** and further **development of the product portfolio**
- **FDA inspection** of Biotest Next Level



# Biotest Group – Highlights FY 2023

## **2** RESEARCH & DEVELOPMENT

- **Yimmugo**<sup>®</sup>: FDA accepted BLA application; FDA inspection
- Acquired **Fibrinogen** Deficiency Phase III trial: primary endpoint met
- **Trimodulin**: two phase III trials ongoing



# Biotest Group – Highlights FY 2023

## **3** PLASMA COLLECTION CENTRES

- Expansion of EU plasma collection centres continued: now **37 centres** in Germany, Hungary and Czech Republic



# Biotest Group – Highlights FY 2023

## **4** COLLABORATION

Biotest AG and Grifols, S.A. have significantly expanded their collaboration

- > Opportunity for Biotest **to produce and market its own new product developments worldwide** using Grifols' organisation and production network



**Sales**  
(+32.6%)



**EBIT**



**EBITDA**





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# Product Portfolio

# Immunoglobulins

## Intratect® and Yimmugo®

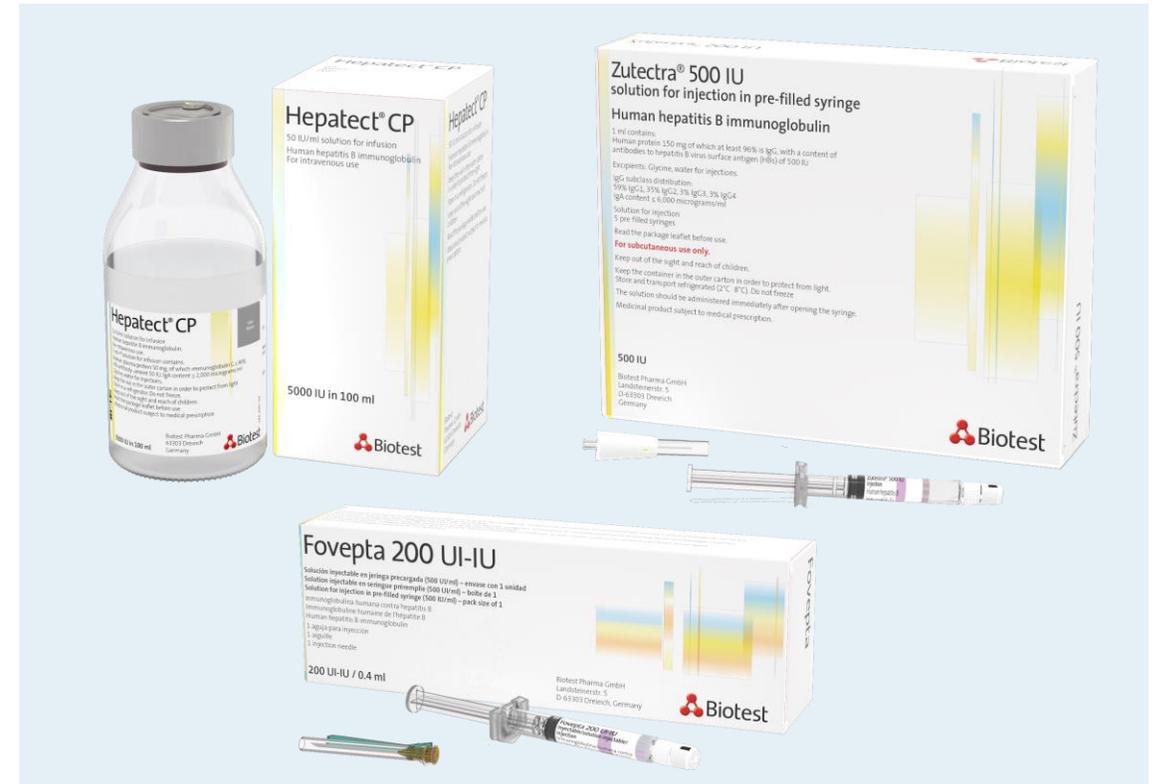
- Demand for immunoglobulins remains at stable high level, growing globally (+6%)
- Intratect® (5%/10%) sold in Europe and international markets
- Focus on high price markets to continue
- Yimmugo® generated sales of € 27 million in Germany and Austria in 2023



# Hepatitis B Hyperimmunoglobulins

## Hepatect<sup>®</sup>, Zutectra<sup>®</sup> and Fovepta<sup>®</sup>

- Biotest is market leader for hepatitis B hyperimmunoglobulins
- With declining Hepatitis B cases in developed markets and new antiviral therapies, the market situation is challenging in this area
- Hepatitis B hyperimmunoglobulins received marketing authorisations in several countries e.g. Hepatect<sup>®</sup> and Fovepta<sup>®</sup> were authorised in Bangladesh
- Zutectra<sup>®</sup> was launched in Turkey and Taiwan



# Other Hyperimmunoglobulins

## Cytotect<sup>®</sup> and Varitect<sup>®</sup>

- For Cytotect<sup>®</sup>, bone marrow transplants and selected areas of solid organ transplantation will continue to be main focus
- Cytotect<sup>®</sup> received marketing authorisations in several EU countries
- Stable revenues were achieved despite challenges



# Haematology Portfolio

## Haemoctin<sup>®</sup> (Factor VIII)

- Haemoctin<sup>®</sup> – natural complex of factor VIII and von Willebrand factor (Wild type factor)

## Haemonine<sup>®</sup> (Factor IX)

- Haemonine<sup>®</sup> posted slight growth
- In Germany the Nextaro transfer system introduced for Haemonine<sup>®</sup> receives good responses



# Intensive Care Portfolio

## Pentaglobin<sup>®</sup>

- Pentaglobin<sup>®</sup> has > 30 years of IgM experience
- Pentaglobin<sup>®</sup> reduces mortality in sepsis patients
- Promising new indications (e.g. eDSA clearance in lung transplant)
- Pentaglobin<sup>®</sup> is the only approved (IgM-enriched) immunoglobulin preparation for treatment of severe bacterial infections
- Pentaglobin<sup>®</sup> revenues increased; growth shown in various European and international markets



# Intensive Care Portfolio

## Albiomin

- **High demand** for therapeutic Albiomin in 2023
- Rising prices especially in important markets as China
- Demand for Albumin in Asia is high; expansion of business in China, Indonesia, UK and Italy
- New marketing authorisations obtained in France for Albumin 5% and 20%

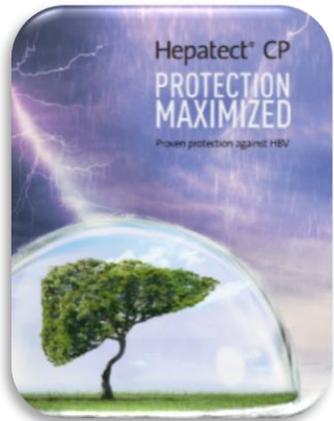


# Biotest Human Serum Albumin

- Biotest Human Serum Albumin is a **multifunctional excipient** for Manufacturing and research use, Pharmaceutical Biotechnology and Diagnostic Industry
- **Cell media:** cell and tissue culture, stem cells, cryopreservation, in vitro fertilisation
- **Drug carrier** – targeted delivery: nanoencapsulation and medical imaging
- **Stabiliser:** drug and vaccine formulations and cell therapy
- Biotest Human Serum Albumin recorded **significant revenue growth in 2023**



# Marketing Visuals



**Hepatect®**

> Protection  
Maximized



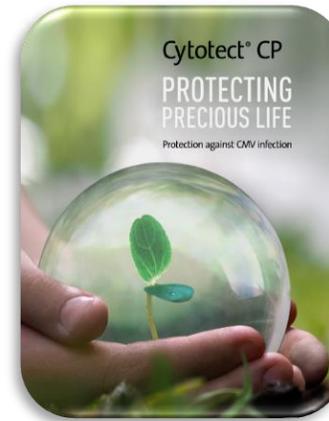
**Zutectra®**

> Freedom in  
your Hands



**Fovepta®**

> Simply  
Protected



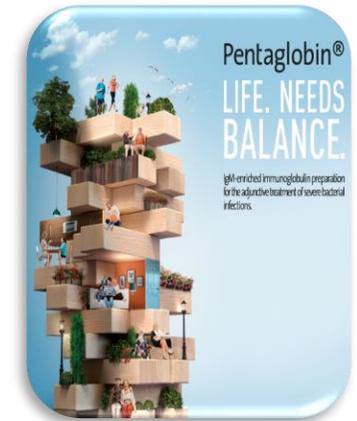
**Cytotect®**

> Protecting  
Precious Life



**Varitect®**

> Counteract  
Complications



**Pentaglobin®**

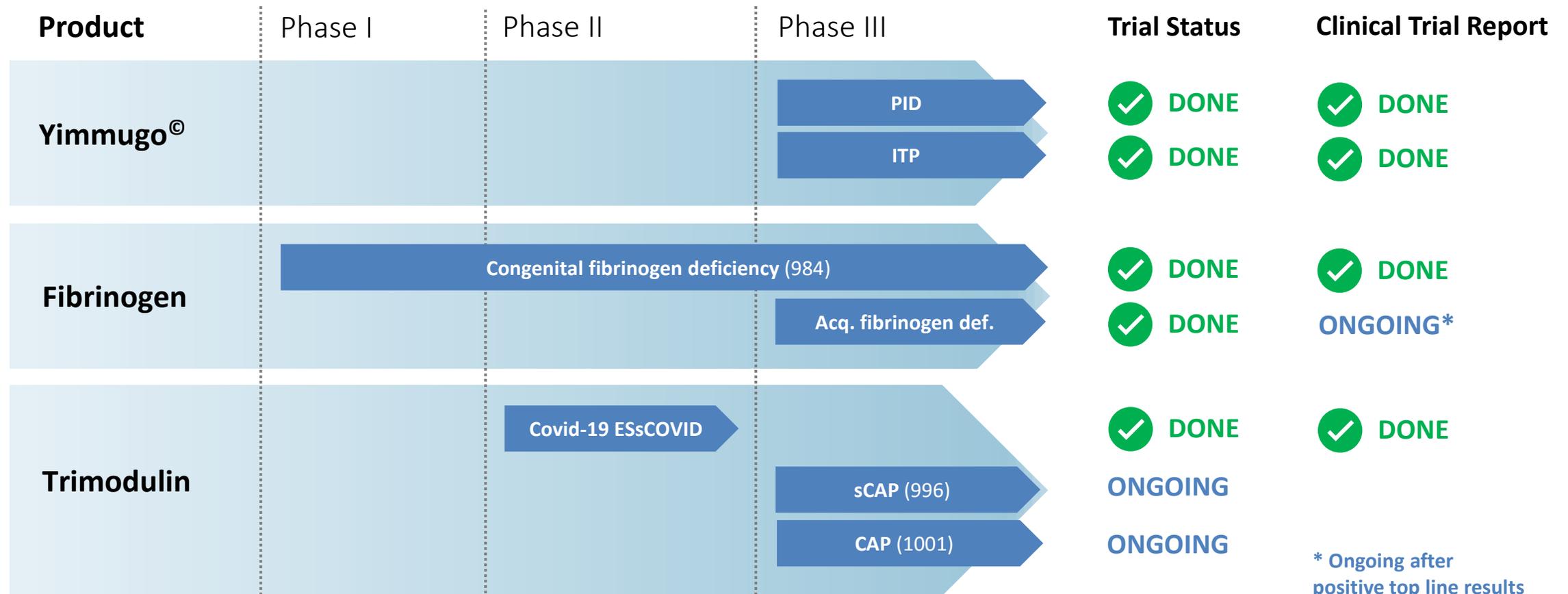
> Life. Needs  
Balance.



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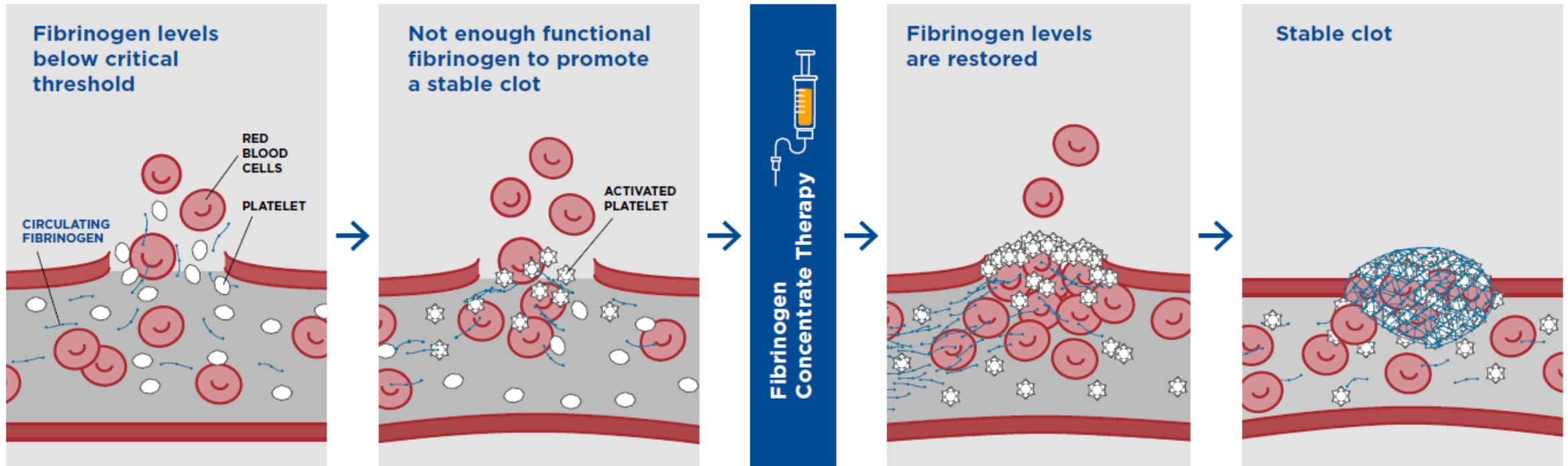
Research & Development

## DEVELOPMENT PROJECTS – GENERAL OVERVIEW



\* Ongoing after positive top line results

# Fibrinogen – a Critical Blood Clotting Factor



When a blood vessel is injured, several processes are initiated to facilitate healing. **Fibrinogen** plays a decisive role in this precisely choreographed sequence of clotting events.

# Fibrinogen Trials Status

## Congenital FD<sup>1</sup>

**Phase I/III study: Largest clinical trial in congenital fibrinogen deficiency worldwide**

*Treatment of adults and children*

- Results confirm high expectations regarding efficacy and safety...
- Study completed



## Acquired FD<sup>1</sup>

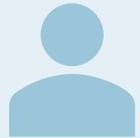
**Phase I/III study: in major spinal surgery and pseudomyxoma peritonei (tumor) surgery**

- Last patient recruited and treated end of Sept. '23; in total 200 evaluable patients
- **Positive top line results**
- **Clinical Trial report** to be finalised by mid 2024

## Two Phase III Trimodulin Trials Ongoing

Randomized, placebo-controlled, double-blind, multi-center, phase III trials investigating the efficacy and safety of Trimodulin in adult hospitalised patients

# CAP Patients



390 SUBJECTS

- Patients on low-flow oxygen, high-flow oxygen, NIV
- Patients with early systemic inflammation
- Indication was extended from COVID-19 to Community Acquired Pneumonia (CAP), incl. COVID-19
- 60 study centres in 14 countries
- Next step: Interim Analysis, dependent on patient rate recruitment



## sCAP Patients



~590 SUBJECTS

- Patients on invasive mechanical ventilation (within 12 h)
- Patients with inflammation (CRP  $\geq$  70 mg/L)
- SARS-CoV-2 negative
- 140 study centres in 18 countries planned





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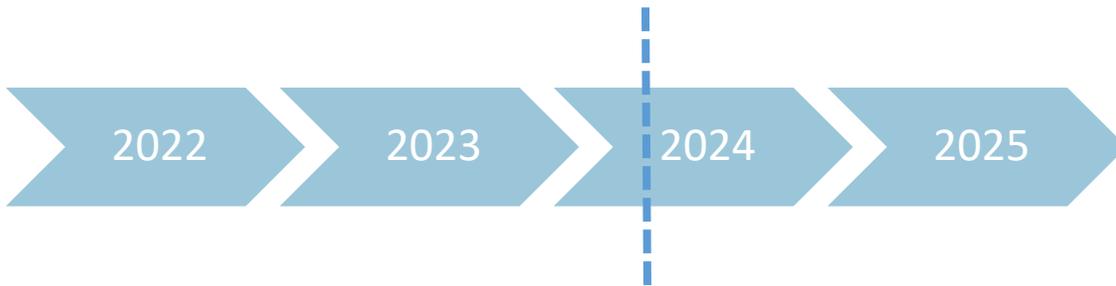
# Biotest Next Level

# Yimmugo<sup>®</sup> – Launch in Germany followed by other markets...

- Germany:** First sales in November 2022
- Austria:** First sales in December 2023
- UK:** Marketing authorisation in August 2023
- EU:** Registration process initiated in France, Italy, Netherlands, Portugal, Ireland, Norway, Hungary and Sweden
- USA:** US Food and Drug Administration (FDA) accepts Biologic License Application (BLA) in August 2023



# Biotest Next Level – Ramp-up Manufacturing of Yimmugo®



- The amount of **Yimmugo**® produced is to be increased to 6–7 batches per week
- **Target:** produce more batches more efficiently
- **Challenge:**
  - Recruiting of skilled and trained personal
  - Sufficient availability of external service providers regarding automation



## Biotest Next Level – FDA Inspection

- December 2023: **Pre-License Inspection** of Biotest Next Level Manufacturing plant by US Food and Drug Administration (FDA)
- **Inspection and validation** of quality systems, Yimmugo<sup>®</sup> manufacturing plant, compliance of the production process with the submitted dossier validated and verified
- **Final report** expected





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# Plasma Collection

# Expansion of Plasma Collection Centres

## Europe: 37 plasma collection centres

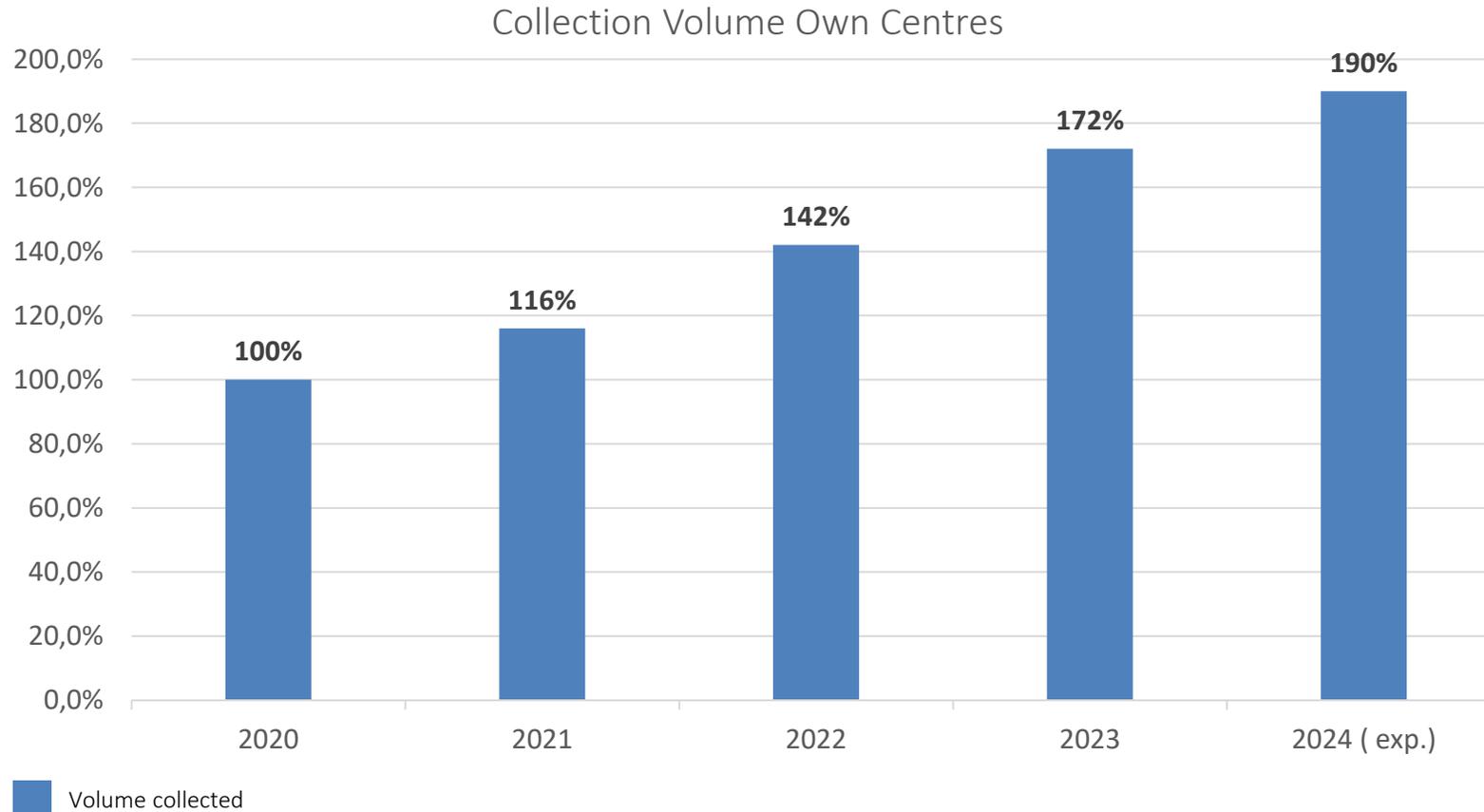
- 2 new centres in Germany in 2024
- 2 new centres in 2023 in Germany and in Hungary
- 7 new centres in 2022 in Czech Republic

## Access to US Plasma

- Long-term supply contracts with Grifols and other third parties



# Biotest Plasma Collection



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**Biotest Plasma collection  
volume: ~90% higher  
than in 2020**

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# Collaboration Biotest and Grifols

> COLLABORATION BIOTEST AND GRIFOLS

Biotest and Grifols has and will join forces in core markets to strengthen their joint position also by securing plasma supply, optimised manufacturing capacity and a strong research pipeline.



**Target:** The availability of leading plasma protein therapies should be ensured!

# Technology Transfer & License Agreement with Grifols S.A.

Know-how for the development and manufacturing of Yimmugo<sup>®</sup>, Trimodulin and Fibrinogen has been and will be disclosed and transferred to Grifols with remuneration on three levels

1. For the **Technology Disclosure** (6 technology components)
2. For **acceleration & completion of the R&D projects**  
  
For 1) and 2) Biotest will receive **in total** a mid three-digit million amount in several installments between 2023 and 2026
3. Grifols will pay Biotest **royalties** in the high single-digit percentage range of net sales of the licensed products for a period of 30 years from the date of commercialization

Grifols has been granted a semi-exclusive license to manufacture and market three products – Yimmugo<sup>®</sup>, Fibrinogen and Trimodulin – worldwide.

**Total valuation:  
€ 1.1 – 1.6 billion**

# Master Distribution Agreement

## CURRENT FOCUS

- **Optimise distribution structures in existing markets**
  - e.g. by selling 5 Biotest sales companies (Spain, Italy, Brasil, UK and France) to Grifols and thereby obtaining „one face to the customer“
  - Preparations for Germany for „one face to customer“ ongoing
- Exploit additional business opportunities through coordinated collaboration between the two companies





Biotest

*From Nature for Life*

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# Biotest Sustainability

# Sustainability Projects at Biotest

- Completion of the **photovoltaic system**
- **Heat recovery system** implemented
- **GoFuture forest**: 12,000 trees, absorption of 3,100 tons of CO<sub>2</sub> in 10 years
- Improvement in the **energy efficiency of production** compared to the previous year (> 5%)



## Daycare “BioNest”

It is important to us that our employees are able to balance family and career. In our in-house daycare center “BioNest” at the Dreieich location we offer:

- 90 childcare places
- Comprehensive care from ages 0 to school entry
- Opening hours: Monday to Friday 6:00 a.m. – 6:00 p.m.
- Indoor play area with ball pit, group rooms and bedrooms
- Outdoor area with sand playground, climbing facility and slide



# Biotest Sustainability Goals

- Sustainable supply chain as a goal
- Transformation concept for emission reduction and efficient use of resources



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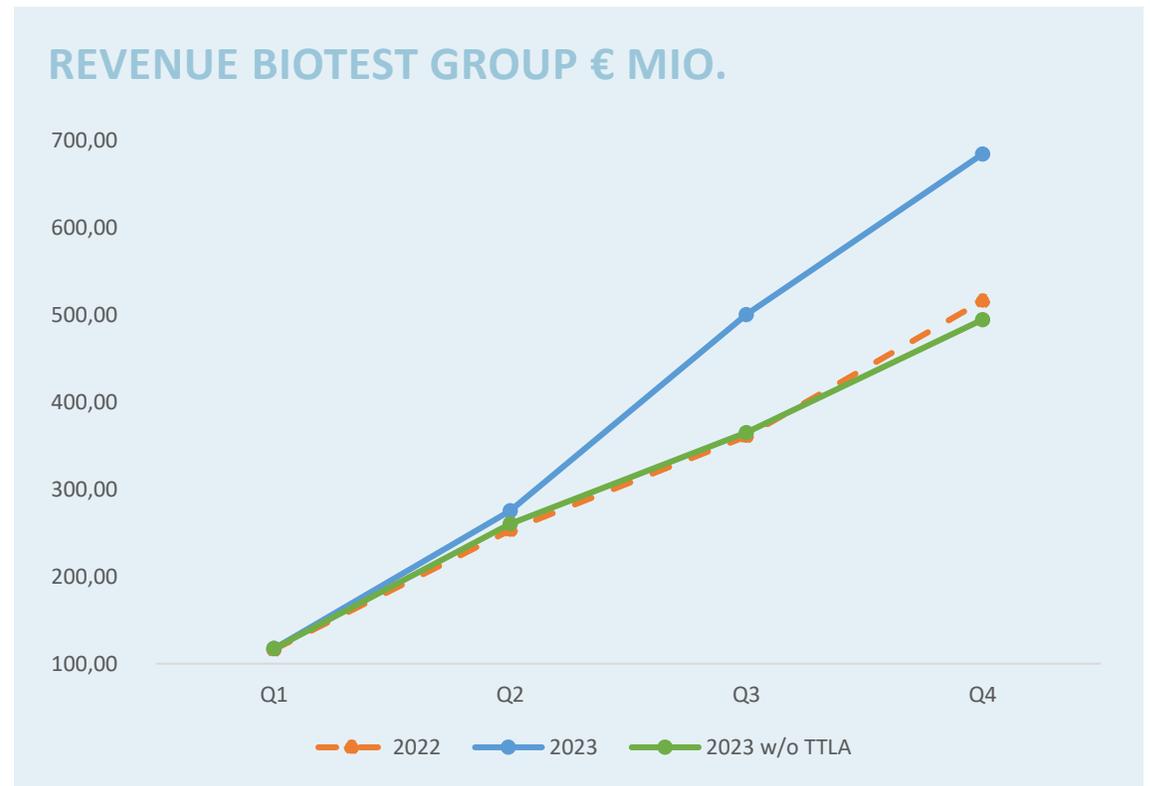
# Financials FY 2023

## Income Statement (€ million)

	<b>FY 2022</b>	<b>FY 2023</b>	Dev. in %
<b>Sales in regions</b>	<b>516.1</b>	<b>684.6</b>	32.6
thereof: European Union	264.6	260.4	-1.6
Rest of World	251.5	234.1	-6.9
Stateless	–	190.1	>100
COGs and operating expenses	-532.7	-541.1	-1,6
<b>Operating profit (EBIT)</b>	<b>-16.6</b>	<b>143.5</b>	>100
Financial result, taxes	-15.1	-16.5	-9.3
<b>Earnings after tax (EAT) Biotest Group</b>	<b>-31.7</b>	<b>127.0</b>	>100

## Revenue 2022 and 2023

- Revenue growth is mainly due to revenue generated from technology disclosure and development services for Grifols S.A., amounting to € 190 million
- Excluding this amount, revenue amounted to € 494.5 million, a 4.2% decrease versus the previous year
- This lower revenue level reflects an IT malfunction that occurred at the end of 2023 and which delayed product releases and shifted revenue to the 2024 financial year

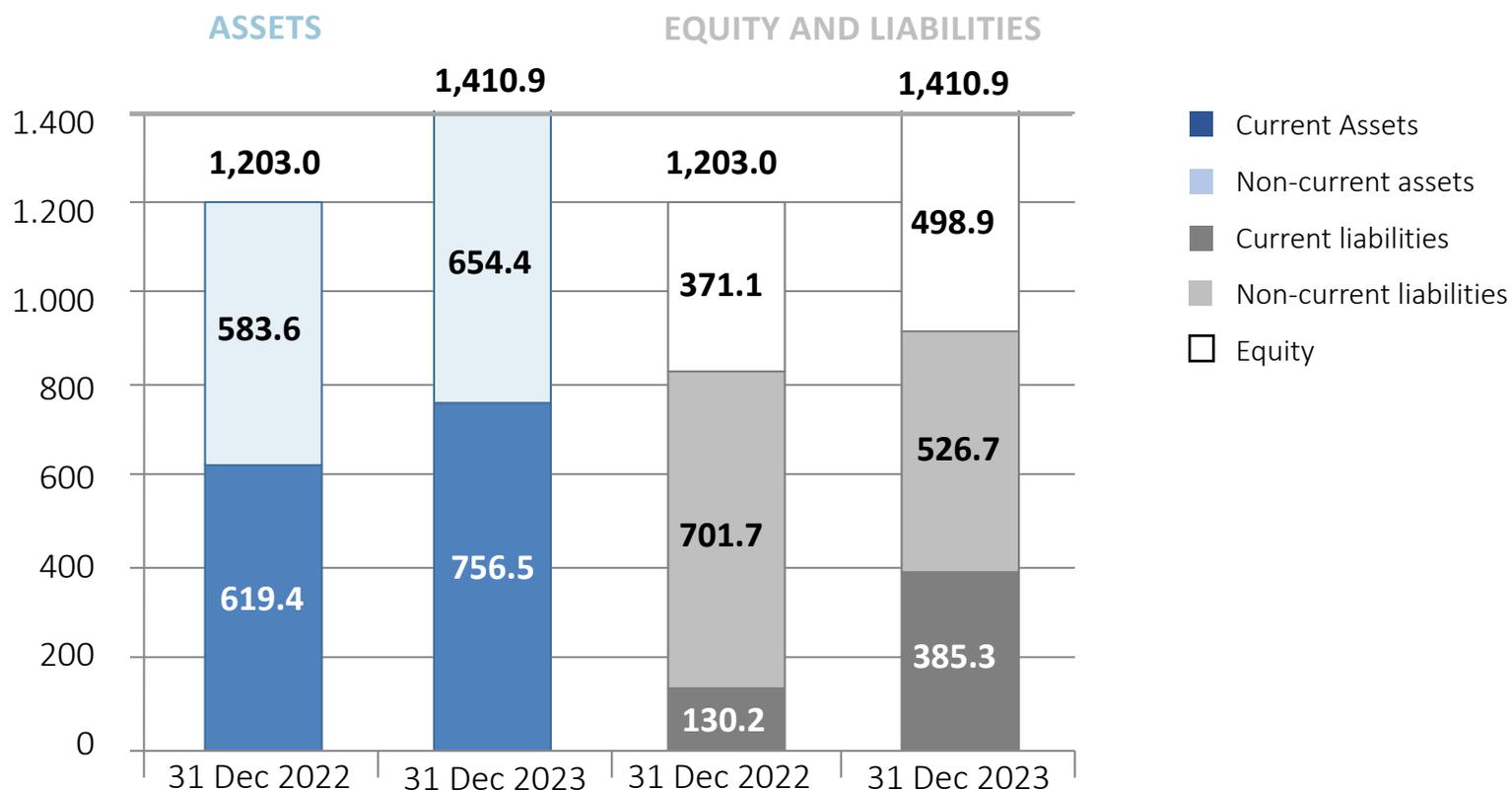


## EBIT Reported and Adjusted (€ million)

	FY 2022	FY 2023	Dev. in %
<b>EBIT reported</b>	<b>-16.6</b>	<b>143.5</b>	> 100
Earnings from technology disclosure	–	-153.5	< -100
Disposal gain from sale of 5 Biotest subsidiaries	–	-23.1	< -100
Earnings from development services	–	-4.7	< -100
Expenses for Biotest Next Level	77.3	79.4	2.7
<b>EBIT adjusted</b>	<b>60.7</b>	<b>41.6</b>	-31.5

- Adjusted EBIT describes the **operating performance** of the Biotest Group excluding special effects.
- In order to ensure continuity and comparability, the **expenses from the Biotest Next Level expansion project** of € 79.4 million (previous year: € 77.3 million) are shown.
- Special effects in 2023 also relate to the first-time income from the **technology disclosure** of € 153.5 million, from **development services** of € 4.7 million generated with Grifols, S.A., and the gain on **disposal of five Biotest subsidiaries** to Grifols, S.A. of € 23.1 million.

# Balance Sheet as of 31 December 2023 (€ million)



**Net debt as of  
31 Dec 2023:  
€ 551.5 m**

**Equity ratio as of  
31 Dec 2023:  
35.4%**

**Improved equity  
ratio of 35.4%  
from 30.8%**

# Cash Flow from Operating Activities

JANUARY – DECEMBER 2023 (€ MILLION)	FY 2022	FY 2023
<b>Operating CF before Changes in Working Capital</b>	<b>19.8</b>	<b>154.0</b>
<b>Cashflow from Changes in Working Capital</b>	-45.2	-120.8
<u>thereof:</u> Changes Inventories	-49.5	-131.2
Changes Trade Receivables	-14.6	-46.3
Other Changes	18.9	56.7
Interest & Tax expense	-15.1	-35.9
<b>Cashflow from Operating Activities</b>	<b>-40.5</b>	<b>-2.7</b>

# Guidance 2024

## Revenue:

Increase in sales in the upper single-digit percentage range vs. 2023, incl. sales from the technology disclosure and development services for Grifols, S.A.

## EBIT:

Operating result expected in the range of **€ 80 to 100 million** for 2024.

## Cash Flow:

Positive cash flow from operating activities above the previous year's level.



# Annual General Meeting

## Dividend

Proposal to Annual General Meeting for preference shares amounts to € 1.6 million (€ 0.04 per preference share for 2023 and 2022)

The Annual General Meeting of Biotest AG will take place on May 7, 2024, at the Alte Oper, Opernplatz, 60313 Frankfurt/Main, Germany.

# Strategic Targets

- **Responsible & sustainable** growth
- Growth through increased new **capacity**
- Increased patient access by **new products** and **new markets**
- Improved **efficiency**
- Extended **partnerships** with Grifols and others





Thank you for your attention.

# Financial Calendar 2024

**07 May 2024** AGM / Q1 Report

**30 Jul 2024** H1 Report

**05 Nov 2024** Q1-Q3 Report

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# Disclaimer

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The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

All comparative figures relate to the corresponding last year's period, unless stated otherwise.