Biotest AG

Half Year Figures 2022

11 August 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.

Facts & Figures H1 2022

Biotest

From Nature for Life

Biotest Group – Overview H1 2022

- **Expansion of plasma collection centres:** 4 new centres in 2022
  In total: 31 Plasma Collection Centres in GER, HU and CZ
- Accelerate **R&D pipeline**: IgG Next Gen submitted for marketing authorization; interim analysis of Fibrinogen in acquired deficiency, phase III trial, Cytotect in pregnancy phase III trial ongoing, two Trimodulin phase III trials to start in 2022
- **Expansion of Production site** in Dreieich, Germany (capacity 6 t IVIG) & 1 production site (BNL) in commissioning (6.5 t IVIG)
- **H1 2022 Sales**: € 253.1 million (-1.8%) compared to H1 2021 of € 257.8 million
- **H1 2022 adjusted EBIT**: € 32.4 million (+9,8%) vs H1 2021 of € 29.5 million
- **H1 EBITDA 2022**: € 8.8 million (+51.7%) vs H1 EBITDA 2021 of € 5.8 million

Biotest
From Nature for Life

Financials H1 2022

Biotest

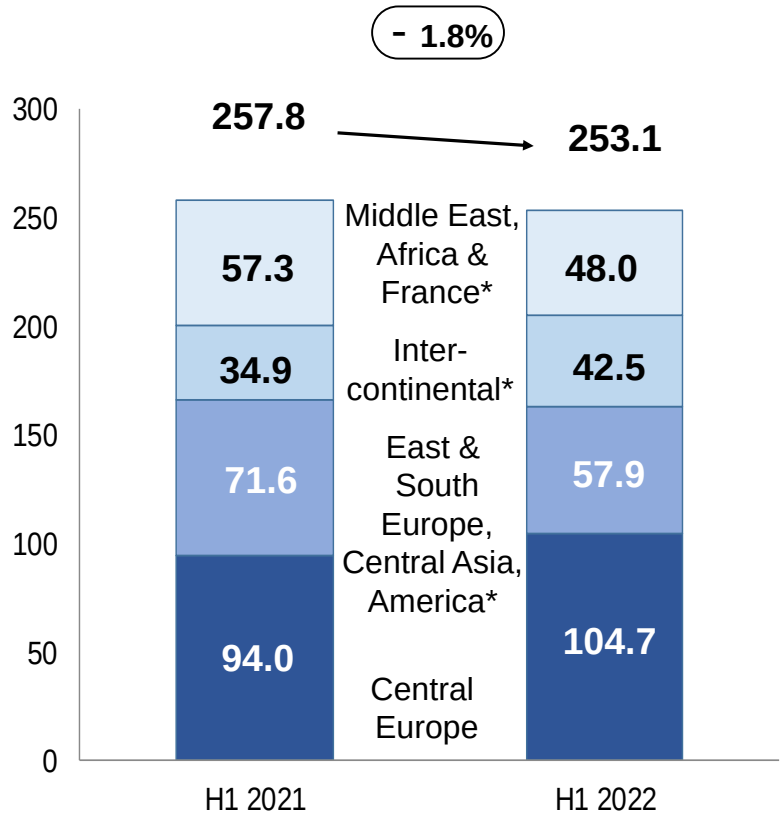
From Nature for Life

Income statement
(€ million)

	H1 2021	H1 2022
Sales	**257.8**	**253.1**
thereof: Therapy	224.1	220.6
Plasma & Services	29.9	29.4
Other Segments	3.8	3.1
Operating costs & expenses	-266.3	-262.2
Operating profit (EBIT)	**-8.5**	**-9.1**
Financial result, taxes	-9.7	-10.8
Earnings after tax (EAT) Biotest Group	**-18.2**	**-19.9**

Biotest
From Nature for Life

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 (+8.7%) and in Intercontinental region of +21.4%.
- **Segment Plasma & Services**: Decline of -1.7% - lower toll manufacturing due to lower plasma availability (Middle East)

Biotest
From Nature for Life

EBIT reported and adjusted
(€ million)

	H1 2021	H1 2022
EBIT reported	**-8.5**	**-9.1**
Biotest Next Level facility costs	18.8	24.4
Biotest Next Level R&D costs*	19.2	17.1
EBIT adjusted	**29.5**	**32.4**

*: R&D costs for BNL development projects

+9,8%

Biotest
From Nature for Life

Biotest Next Level costs in H1 2022

1. **BNL facility costs**: **€ 24.4 million**;
   - Facility costs (energy, building costs, security, etc.)
   - Depreciation
   - Personnel costs (for ramp-up, commissioning etc.)
   - Project administration

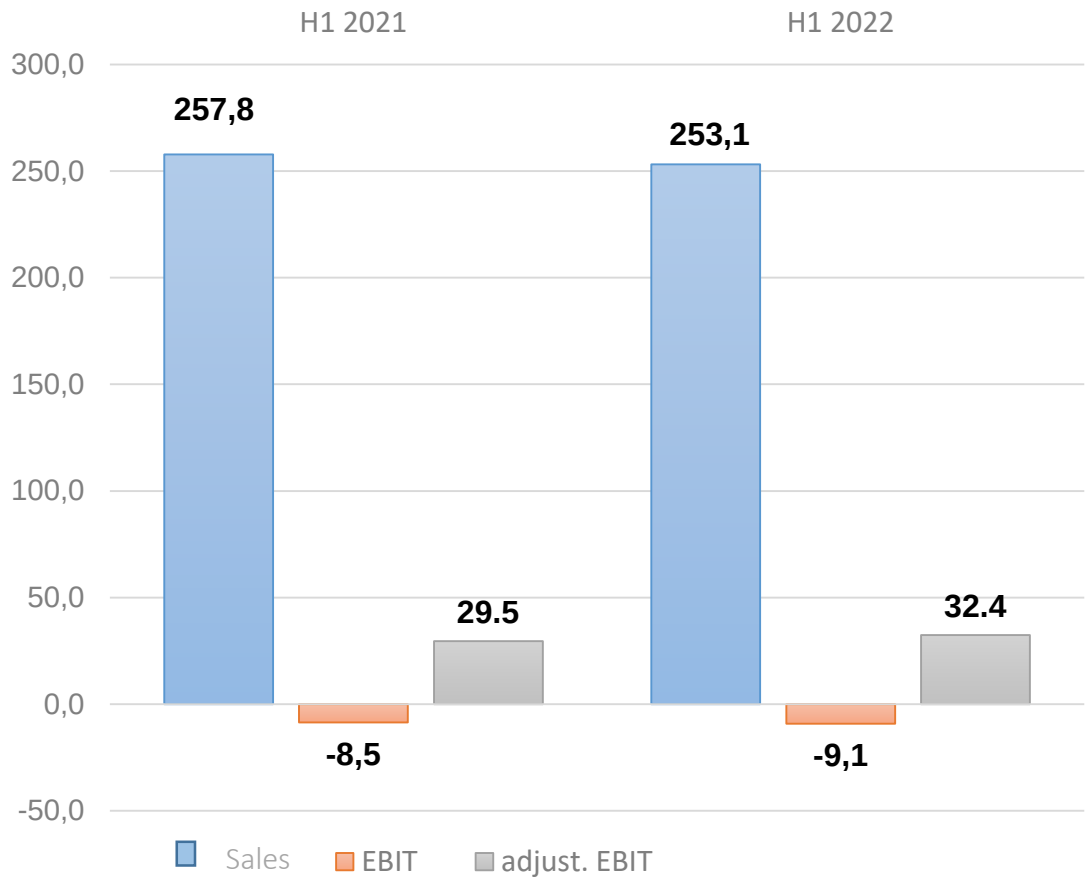
2. **BNL R&D** costs in total: **€ 17.1 million**; thereof:
   - € 3.6 million - IgG Next Generation
   - € 8.0 million - Trimodulin (IgM Concentrate)
   - € 5.5 million - Fibrinogen

Total BNL costs: **€ 41.5 million** in H1 2022

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.

Acceleration of phase III R&D projects Trimodulin and Fibrinogen, IgG Next Gen has been submitted.

H1 2022 at a glance



- **Sales increase** in **Central Europe** and **Intercontinental** compared to the previous year
- H1 EBIT 2022 on comparable level to H1 2021
- H1 2022 EBIT includes **Biotest Next Level expenses of € 41.5 m** (H1 2021: € 38.0 m)
- **H1 adjusted EBIT: € 32.4 m** (+9.8%) vs. H1 2021 EBIT of € 29.5 m

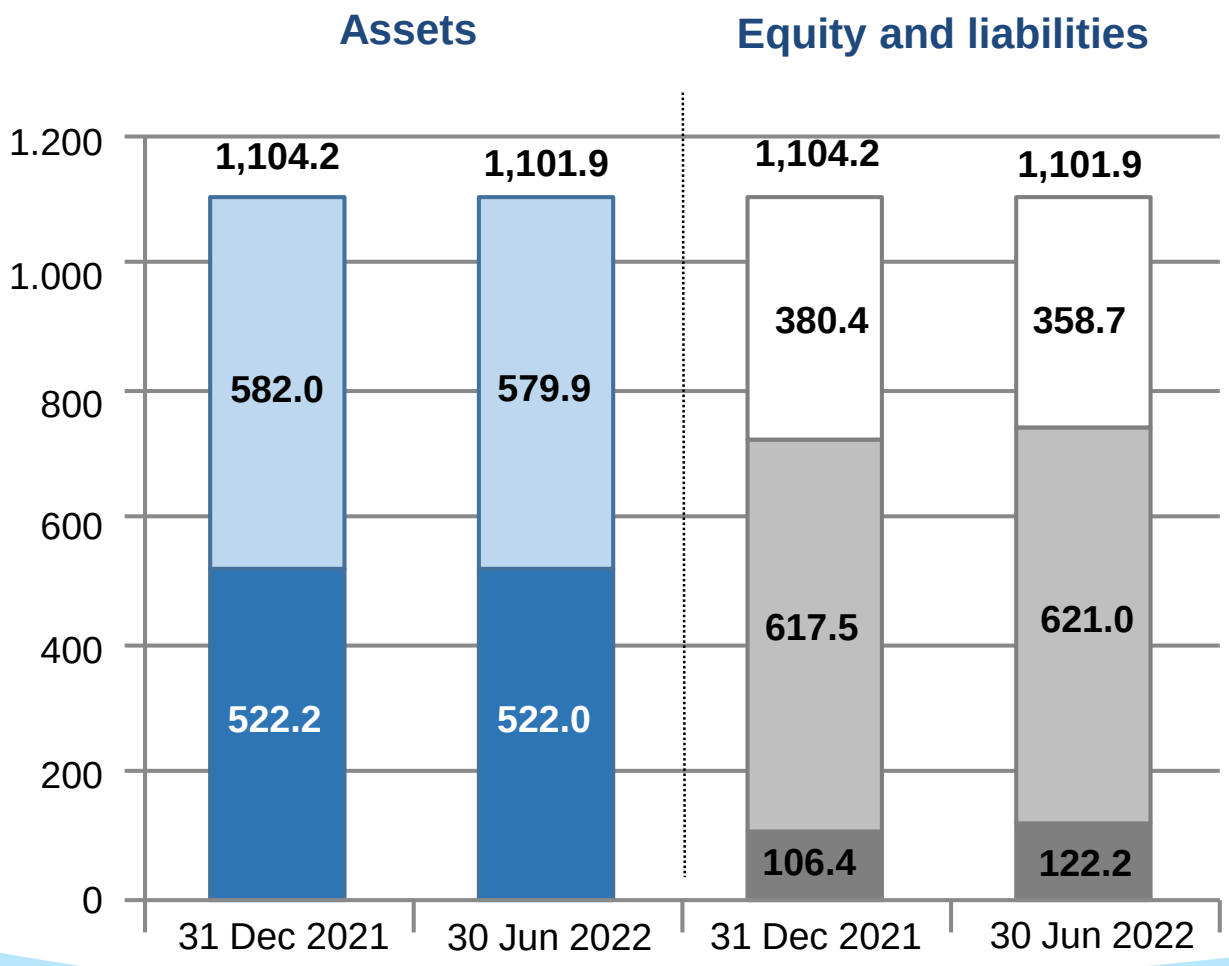
Biotest
From Nature for Life

Reconciliation financial result
(€ million)

	€ million
Financial result, taxes H1 2021	**-9.2**
Variation in valuation of ADMA shares held by trustee	2.9
Higher interest expenses	-2.6
Financial result, taxes H1 2022	**-8.9**

Biotest
From Nature for Life

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

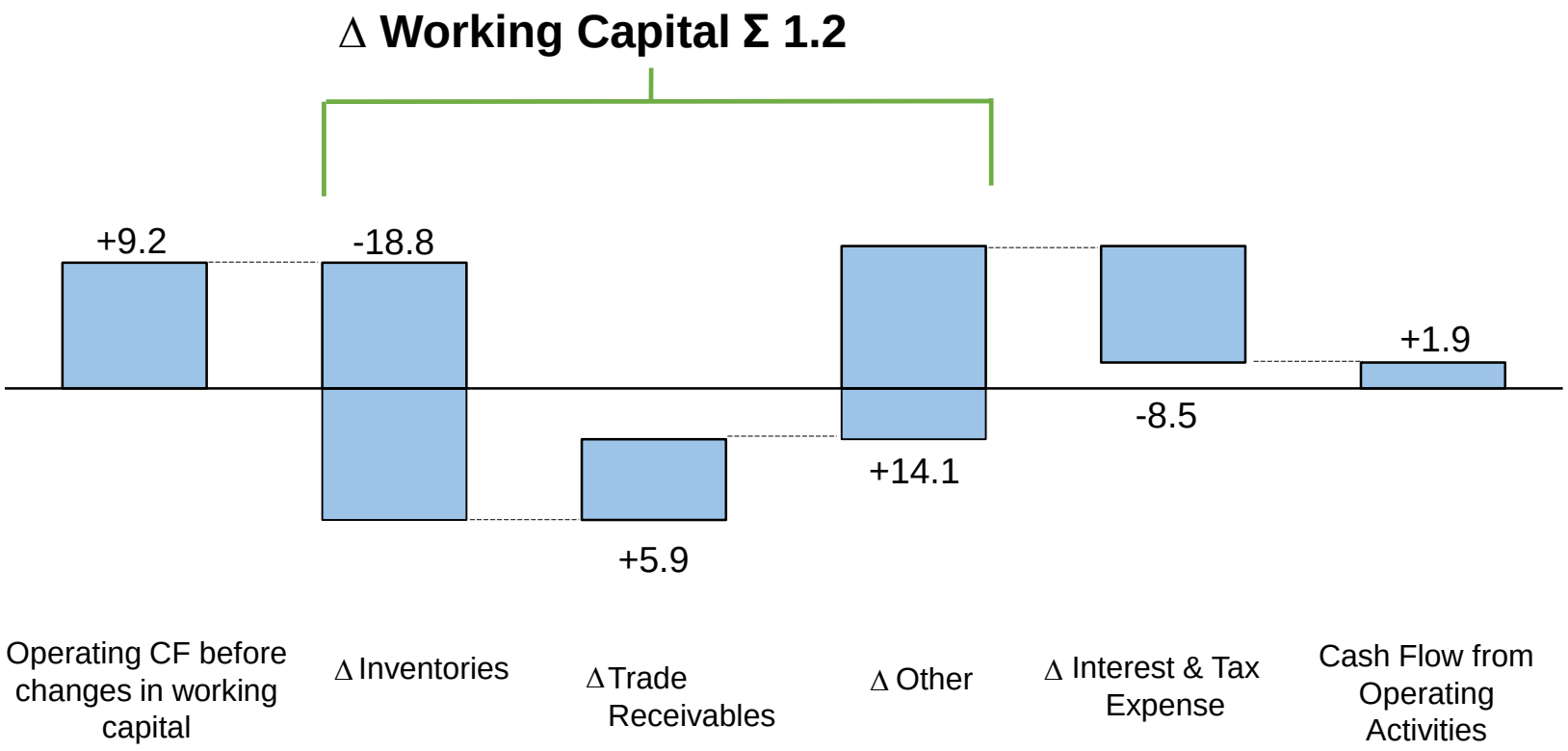


Net debt as of 30 June 2022: 417 m€

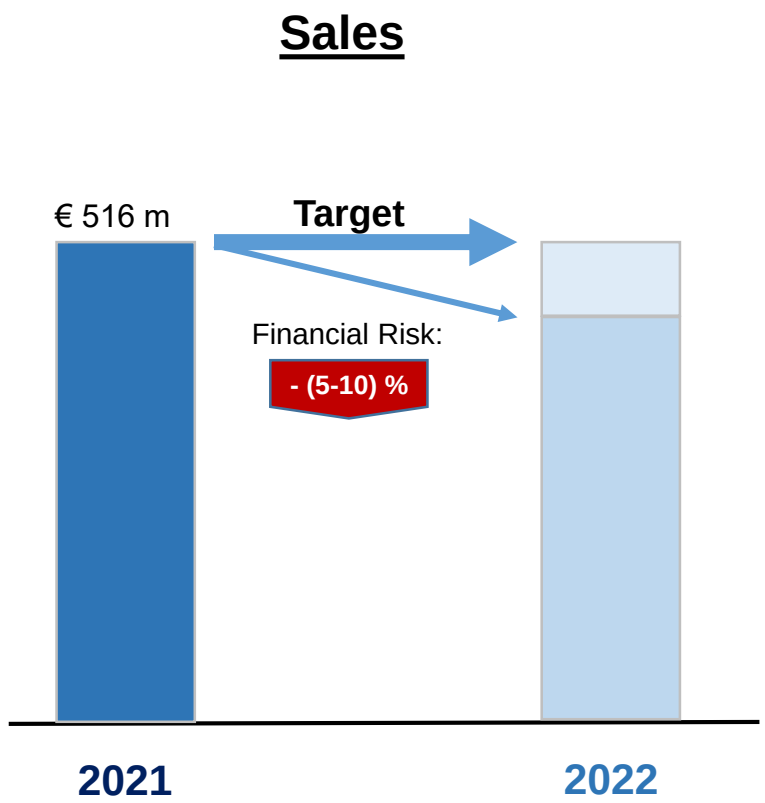
Equity ratio as of 30 June 2022: 32.6%

Biotest
From Nature for Life

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



Outlook 2022: Sales & risks



- No decline in demand or medical necessity

BUT:

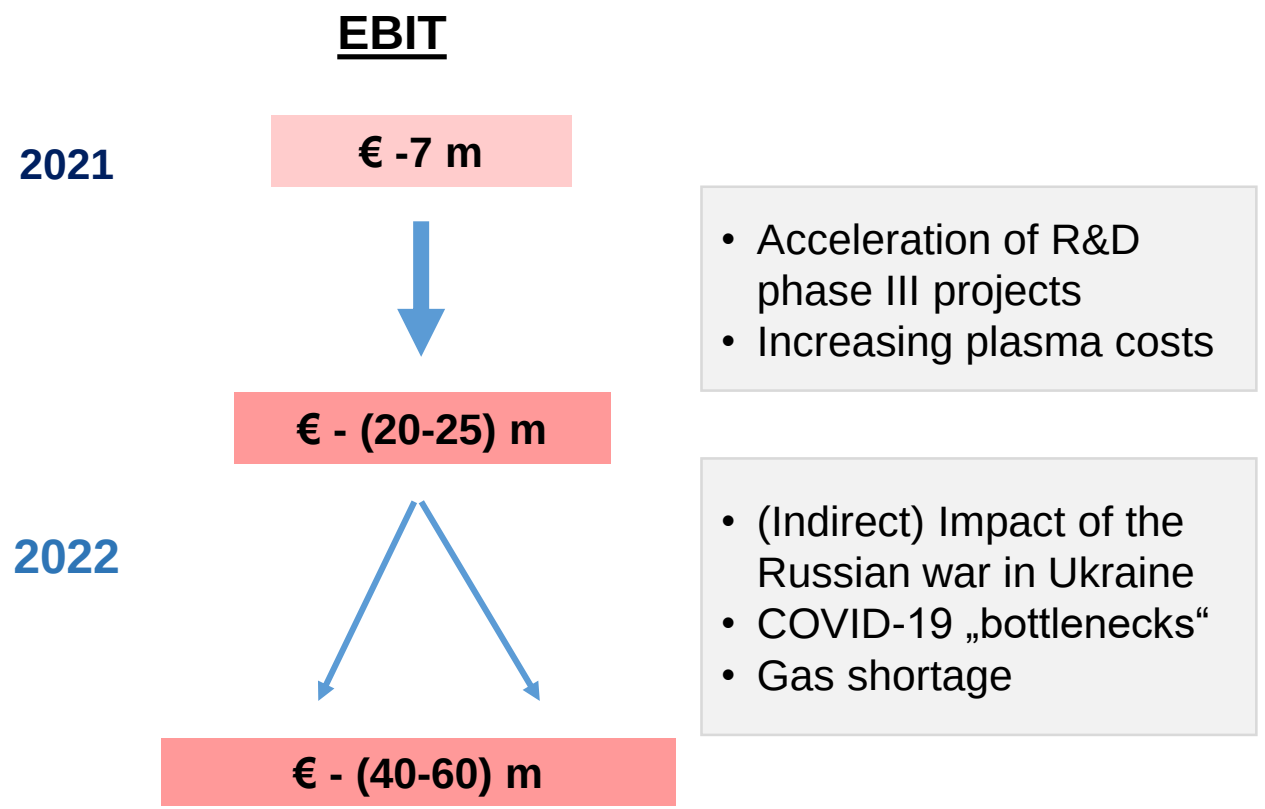
- The general economic situation may reduce the "purchasing power" of health systems

Increased risk:

- Slowdown or interruption of production
  - COVID-19-related staff shortage
  - Delayed delivery of plasma
  - Postponed inspections of new plasma centers
  - Limited availability of spare parts and essential tools
  - Energy shortages

Biotest
From Nature for Life

Outlook 2022: EBIT



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

Biotest
From Nature for Life

Marketing & Sales update

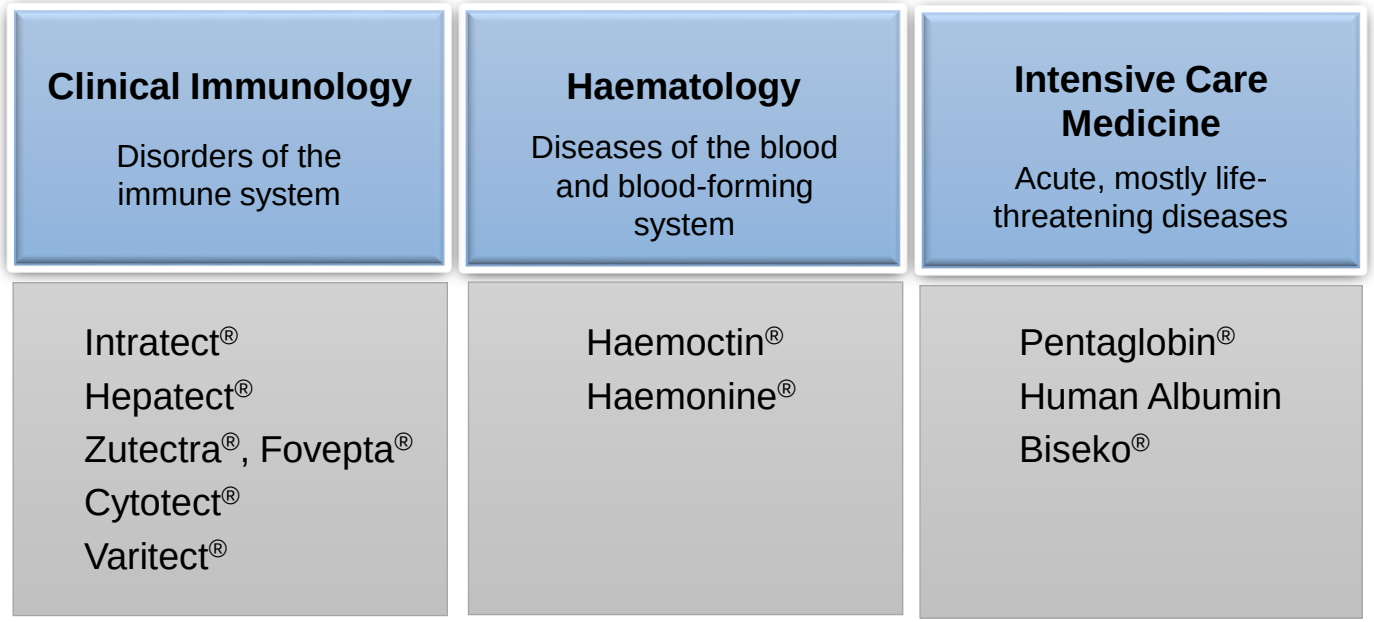
Biotest

From Nature for Life

Specialist for life

Basis for all our products: human blood plasma

Three Therapeutic Areas



Biotest produces and sells biological medicinal products in three therapeutic areas

Biotest
From Nature for Life

Update Biotest product portfolio

Clinical Immunology

Intratect®,Hepatect®CP
Zutectra®, Fovepta®
Cytotect®CP, Varitect®

Intratect®: Volume increases in key markets such as Central Europe. Increase in sales prices in numerous countries. Demand for IvIG high, despite difficult supply situation.
Cytotect®CP: Transplantation activities slowly resume
Zutectra®: New marketing authorization in Turkey
Hepatect®: New marketing authorisation in Lithuania, new tenders won

Haematology

Haemoctin®
Haemonine®

Haemoctin®: The current contract in Algeria was extended and a new tender was won. Significant increase in sales in Turkey.
Haemonine®: A tender for Haemonine was won in Algeria

Intensive Care

Pentaglobin®
Human Albumin
Biseko®

Albiomin 5% and 20%: new marketing authorization in Ghana and new distributor contract in China

Biotest
From Nature for Life

R&D update

Biotest
From Nature for Life

Advanced development pipeline – profitability for the future

New products

IgG Next Generation	*Registration*
Fibrinogen	*Phase III*
Trimodulin (IgM Conc.)	*Phase III*

New indications

Cytotect®CP: CMV in pregnancy	*Phase III*
Cytotect®CP: CMV treatment	*Real Life Data**
Varitect®: Herpes Zoster	
Zutectra®/Hepatect®CP: Chron. Infection	

**: Non-Interventional Studies (NIS)*

R&D pipeline progress in H1 2022

	Status of R&D development
IgG Next Generation	Two Phase III studies are in **registration** process since March 2022. A further study with high-dose therapy in the **dermatological field** is currently being planned for Europe and the USA. Submission is planned for the end of 2022.
Fibrinogen	The **interim analysis** in Phase III (acquired) trial (AdFirst Study) was successful. A further interim analysis to confirm the patient number planned will take place once 80% of the planned patients have been treated.
Trimodulin (IgM Concentrate)	The initiation of two **Phase III studies** in COVID-19 (TRICOVID) and sCAP (ESsCAPE) are in preparation.
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): Cytectra®CP in CMV treatment; Varitect® in Herpes Zoster; Zutectra® and Hepatect® in chronic infection treatment.

IgG Next Generation: polyspecific immunoglobulin

Intratect®

Maintain:

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

IgG Next Generation

IgG Next Gen: Documents submitted for **Marketing Authorization** in March 2022

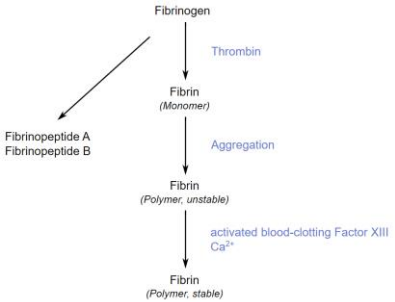
Further improve:

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

Fibrinogen – it´s essential role in blood clotting and hemostasis

Fibrinogen
is an abundant, large, and complex protein, which makes it ideally suited to be isolated from human plasma. It accounts for 95% of all coagulation factors in the blood.

Function of Fibrinogen
Fibrinogen promotes platelet aggregation. Fibrinogen is converted to fibrin which forms the connecting glue in blood clots. Fibrin clots function primarily to occlude blood vessels to stop bleeding.



Fibrinogen concentrate
is a highly pure preparation of human fibrinogen that can be used to safely replace the absence or deficit of fibrinogen - safer, much faster and with greater efficiency and precision than the current treatment options of fresh frozen plasma or cryoprecipitate.

Biotest
From Nature for Life

Congenital and acquired Fibrinogen deficiency
Playing an essential role in blood clotting and hemostasis

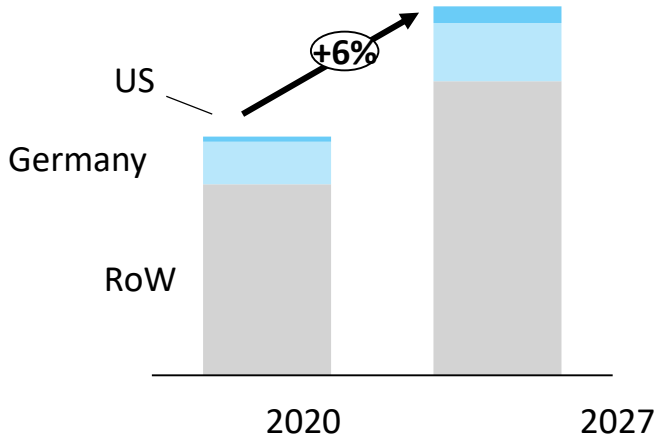
Congenital Deficiency

- Very rare, inherited bleeding disorder in which the body's ability to form blood clots is impaired
- Fibrinogen is used for treatment and prophylaxis of bleeding episodes in these patients

Acquired Deficiency

- Body's own fibrinogen lost due to major bleeding during elective surgical procedures or unexpected trauma events
- Fibrinogen is the **first coagulation factor** missing in major blood loss
- Replacement of lost fibrinogen is critical to restore effective hemostasis

Global Fibrinogen Conc. Market Dev. [kg]



- Germany: 2nd largest market for fibrinogen conc. (after China)
- Globally, markets are underdeveloped offering significant potential for growth

Source: IMS Data 2-2017, LEK Critical Bleeding market assessment 2017, and Biotest market research

Promising result in congenital and acquired Fibrinogen clinical trials

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…

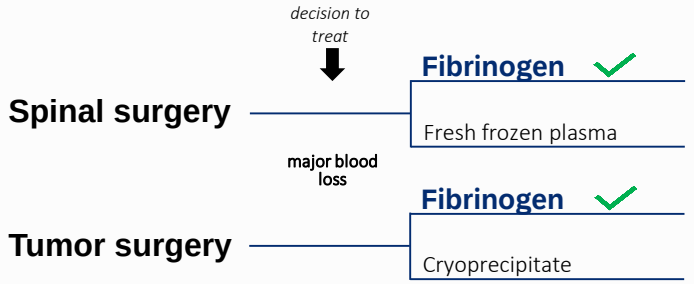
- Expected pharmaco-kinetics and -dynamics (Phase I), excellent efficacy and safety (Phase III)
- 175 bleeding events (BEs) treated in 36 patients of all age groups
- Overall hemostatic response assessments of 175 BEs demonstrated a treatment success in nearly all cases
- Study completed

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 – 150 of 200 patients recruited
- Other interim analysis to define final sample size expected in December ’22



[1] FD: Fibrinogen deficiency

Biotest
From Nature for Life

Clotting assessment: critical to monitor deficiency
Monitoring patient coagulation status allows administering precise therapies

Point-of-Care (PoC) diagnostic…

Prediction of massive transfusion requirement

Creation of goal-directed and individualized coagulation algorithms that may improve patient outcome

Distinguish the most important coagulation deficiencies (including fibrinogen)

… bringing in positive **market implications**

Goal-oriented treatment protocols proposed for bleeding management in surgery and trauma patients

Rapidly developing field of acute medicine

➢ **Point of Care (PoC) diagnostic enhances Fibrinogen use**

Most widely-used devices…

TEG®

ROTEM®

Source: Benes, Jan et al. "Viscoelastic Methods of Blood Clotting Assessment - A Multidisciplinary Review." Frontiers in medicine vol. 2 62. 14 Sep. 2015, doi:10.3389/fmed.2015.00062

Trimodulin: unique polyvalent immunoglobulin with special Ig composition

Important functions of Trimodulin

- **Recognizes pathogens**, also part of innate immune system
- IgM and IgA can be secreted and are present directly on the pulmonary surface
- **Strong anti-inflammatory effects** by acting through cellular receptors
- Scavenge virulence factors, such as lipopolysaccharides which lead to inflammation
- **Binds and modulates** activated coagulation factors, complement factors, and cytokines

	IVIG	Trimodulin
IgM	-	~23%
IgA	-	~21%
IgG	≥95%	~56%
Patient target	e.g., patients with immunodeficiency	Clinical development in severe COVID-19 and sCAP[1]

[1] *Severe community acquired pneumonia: Severe CAP (sCAP) is usually defined as CAP that requires admission to the intensive care unit (ICU)*

sCAP[1]: a leading cause of illness and death worldwide[2]
A high unmet medical need

Pneumonia requiring supportive therapy within a critical care environment

>350k patients[3]

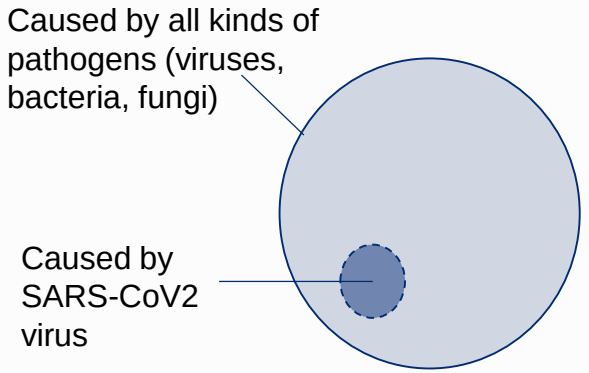
suffer sCAP each year

23-58%[4,5]

mortality range

no significant changes over the past decades despite the availability of improved broad-spectrum antibiotics

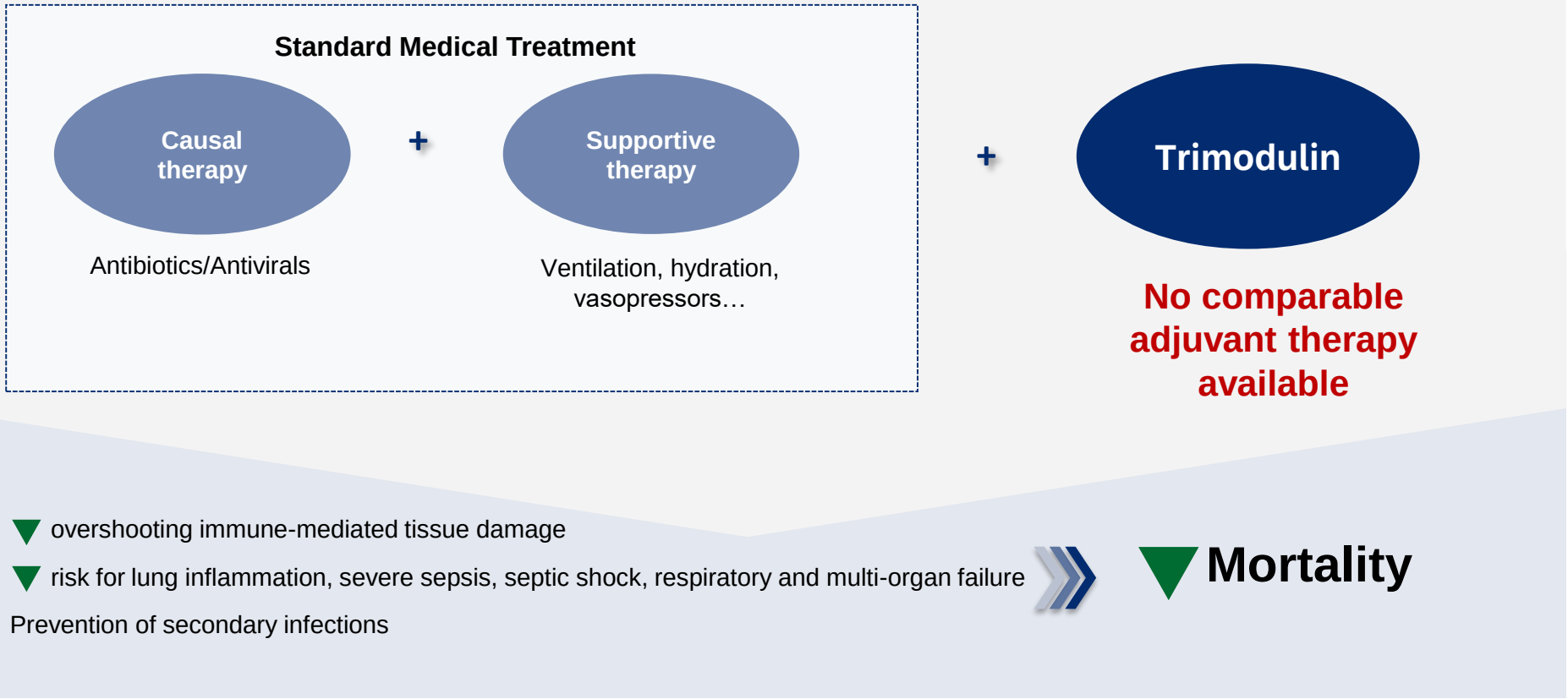
COVID-19 is a subtype of sCAP



[1] *Severe community acquired pneumonia: Severe CAP (sCAP) is usually defined as CAP that requires admission to the intensive care unit (ICU)*
[2] *Wunderink 2014, N Engl J Med 370;6.*
[3] *Chest Journal (CHEST) (chestnet.org)*
[4] *Woodhead, 2006, Critical Care 10:S1, p3.*
[5] *Sirvent et al. 2013, Med. Intensiva 37:308e 15.*

Biotest
From Nature for Life

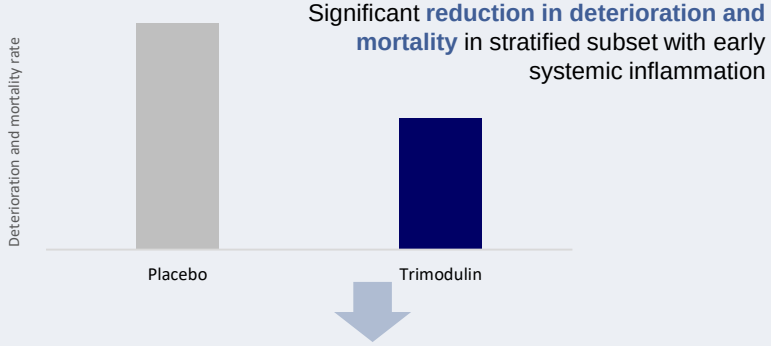
Changing the sCAP treatment paradigm
Trimodulin improves patient response with further decrease in mortality



Extensive development program in severe pneumonia
Patient groups and disease stages for optimal therapy identified in two phase II Studies

Severe COVID-19

ESsCOVID Phase II Completed ✓



Significant **reduction in deterioration and mortality** in stratified subset with early systemic inflammation

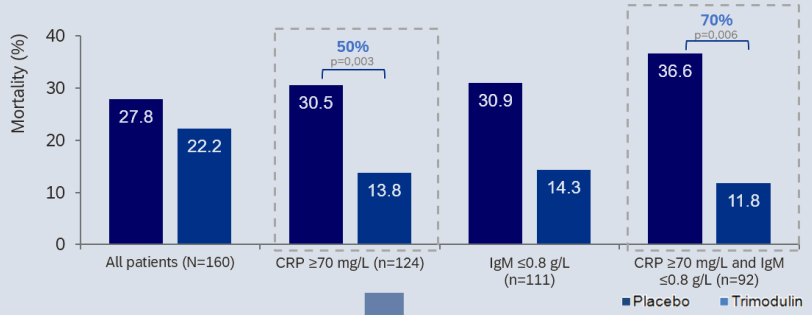
TRICOVID Trimodulin Phase III **Phase III Start 2022**

Severe Community Acquired Pneumonia (sCAP)

CIGMA Phase II Completed ✓

✓ Very positive feedback from FDA[1], EMA[2], PEI[3] and clinical experts

50-70% relative reduction in mortality in target population



ESsCAPE Trimodulin Phase III **Phase III Start 2022**

[1] U.S: Food Drug and Administration; [2] European Medicines Agency; [3] Paul-Ehrlich-Institute;

Leveraging on phase II results to start phase III trials in 2022

TRICOVID Trimodulin Phase III (Start 2022)

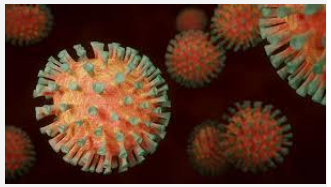
ESsCAPE Trimodulin Phase III (Start 2022)

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

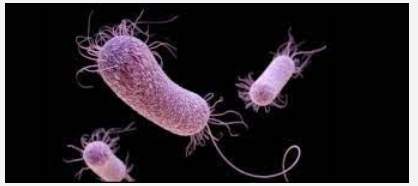
- Patients on low-flow oxygen, high-flow oxygen, NIV
- Patients with early systemic inflammation



sCAP patients

480-780 subjects

- Patients on invasive mechanical ventilation (within <12h)
- Patients with inflammation (CRP >70 mg/L)
- SARS-CoV-2 negative

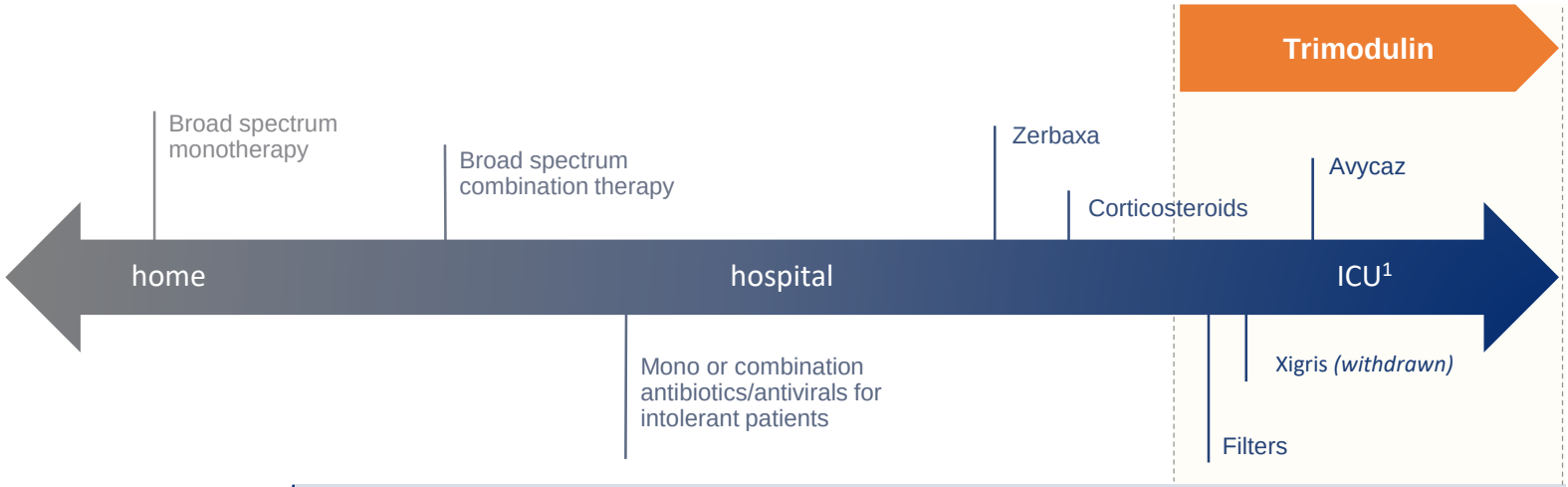


Capacities to help address the opportunity with Grifols
Potential addressable markets

	Potential treatment	Opportunity
COVID-19	Add-on therapy to standard of care in adult patients with **severe COVID-19** and **CRP ≥50 mg/L**	• **Early approval** will be **beneficial for faster sCAP approval** • Development risk covered by public funding • Even with vaccination, **> 20,000 patients/year** in **EU** are expected over the **next three years**
sCAP	Adjunctive treatment of patients with severe Community **Acquired Pneumonia (sCAP)** who require invasive mechanical ventilation and have **CRP[1] >70 mg/L**	**sCAP market size** **~ 350,000 patients** **initial target population** **> 80,000 patients/year** • Significant **upside** due to **higher price** depends on clinical trials' data

Source: Biotest market research
[1] C-reactive protein (CRP)

No direct competitors for Trimodulin in sCAP
Opportunity to address a critical medical need



- No direct competitors: no IgM enriched immunoglobulins on the market or in clinical trials
- High medical need: high mortality rate despite antibiotics or antivirals

[1] *Intensive Care Unit (ICU)*

Biotest
From Nature for Life

CMV[1] Infection: a disease with large unmet medical need
No approved treatment for this disease

The most common congenital infection in developed countries

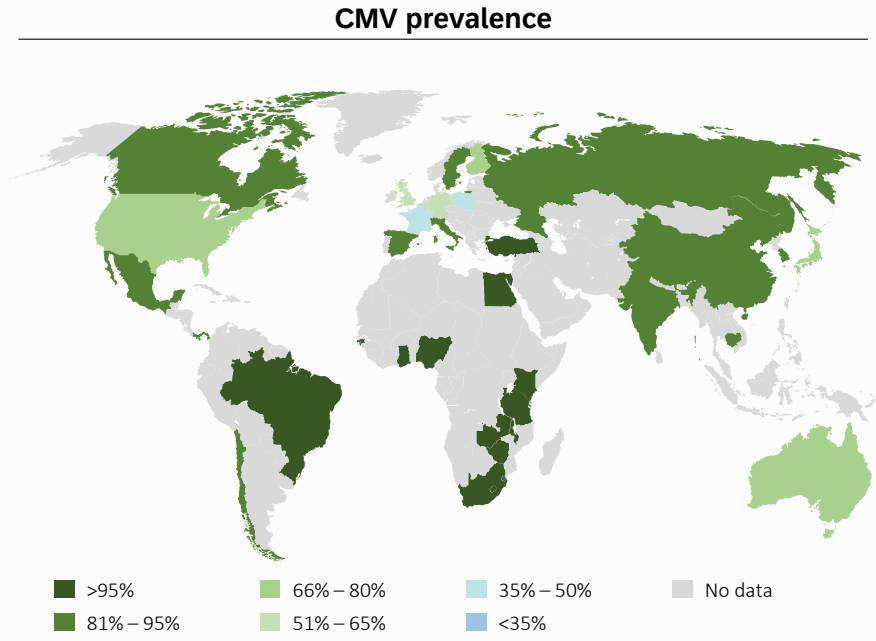
Infected women may transmit the virus to the fetus

0.3-2.4%
prevalence in newborns

Higher rates ▲ Lower rates ▼

CMV-related disorders

- Hearing loss
- Intellectual disabilities
- Premature birth
- Development delays
- Death

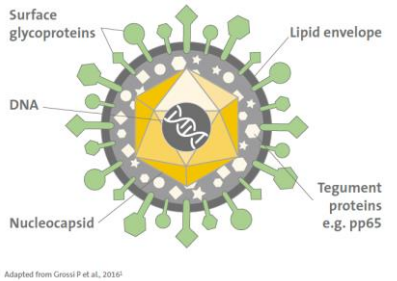


[1] *Cytomegalovirus (CMV)*

Cytotect®: tackling CMV with a high-potential specialty protein
First treatment to prevent transmission from the mother to the unborn child

Cytotect®

- Cytotect® **binds to CMV** and avoids infections of host cells and presents CMV particles for phagocytosis
- **Modulates and interacts** with immune cells (dendritic cells, monocytes, B- and T-cells), exerting a positive immunological balance
- **Anti-CMV antibodies in Cytotect®** are actively shuttled **through the placenta**
- These CMV-specific antibodies block the infection from all CMV genotypes and from virus variants that are resistant to virostatics

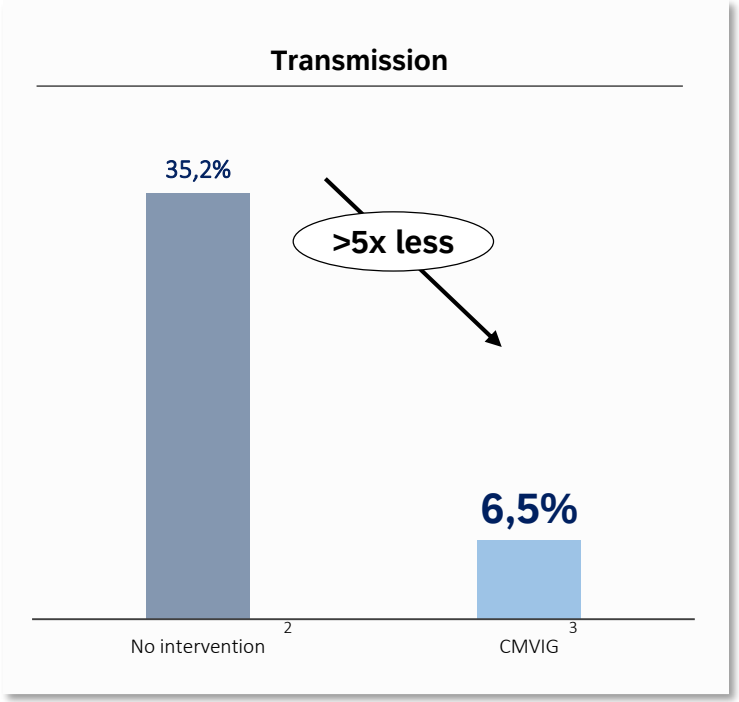


Clinical experience suggests good efficacy of Cytotect®
Significant transmission reduction when CMV IG[1] is administered

Previous prospective, observational study has described success of **study protocol**

Adequate criteria for Phase III leveraging on previous experience:

- Inclusion and diagnosis **criteria revised**
- **Accelerating** treatment start
- Adjusting the **dose**
- Establishing right **intervals**



[1] *CMVIG: Cytomegalovirus Immunoglobulin*
[2] *No intervention group (n=108), Maternal-fetal transmission at gw20: 35,2% (38/108). Kagan et al. Ultrasound Obstet Gynecol 2019; 53(3): 383-390*
[3] *Treatment group (n=153), Maternal-fetal transmission at gw20: 6,5% (10/153). Kagan et al. Ultrasound Obstet Gynecol 2021; 57: 560-567*

PreCyssion Trial: prevention of maternal-fetal CMV transmission
Following primary maternal infection with gestational age ≤ 14 Weeks

Objective:

Demonstrate **efficacy and safety** of Cytotect® 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 – 13 of 80 patients recruited** *(as of June 15, 2022).*
  Recruitment dependent on the course of the pandemic (hygiene measures reduce CMV transmissions).

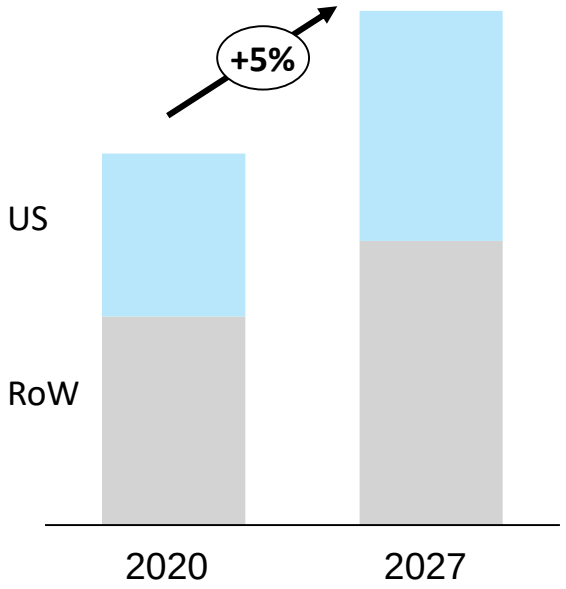
Biotest
From Nature for Life

Market Dynamics & Plasma

Biotest
From Nature for Life

Global IgG demand growth expected to remain strong

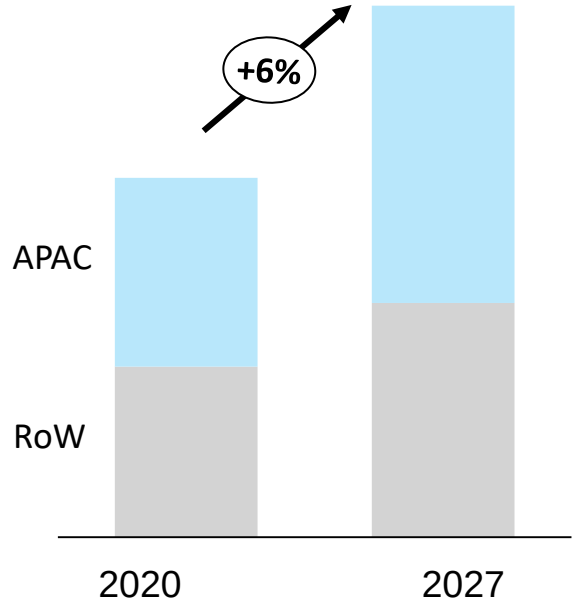
Global **IgG** market development [t]



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]

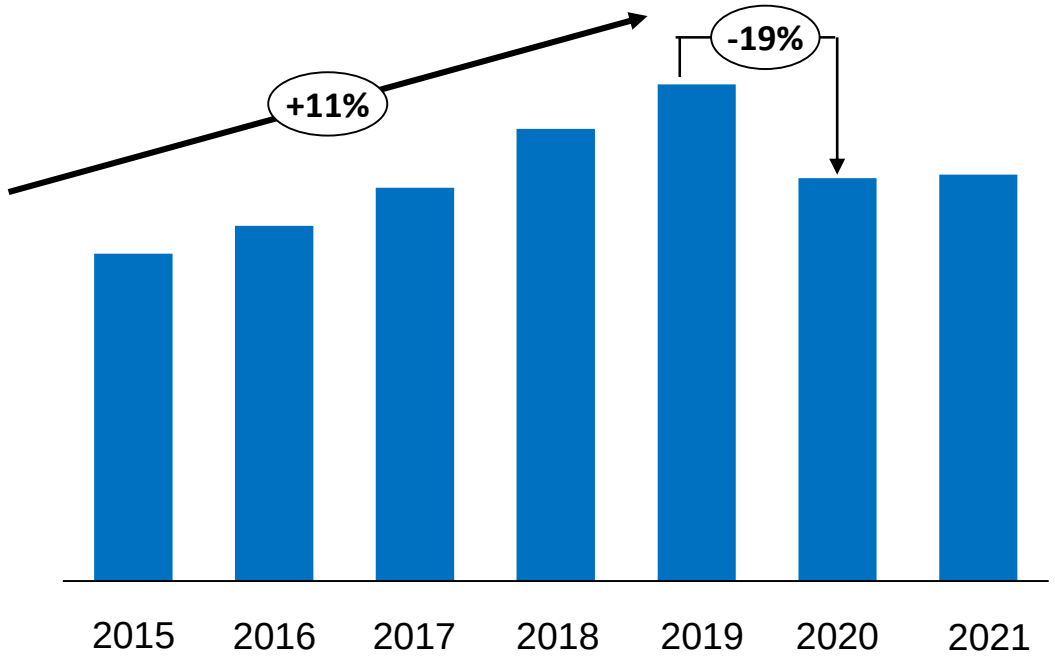


Source: Biotest based on MRB (2022) and MarketsAndMarkets (2020)

Biotest
From Nature for Life

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

US Plasma Collections
[mn L]



- Strong and persistent impact of COVID-19 on plasma collections in the USA
- > 60% of the world's plasma is collected in the USA
- 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 H1 2022 Biotest plasma volume showed strong growth vs. H1 2021 despite two Corona waves

Biotest
From Nature for Life

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

Europe: 31 plasma collection centres

- 4 new centres in 2022 – 3 additional centres planed

Access to US Plasma

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

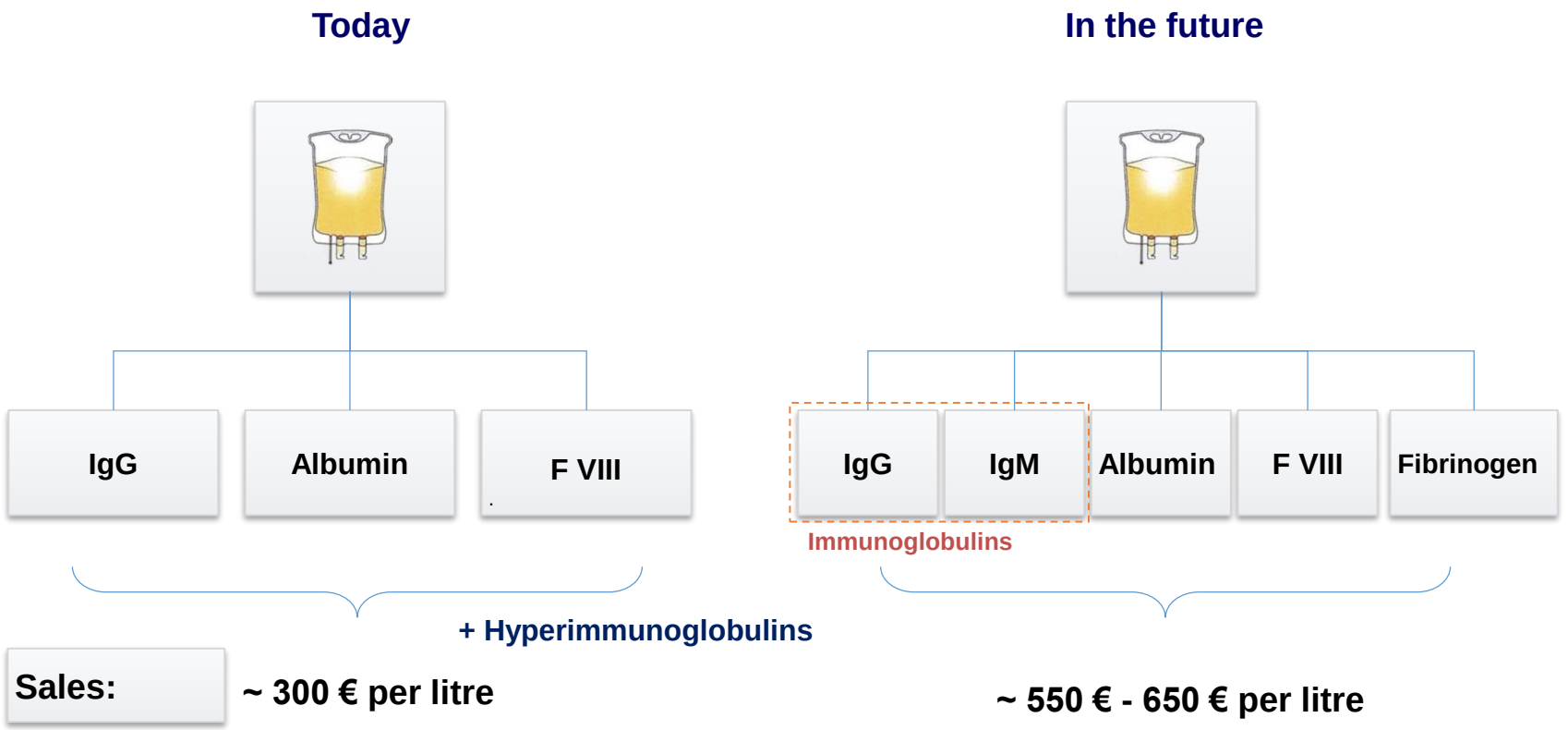
Biotest
From Nature for Life

Biotest Next Level

Biotest

From Nature for Life

Improving plasma utilization and cost structure



Progress BNL – IgG Next Generation

Today

Manufacturing licence granted GMP

T = 0 Start of stability period

Submission dossier 31 March 2022

Approval 11/2022

>> Launch 2022/ 2023

Next steps

Ramp-up IgG Next Generation

2022 → 2023 → 2024

Continue Commissioning

- Trimodulin (IgM-Concentrate)
- Fibrinogen
- Human Albumin

With Grifols as a strategic partner: new products gain in reach & value

Today

F VIII | Albumin | IgG

BNL

F VIII | Albumin | IgG | Trimodulin | Fibrinogen

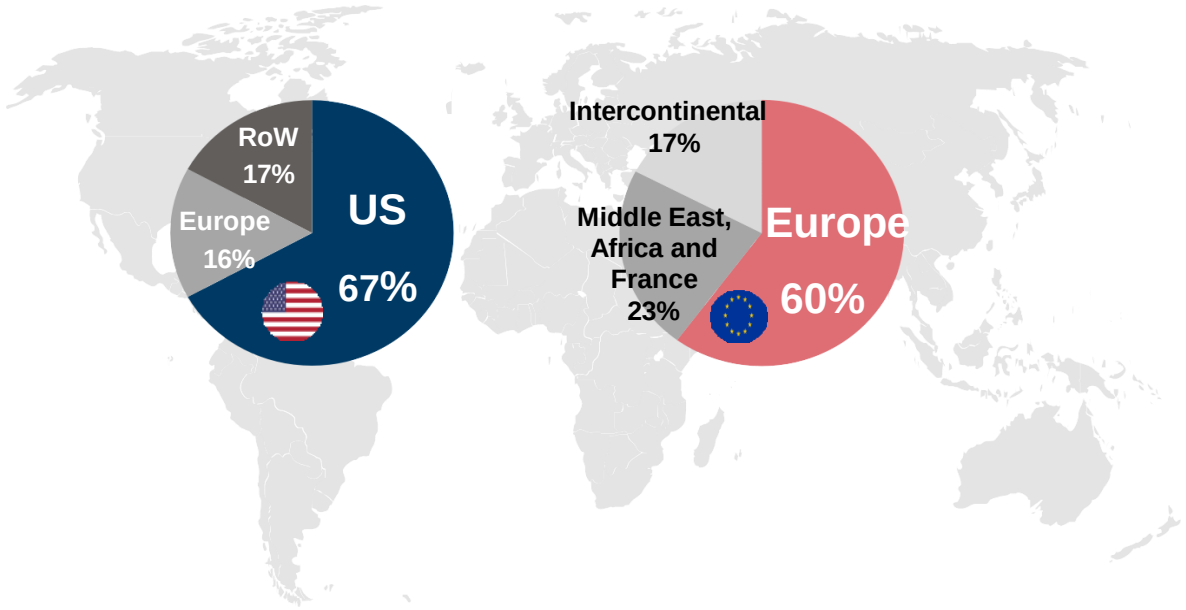
GRIFOLS

Biotest

Geogr. Reach | **Size**

Grifols is a perfect partner in the US for Biotest

GRIFOLS Biotest



- Biotest‘s research pipeline is increasing in value and importance for Biotest and for the business association with Grifols
- Higher investments and thus an acceleration of developments become possible and are in the interest of all shareholders

Biotest
From Nature for Life

Financial calendar 2022 and contact

Financial calendar 2022

11 Nov 2022 Q1-Q3 Report

Investor Relations

Dr. Monika Buttkereit
Tel.: +49-6103-801-4406
ir@biotest.com

Public Relations

Dirk Neumüller
Tel.: +49-6103-801-269
pr@biotest.com

Biotest
From Nature for Life