Biotest AG

Nine Month 2022 Results
Conference call

November 14, 2022

Biotest
From Nature for Life

Disclaimer

- This document contains forward-looking statements on overall economic development as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments.
- 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.

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Biotest Group – Great News

IgG Next Generation now:

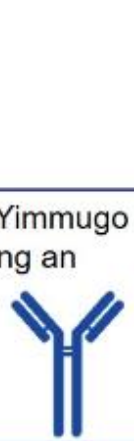
Yimmugo®

Approval by Paul Ehrlich Institute

Yimmugo®

The brand name Yimmugo is coined from the word **immu**noglobulin.

The „Y“ in Yimmugo is suggesting an Antibody.



Yimmugo®

The icon stands for protection, both of our patients as well as the nature.

The colors blue and green are the predominant colors in nature. They symbolize nature and tranquility but also depth and trust.

The “go” in Yimmugo stands for a future-oriented vision.

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Yimmugo®
Higly tolerable replacement therapy, sustainably delivered [1-3]

- **Yimmugo®** is a 10% immunoglobulin preparation for intravenous treatment [4,5]
- **Yimmugo®** is not only produced through an innovative and unique manufacturing process resulting in an IgG with high efficacy and tolerability [1,2], it is also made sustainably[3]

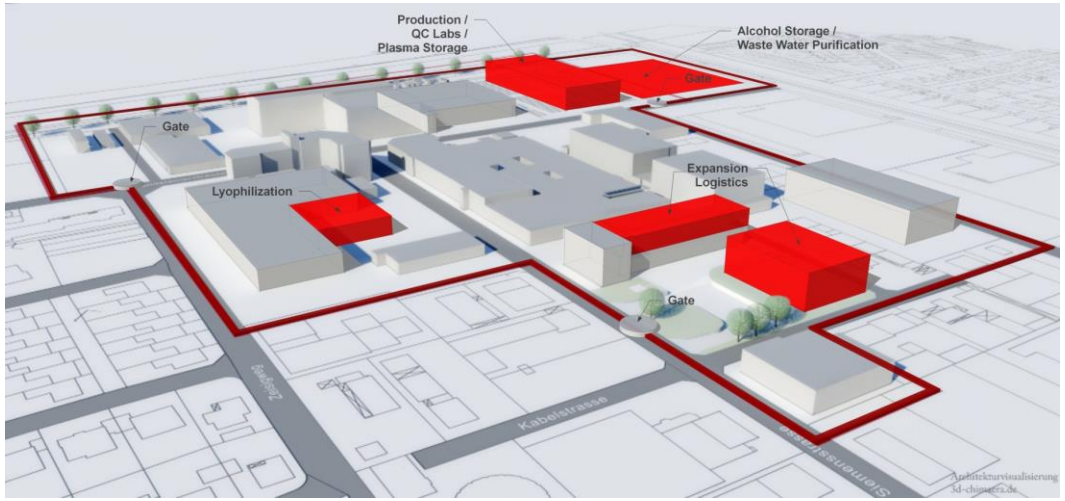
  - Proven high efficacy
  - Well tolerated with a favourable safety profile
  - Convenient dosing schedule, rapid infusion rate
  - Innovative and sustainalble manufacturing process

1. Krivan et al. Efficacy, safety and pharmacokinetics of a new 10% normal human immunoglobulin for intravenous infusion, BT 595, in children and adults with primary immundeficienc diseases. Vox Sanguinis. 2022;117:1153-1162
2. Demeter et al.Efficacy and safety of Yimmugo® (10% IVIg) in adult patients with chronic immune thrombocytopenia (ITP), Transfusion medicine. Manuscript submitted for publication.
3. Declaration of compliance of Biotest AG with German Sustainability Code DNK.2021
4. Biotest: Biochemical characterization and stability of IgG Next Generation. 2022. Manuscript in preparation.
5. Yimmugo® SmPC

**: Infusion rate: (up to 6mL/kg/h in immunomodulation, 8 mL/kg/h in replacement) is as high, or higher than common European competitor IVIgGs [1,2,5]. IgG, Immunglobulin G, Intravenous immunglobulin G.*

Yimmugo®: First product produced for the market in Biotest Next Level

Expansion of global capacity started in 2013



Launch of first BNL product: **Yimmugo**®

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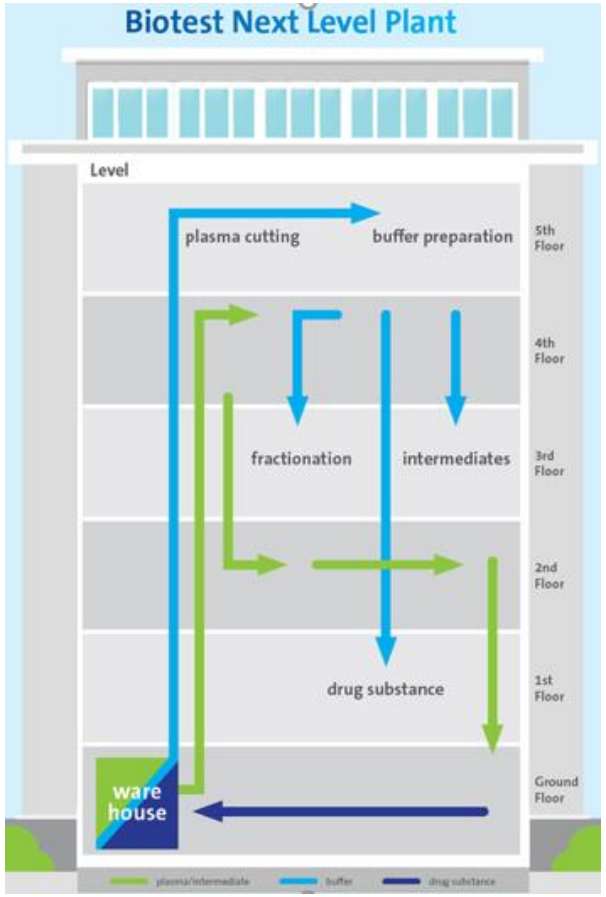
Biotest Next Level – state of the art production plant



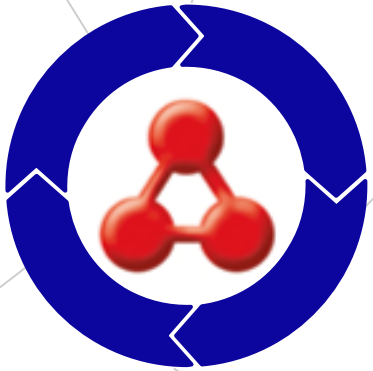
- **Yimmugo®** is produced in Biotest's new, state of the art production plant Biotest Next Level
- The innovative production process allows a high product quality and safety while producing more sustainably than before

  - ✓ BNL is constructed as green building with low pollution and low emission materials
  - ✓ A top-down multi-storey system uses gravity to conserve energy
  - ✓ Many environmentally friendly chemicals are used where possible
  - ✓ Optimized processes maximizes yields of the donor plasma
  - ✓ A cogeneration plant uses waste heat for air conditioning
  - ✓ Less water is needed and less waste is produced

Yimmugo® provides an important contribution to the future profitability of Biotest

1st product from BNL
- Big milestone for Biotest

The future IVIG
- Secure future profitability (increased production capacity and higher yield)



Manufacturing based in Dreieich
- Protect local jobs

1st US product
- Re-enter the most important pharma market

1st product with a sustainability focus
- Initiate a sustainability mindset
- Give strong signal to external stakeholders

Financials Q1-Q3 2022

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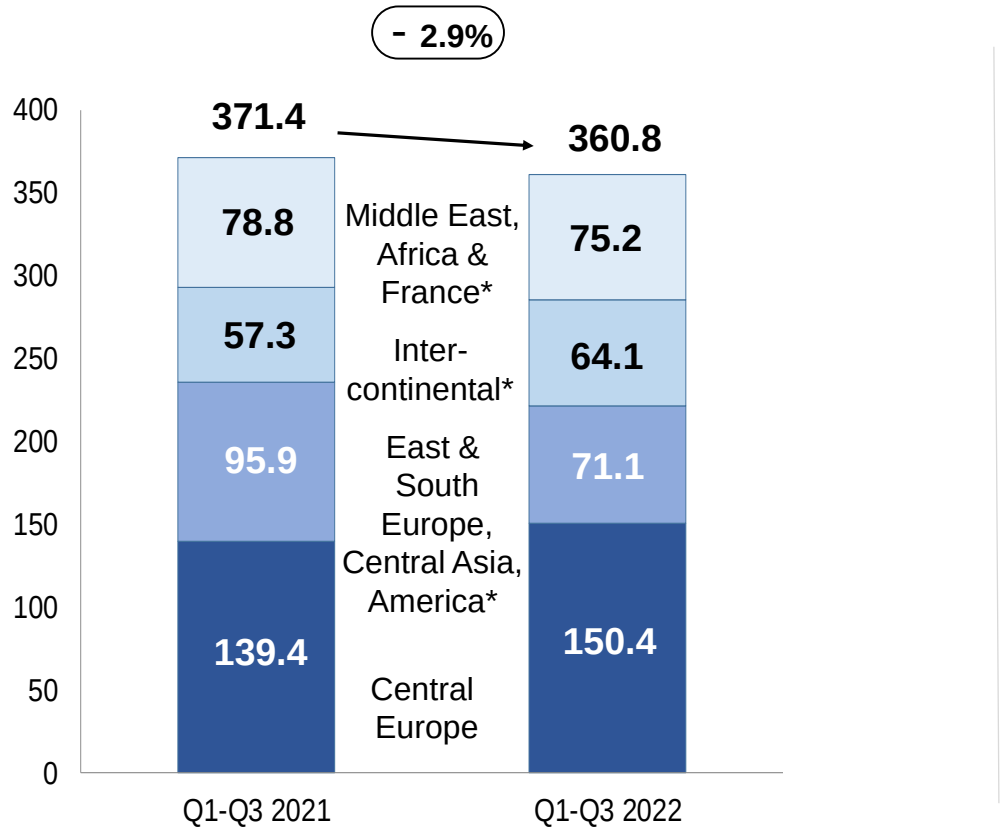
Income statement
(€ million)

	Q1-Q3 2021	Q1-Q3 2022
Sales	**371.4**	**360.8**
thereof: Therapy	329.8	317.8
Plasma & Services	36.3	38.5
Other Segments	5.3	4.5
Operating costs & expenses	-382.6	-379.8
Operating profit (EBIT)	**-11.2**	**-19.0**
Financial result, taxes	-17.1	-15.2
Earnings after tax (EAT) Biotest Group	**-28.3**	**-34.2**

Sales development of sales regions
(€ million)



*: The prior-year figures have been adjusted in line with the definition of the sales regions in 2022

- **Therapy sales:** strong growth in Central Europe (+7.9%) and in Intercontinental region of +11.9%.
- **Segment Plasma & Services**: Increase of 6.1% due to higher toll manufacturing

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EBIT reported and adjusted
(€ million)

	Q1-Q3 2021	Q1-Q3 2022
EBIT reported	**-11.2**	**-19.0**
Biotest Next Level facility costs	27.7	33.6
Biotest Next Level R&D costs*	29.3	29.8
Biotest Next Level administration costs	0.5	0.5
EBIT adjusted	**46.3**	**44.9**

**: R&D costs for BNL development projects*

Reconciliation EBIT Q1-Q3 2021 – EBIT Q1-Q3 2021
(€ million)

EBIT Q1-Q3 2021	**-11.2**
Higher BNL ramp-up costs	-5.9
Higher BNL R&D costs	-0.5
Others	-1.2
EBIT Q1-Q3 2022	**-19.0**

**: a positive sign is favorable to EBIT, an negative sign is unfavorable to EBIT*

Biotest Next Level costs in Q1-Q3 2022

1. **BNL facility costs**: **€ 33.6 million**;
   - Facility costs (energy, building costs, maintenance, etc.)
   - Depreciation
   - Personnel costs (for ramp-up, commissioning etc.)
   - Project administration

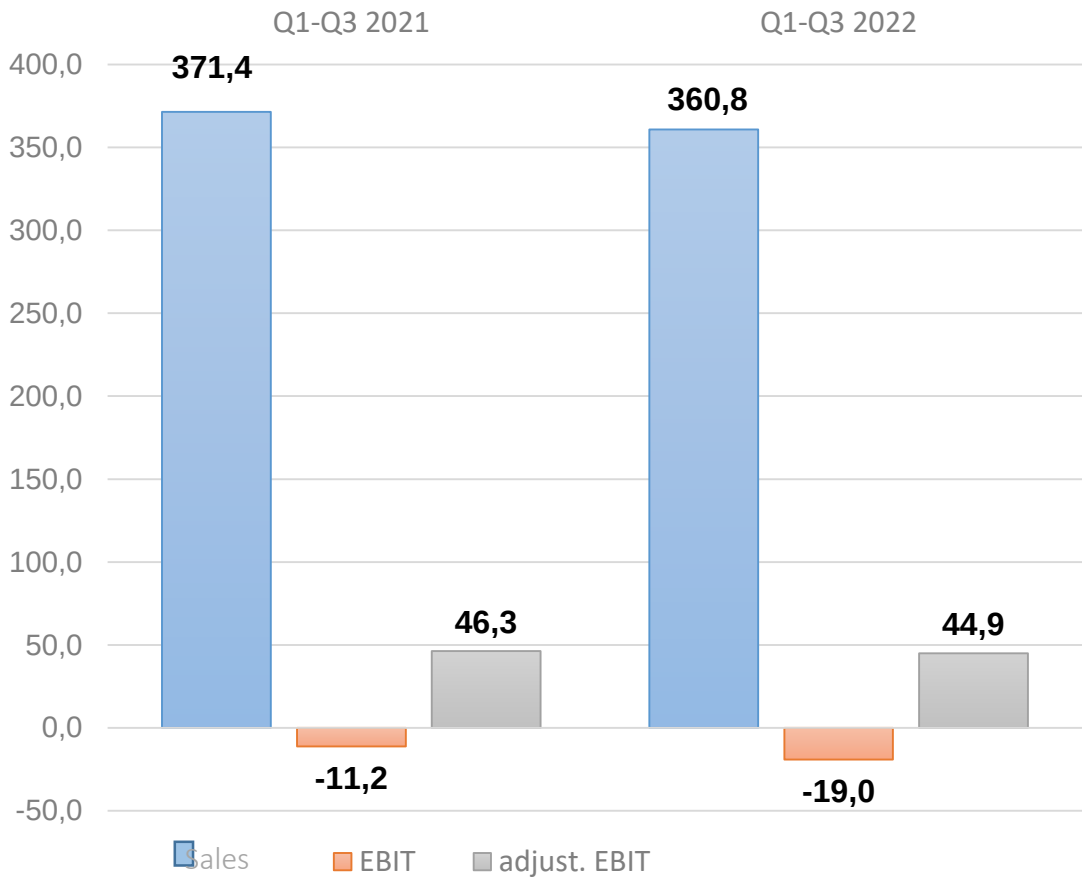
Ramp-up of BNL: for IgG Next Generation the routine production has started in May 2022. For Trimodulin and Fibrinogen the commissioning of the production lines is being prepared.

2. **BNL R&D** costs in total: **€ 29.8 million**; thereof:
   - € 5.6 million - IgG Next Generation
   - € 16.1 million - Trimodulin (IgM concentrate)
   - € 8.1 million - Fibrinogen

Acceleration of phase III R&D projects Trimodulin and Fibrinogen

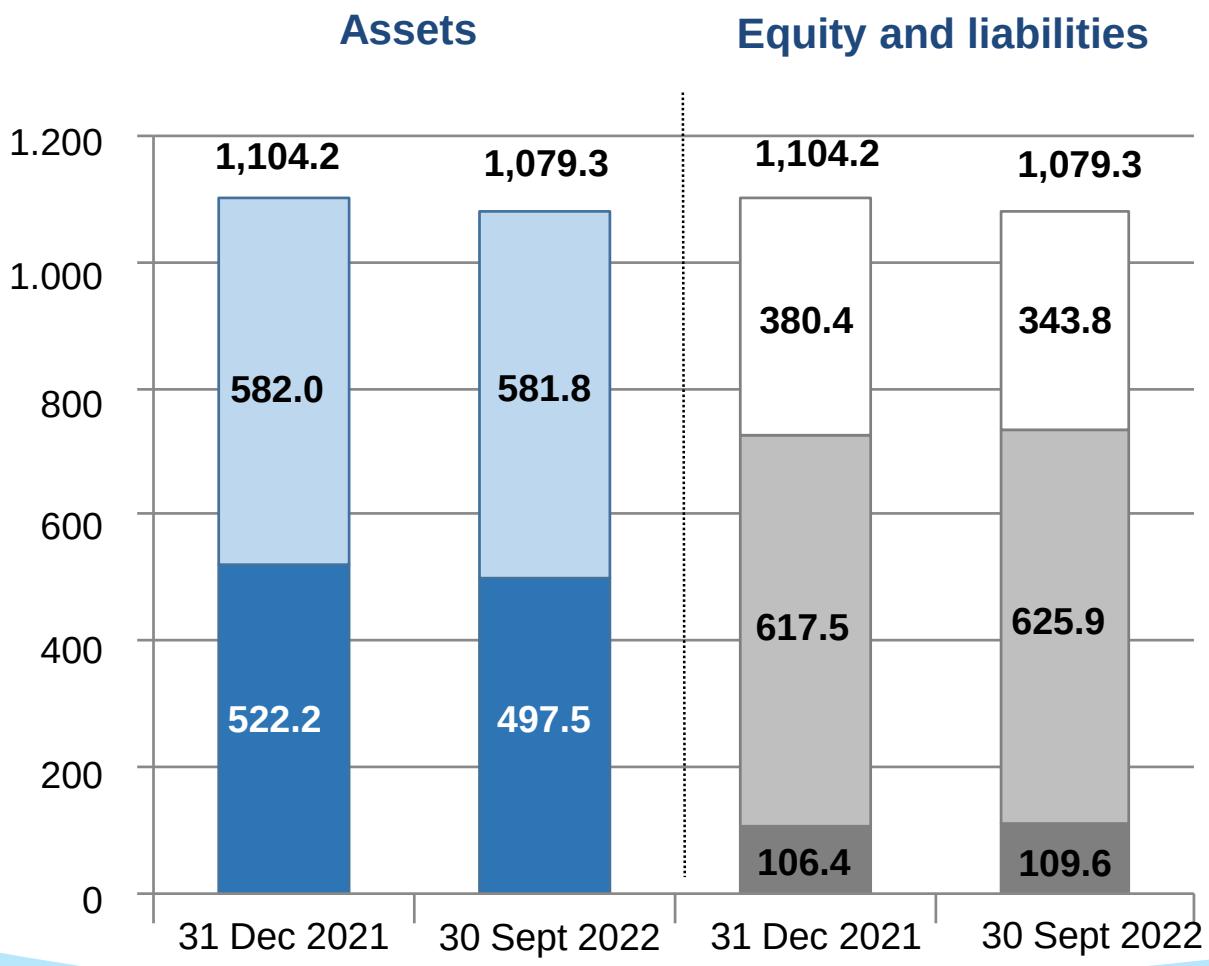
Total BNL costs: **€ 63.9 million** in Q1-Q3 2022

Q1-Q3 2022 at a glance



- **Sales increase** in **Central Europe** and **Intercontinental** compared to the previous year
- Q1-Q3 EBIT 2022 lower compared to Q1-Q3 2021
- Q1-Q3 2022 EBIT includes **Biotest Next Level expenses of € 63.9 m** (Q1-Q3 2021: € 57.5 m)
- **Q1-Q3 adjusted EBIT: € 44.9 m** (-3.0%) vs. Q1-Q3 2021 adjusted EBIT of € 46.3 m

Statement of financial position as of 30 September 2022
(€ million)



Net debt as of 30 Sept 2022:
€ 417 m

Equity ratio as of 30 Sept 2022:
32.6%

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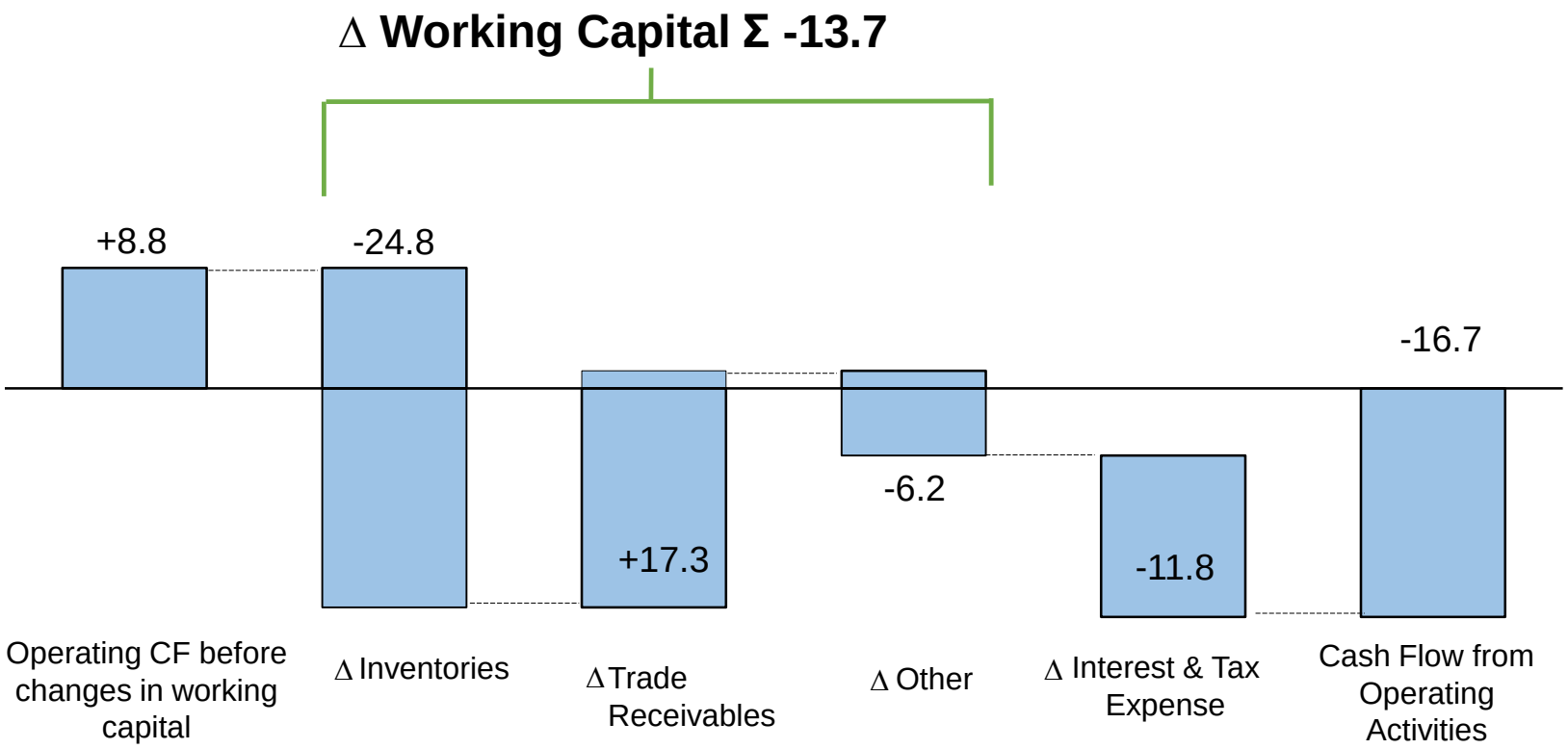
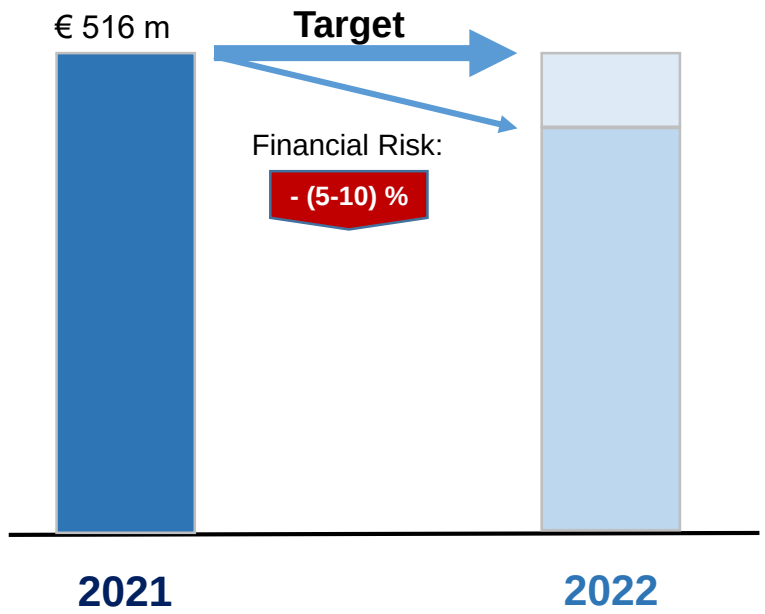
Cash flow from operating activities
January – September 2022 (€ million)



Outlook 2022: Sales & risks - Status as of 24 March, 2022

Sales

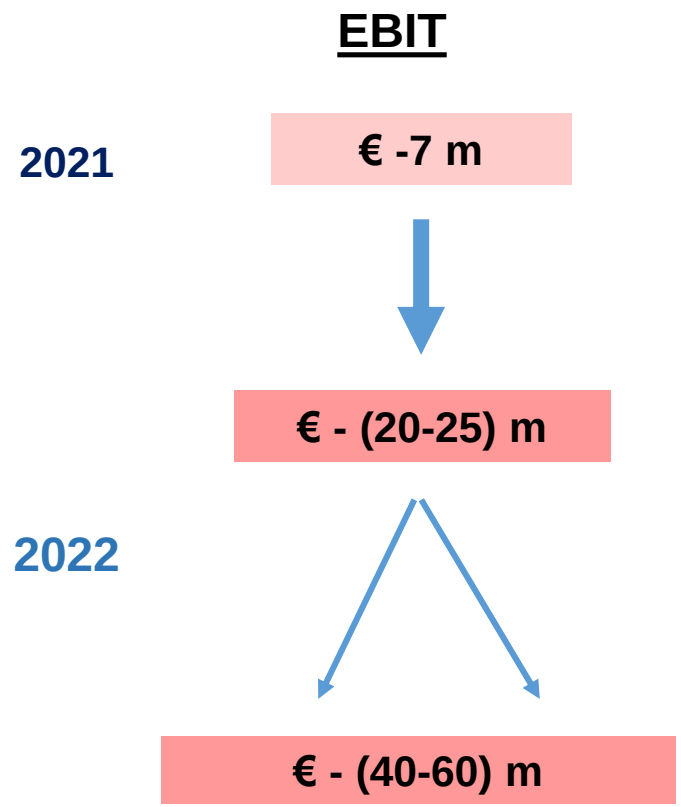


- No decline in demand or medical necessity

BUT increased risk:

- The general economic situation may reduce the "purchasing power" of health systems
- Slowdown or interruption of production
  - COVID-19-related staff shortage
  - Delayed delivery of plasma
  - Limited availability of spare parts and essential tools
  - Energy shortages

Outlook 2022: EBIT – Status as of 24 March, 2022



- Acceleration of R&D phase III projects
- Increasing plasma costs

- (Indirect) Impact of the Russian war in Ukraine
- COVID-19 „bottlenecks“
- Gas shortage

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Outlook 2022: EBIT – Our todays assessment

EBIT

2021	**€ -7 m**
2022	**€ - (20-25) m**

- Acceleration of R&D phase III projects
- Increasing plasma costs
- (Indirect) Impact of the Russian war in Ukraine
- COVID-19 „bottlenecks“
- Gas shortage

Sustainability

Can there be anything more sustainable than just securing and protecting the livelihoods of future generations and those of today?

The SUSTAINABILITY Code Signatory 2021

prepared according to CSR Directive Implementation Act

- Based on products made from renewable raw materials
- Low environmental impact
- Climate-neutral production (scope 1 and 2)
  - By switching to green electricity and
  - Voluntary compensation measures for all greenhouse gas emissions

Goal: Complete climate neutrality of the Biotest Group **by 2035** at the latest

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R&D update

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R&D in the three Therapeutic areas

	New products	New indications/ LcM
Clinical Immunology Intratect®,Hepatect®CP Zutectra®, Fovepta® Cytotect®CP, Varitect®	**Yimmugo (IgG Next Gen)** *Marketing authorization*	**Cytotect®CP:** phase III in CMV in pregnancy Cytotect®CP: CMV in Heart and Lung TX (Real Life Data *) Varitect®: Herpes Zoster (Real Life Data *) Zutectra®/Hepatect®CP: Chronic HBV Infection (ISS)**
Haematology Haemoctin® Haemonine®	**Fibrinogen** *Phase III congen. fibrinogen def. completed* *Phase III acquired fibrinogen deficiency*	
Intensive Care Pentaglobin® Human Albumin Biseko®	**Trimodulin (IgM Conc.)** *Phase III in COVID-19* *Phase III in sCAP*	

*: Non-Interventional Studies (NIS) **: Investigator Sponsored Study

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R&D pipeline progress in Q1-Q3 2022

	Status of R&D development
IgG Next Generation	A further study with high-dose therapy in the **dermatological field** is being planned for Europe and US.
Fibrinogen	The **interim analysis** in Phase III (acquired) trial (AdFirst Study) was successful. A further interim analysis to confirm the planned patient number will take place after data of 80% evaluable patients are available.
Trimodulin (IgM Concentrate)	The submissions of two **Phase III studies** in COVID-19 (TRICOVID) and sCAP (ESsCAPE) are ongoing.
Cytotect®CP	A **phase III clinical trial** (PreCyssion) to prevent transmission of maternal CMV infection to the unborn child is currently in the treatment phase.
Cytotect®CP, Varitect® , Zutectra®, Hepatect®CP	**Non- interventional studies** (Real life data) and ISS: Cytotect®CP in in Heart and Lung TX; Varitect® in Herpes Zoster; Zutectra® and Hepatect®CP in chronic HBV infection treatment.

Yimmugo® (IgG Next Generation): Polyspecific immunoglobulin

Intratect®

Maintain:

- ✓ Excellent efficacy in immunodeficiency and autoimmune diseases
- ✓ Excellent safety
- ✓ Highest quality

Yimmugo® (IgG Next Generation)

Yimmugo®: Marketing Authorization as of Nov. 2022

Further improve:

- ✓ Increased user-friendliness
- ✓ Higher tolerability
- ✓ Optimised yield
- ✓ Suitable for worldwide commercialisation

Clinical phase III trials in congenital and acquired Fibrinogen deficiency

Congenital FD[1]

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…

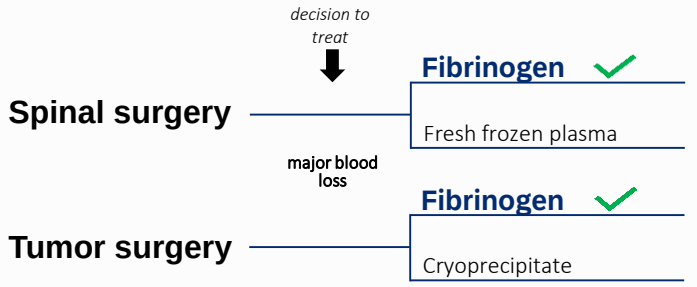
- Expected pharmaco -kinetics and -dynamics (Phase I), excellent efficacy and safety (Phase III)
- 175 bleeding events (BEs) treated in 36 patients of all age groups
- Overall hemostatic response assessments of 175 BEs demonstrated a treatment success in nearly all cases
- **Study completed**

Acquired FD[1]

ADFIRST

Phase III study in **severe spinal surgery** and **pseudomyxoma peritonei (tumor) surgery**

- Non-inferiority study compared to standard of care (fresh frozen plasma or cryoprecipitate)
- Interim analysis with 120 patients (June ’22) confirms planned patient number
- Recruitment ongoing – 168 of 200 evaluable patients treated
- Other interim analysis to define final sample size expected in Q1 2023



[1] FD: Fibrinogen deficiency

Two Trimodulin phase III trials in COVID-19 and sCAP*

TRICOVID Trimodulin Phase III (Start 2022)

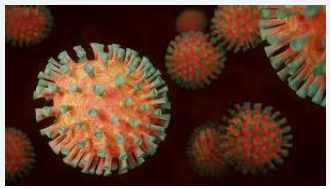
ESsCAPE Trimodulin Phase III (Start 2022)

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

COVID-19 patients

334 subjects

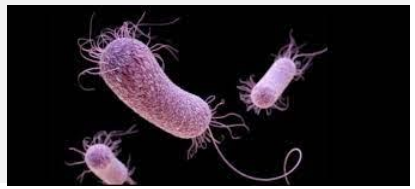
- Patients on low-flow oxygen, high-flow oxygen, non invasive ventilation
- Patients with early systemic inflammation (CRP> 50 mg/L)



sCAP patients

480 to 590 subjects

- Patients on invasive mechanical ventilation
- Patients with inflammation (CRP >70 mg/L)
- SARS-CoV-2 negative



** sCAP: severe community acquired pneumonia*

Clinical phase III trial with Cytotect® CP in preventing maternal-fetal transmission of CMV*

Objective PreCyssion trial: **Pre**vention of maternal-fetal **Cy**tomegalovirus transmi**ssion**

Demonstrate efficacy and safety of Cytotect® CP in preventing maternal-fetal transmission of CMV

Study Design

- Pivotal, clinical **Phase III**
- Open-label
- Single-arm
- Prospective
- Multicenter
- With historical control group
- **80 patients – 22 of 80 patients recruited** *(as of Nov 7, 2022).*
  Recruitment dependent on the course of the pandemic (hygiene measures reduce CMV transmissions).

** CMV: Cytomegalovirus*

Market Dynamics & Plasma

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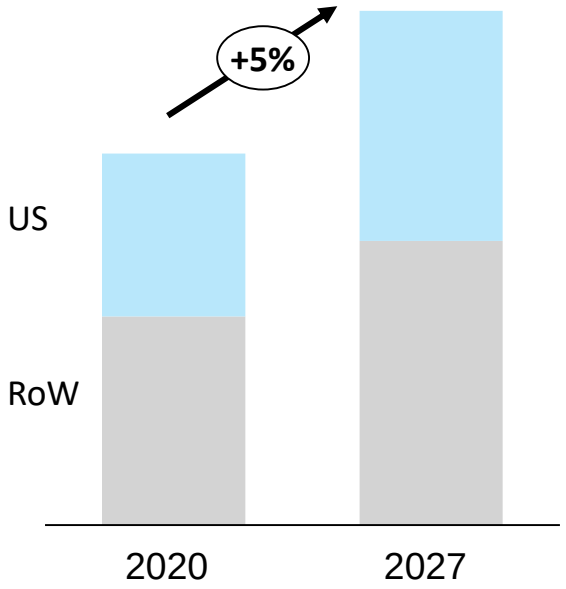
Global IgG demand growth expected to remain strong

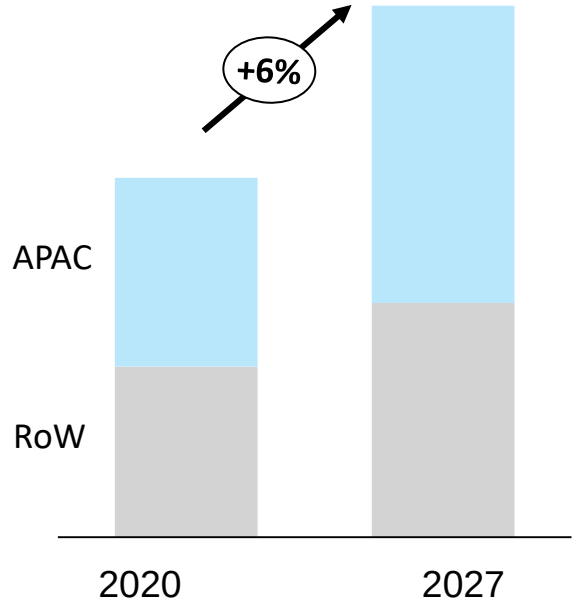
Global **IgG** market development [t]



Source: Biotest based on MRB (2021), PPTA, internal analysis

- **IgG** market development expected to remain strong and limited by supply rather than demand
- **IgG** Demand did not decline significantly during COVID-19 pandemic due to mostly chronic patients
- The **human Albumin** market is expected to continue growing driven by strong Chinese demand

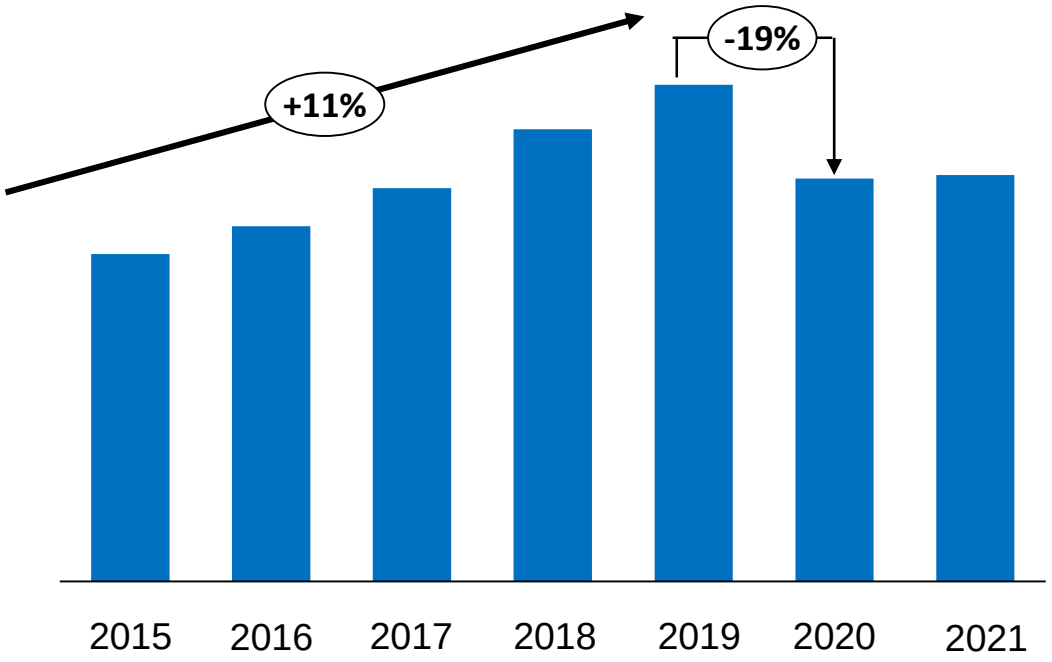
Global **human Albumin** market dev. [t]



Source: Biotest based on MRB (2022) and MarketsAndMarkets (2020)

Impact of COVID-19 on commercial plasma collections in the US and EU

US Plasma Collections
[mn L]



Source: PPTA

- > 60% of the world's plasma is collected in the USA
- Strong and persistent impact of COVID-19 on plasma collections in the USA in 2020 and 2021
- US collections speeding up through 2022 and back at pre-pandemic levels. Additional upside expected from re-opening of US-Mexican boarder
- Plasma/production costs expected to remain high due to inflation, increased donor fees, energy and labor costs.
- Due to long lead times, resulting product supply will only be available in H1 2023, earliest.
- Collected plasma volumes by Biotest in Europe (GER, CZ and HU) in 2021 were back on the 2019 levels, despite a difficult market environment
- In Q1-Q3 2022 Biotest plasma volume showed strong growth vs. Q1-Q3 2021 despite two Corona waves

Expansion of plasma collection centres – incl. access to US Plasma

Europe: 34 plasma collection centres

- 7 new centres in 2022 as of Nov. 14, 2022

Access to US Plasma

- Establishment of own centres
- Long-term supply contracts with **Grifols**

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Financial calendar 2023 and contact

Financial calendar 2023

23 Mar 2023	FY 2022
04 May 2023	Q1 Report
10 Aug 2023	H1 Report
02 Nov 2023	Q1-Q3 Report

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