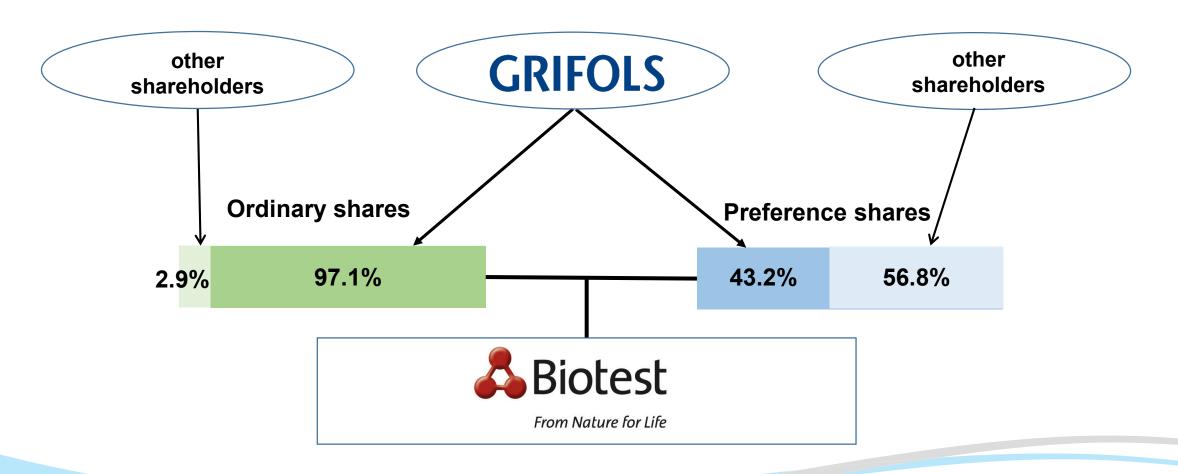


## **Shareholder Structure Biotest AG**





# **New Supervisory Board**

**Independent members** 

Bernhard **Ehmer** 

Uta **Kemmerich-Keil** 





**Grifols** 



David **Bell** 



**Employee representatives** 

Dirk Schuck



Jürgen **Heilmann** 

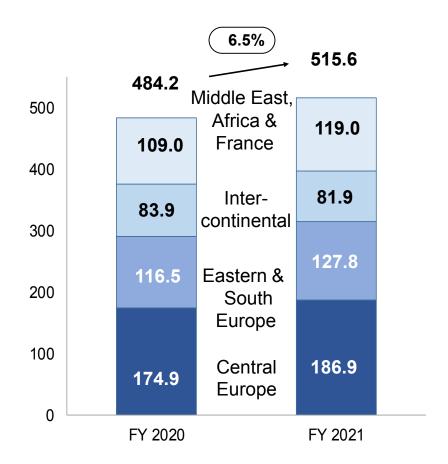


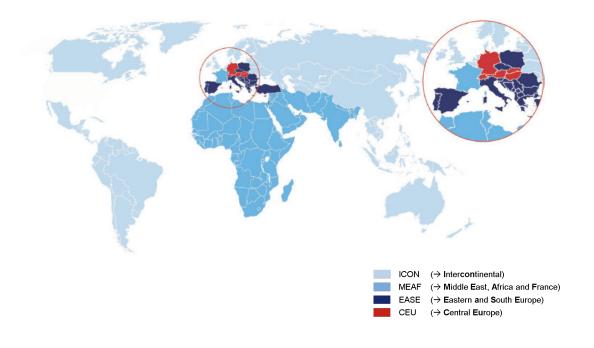




# Sales development of sales regions

(€ million)





Therapy sales up +7,2%



# **EBIT** reported and adjusted

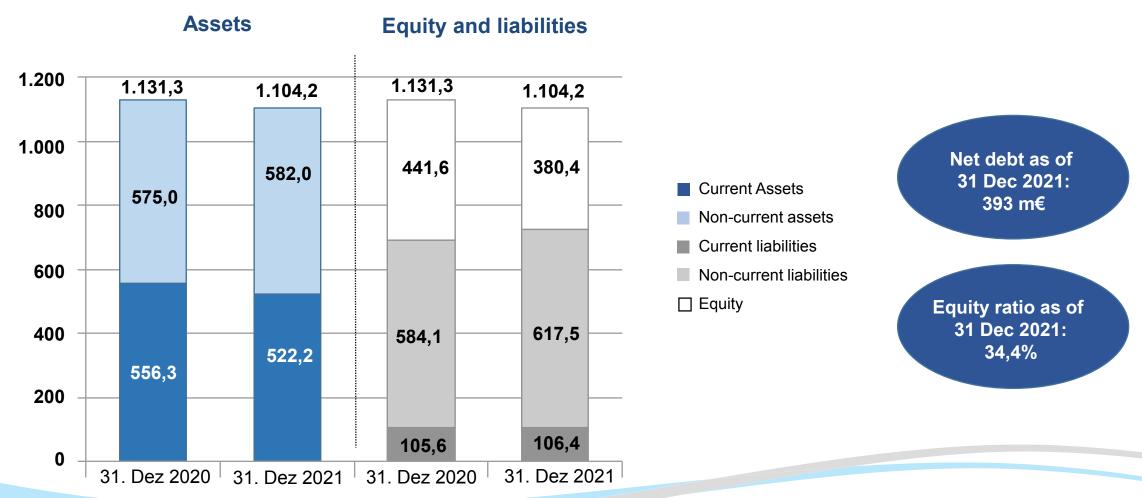
(€ million)

	2020	2021	2021 without FVIII one-time effect
EBIT reported	-1.3	-47.1	-7.0
Biotest Next Level costs*	79.6	76.5	76.5
Monoklonale antibodies	0.1	0.0	0.0
EBIT adjusted	78.4	29.4	69.5

<sup>\*:</sup> including R&D costs for BNL development projects



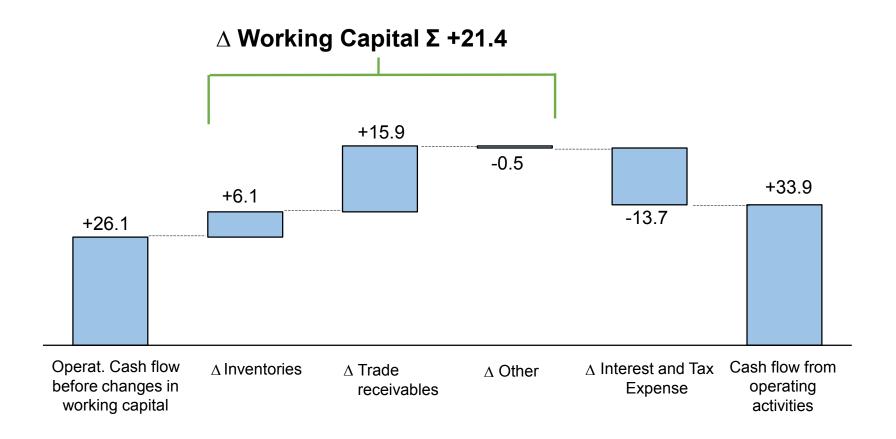
# Consolidated statement of financial position as of 31 Dec 2021 (€ million)





## Cash flow from operating activities

January – December 2021 (€ million)





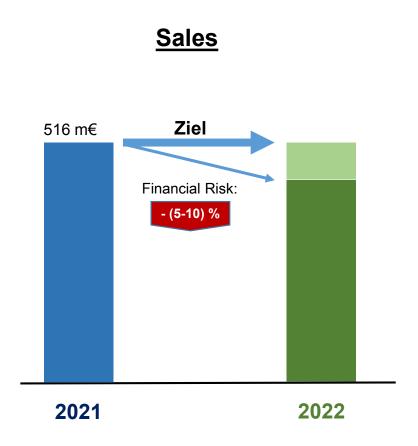
## Q1 2022 at a glance



- Sales increase in Central Europe and Intercontinental compared to the previous year
- EBIT significant higher compared to the previous year
- EBIT development due to increased gross profit
- EBIT includes Biotest Next Level expenses of
   -20.3 m€ (2021: -18.5 m€)



## Forecast 2022: Sales & risks



No decline in demand or medical necessity

#### BUT:

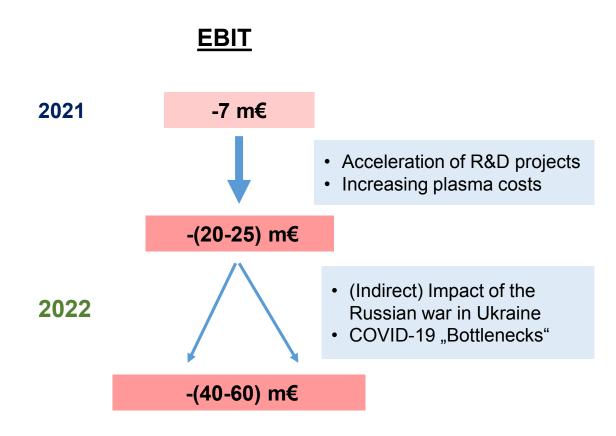
➤ The general economic situation may reduce the "purchasing power" of health systems

#### Increased risk:

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

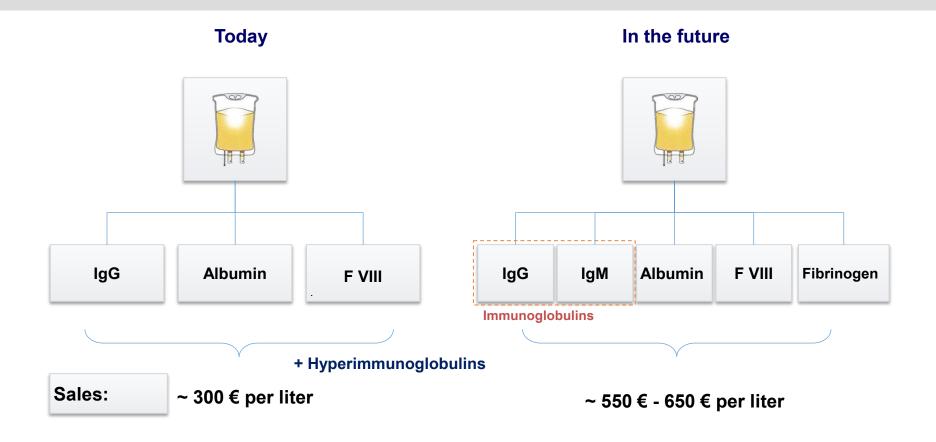


## Forecast 2022: EBIT





## Improving plasma utilisation and cost structure





# Progres BNL 2021 & Q1/2022 – IgG Next Generation



Manufacturing licence granted GMP

T = 0 Start of stability period Submission dossier 31.03.2022

Approval 11/2022

>> Launch 2022/ 2023





## **Next Steps**

## Ramp-up IgG Next Generation

150.000 Liter 2022 450.000 Liter 2023

800.000 Liter 2024



## **Continue Commissioning**

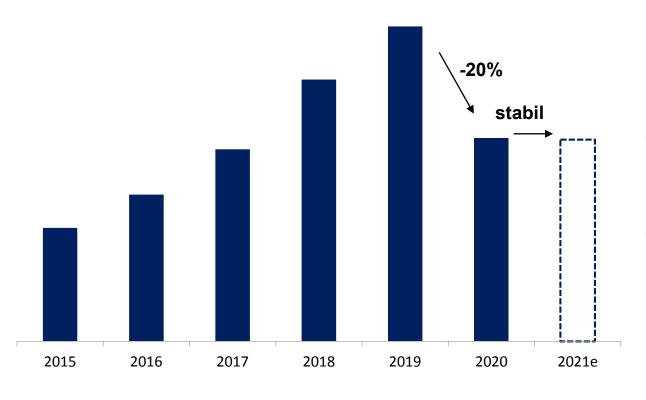
- Trimodulin (IgM-Concentrate)
- Fibrinogen
- Human Albumin





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

#### **Development of the US plasma collection volume**



- Strong and persistent impact of COVID-19 on plasma collections in the USA
- > 60% of the world's plasma is collected in the USA



## Expansion of plasma collection centres – Access to US Plasma

#### **Access to US Plasma**

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









## **Biotest – Sustainability Report 2021**

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





- 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





# For climate protection: reducing our CO<sub>2</sub> emissions

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

#### Measures:

- Conversion of the electricity supply
- BNL: Operation of own combined heat and power plant



## Advanced development pipeline – Profitability in the future













## **New Products**

IgG Next Generation Registration

Trimodulin (IgM Conc.) Phase III

Fibrinogen Phase III

### **New Indications**

Cytotect: CMV in pregnancy Phase III

Cytotect: CMV treatment
Varitect: Herpes Zoster

Zutectra/Hepatect: Chron. Infection

Real Life

Data



## With Grifols as a strategic partner: New products gain in value



**Today** 

F VIII

**Albumin** 

IgG









Size





Range







**BNL** 

F VIII

**Albumin** 

IgG

Trimodulin

Fibrinogen





## IgG Next Generation: Polyspecific i.v. immunoglobulin

Intratect®



#### Maintain:

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

## **IgG Next Generation**





## Further improve:

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



# IgG Next Generation – Advanced devolpement programme



## **Today**

Completion of the clinical development

Commissioning of the new production plant

Dossier submission 31 March 2022

Approval 11/2022

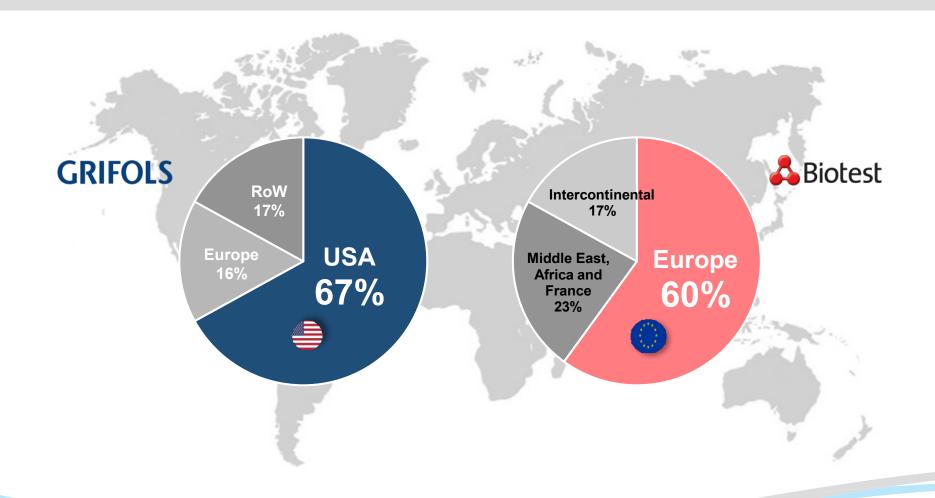
Launch EU 2022/2023

Launch US 2023/2024





## **Grifols is the perfect Partner for USA**





# Trimodulin: Unique innovative immunoglobulin



Trimodulin is a new polyclonal antibody preparation with **high** content of **IgM** + **IgA** 



For treatment of ...

- 1) ... severe COVID-19
- 2) ... severe pneumonia (sCAP)



Several major other indications possible (e.g. in the area of sepsis)



High medical need, high patient benefit and high commercial potential





## Trimodulin – Extensive development programme in severe pneumonia

### **Severe Pneumonia (sCAP)**

Caused by all kinds of pathogens (viruses, **bacteria**, fungi)

#### Clinical trial:

CIGMA Phase II completed



Clinical trial:

ESSCAPE Phase III
Start 2022

#### **Severe COVID-19**

Caused by SARS-CoV-2

#### Clinical trial:

ESsCOVID Phase II completed



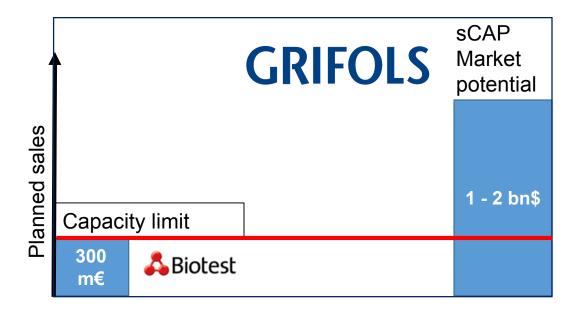
Clinical trial:

TRICOVID Phase III
Start 2022

- Patient groups and disease stages for optimal therapy were identified in Phase II studies
- Positive recommendations for Phase III development in both indications (experts and authorities: sCAP: Europe/US, COVID-19: Europe)
- ➤ TRICOVID study is funded by the German government with 29 m€



## Trimodulin: Exploit market potential through Grifols' economies of scale



- Increase in value through scalability of production volumes
- Full market potential of the main indications becomes addressable
- Other indications of a similar magnitude conceivable (e.g. peritonitis)



# Fibrinogen Concentrate – A development for growing markets

 Growing markets through increased use of point-of-care diagnostics and changing treatment concepts\*







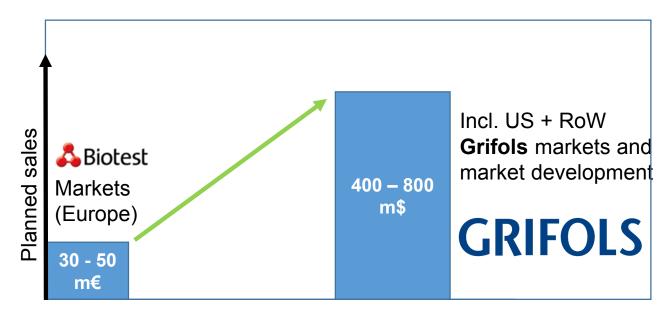
#### **Development status**

- ✓ Congenital fibrinogen deficiency phase I/III (adults & children) completed
- Acquired fibrinogen deficiency due to major bleeding at surgical interventions Phase III patient recruitment ongoing

\*Source: IMS Data 2-2017, Internal Critical bleeding market research, Data provided by affiliate



# Fibrinogen: Commercial strength of Grifols opens new market opportunities



- Increased value through greater commercial reach
- Complementary presence in important future markets and in the US
- Ability to develop new markets (e.g. through diagnostics, outreach and education)



## Grifols and Biotest – Use of common strengths & create values





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



Thank you very much for your attention!



