



**Biotest AG**

**FY 2021 Results**  
Conference call

March 24, 2022

# 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 FY 2021

# Biotest Group – Overview FY 2021

- **Voluntary takeover offer** by Grifols, S.A.: almost completed
- Expansion of **EU plasma collection centres** continued: now 29 centres
- **R&D** pipeline projects are progressing
- German Federal Ministry of Education and Research (BMBF) and German Federal Ministry of Health (BMG) awarded Biotest's **Trimodulin** project with financial support in the volume of up to **€ 29 million**
- **Sales** FY 2021: € 515.6 million, +6.5% compared to FY 2020;  
Adjusted **EBIT** FY 2021: € 29.4 million after one-time write-off of € 40.1 million
- Manufacturing licence granted for Biotest Next Level facility in July 2021
- New Management Board member Dr. Jörg Schüttrumpf (CSO) appointed





# Grifols S.A. – voluntary public takeover offer for all shares of Biotest AG

GRIFOLS

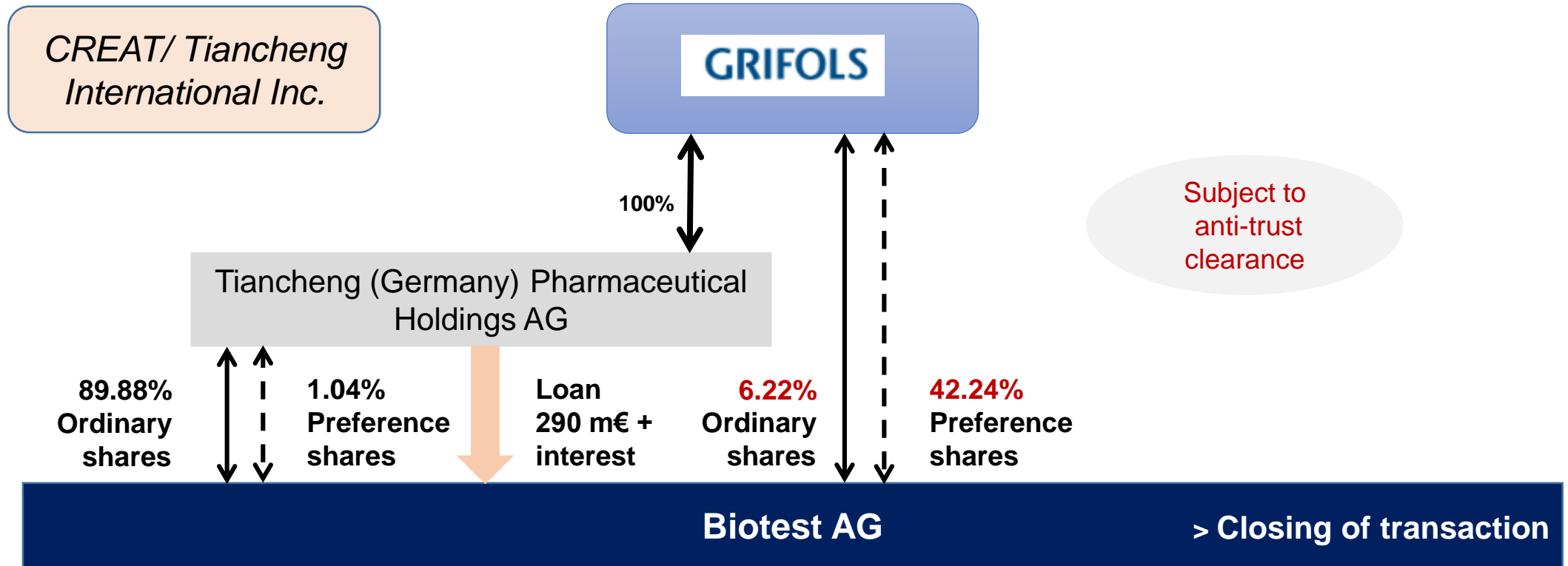


## Grifols S.A. voluntary public takeover ongoing:

Status as of Jan 21, 2022:

- ❖ 6.22% outstanding ordinary shares and 42.24% outstanding preference shares were tendered
  - ❖ After closing, Grifols S.A. will own 96.2% ordinary shares and 43.2% preference shares
- 
- Anti-trust/merger control filings settled in Austria, Germany, Spain; ongoing in Turkey
  - Closing expected within the next weeks
  - Squeeze out for ordinary shares planned

# Current Status CREAT - Grifols – Biotest - as of Jan 21, 2022



# Strategic considerations for Grifols S.A. takeover of Biotest

- Providing a more **complete range of plasma derived products** of both companies
- Improved availability of **life saving medicines** by combining Biotest innovative pipeline and manufacturing capacities with existing Grifols activities
- **Intention:**  
Intensify and accelerate Biotest's **Trimodulin** and **Fibrinogen** development



# Biotest COVID-19 challenge

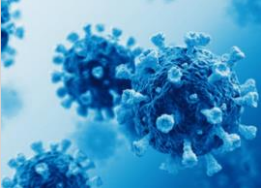
## Biotest COVID-19 update

- Biotest has **managed well** the COVID-19 situation so far
- **Antigen tests** introduced for employees in late 2020
- 1<sup>st</sup> & 2<sup>nd</sup> **vaccination** offered to employees starting in June 2021
- **Booster vaccination** offer from December 2021 onwards
- Little **quarantine** was experienced during the past 2 years
- Current absenteeism among employees like severe flu





# Corona vaccination activities



# Biotest – Sustainability Report 2021

**Can anything be more sustainable than ensuring and protecting not only the basis of life of future generations, but already this of today?**



- based on products made from renewable raw materials
- with low environmental impact and
- climate-neutral production (Scope 1 and 2)
  - due to the switch to green electricity and
  - voluntary compensation measures for all greenhouse gas emissions



Report on the EU Taxonomy Regulation



# Financials FY 2021

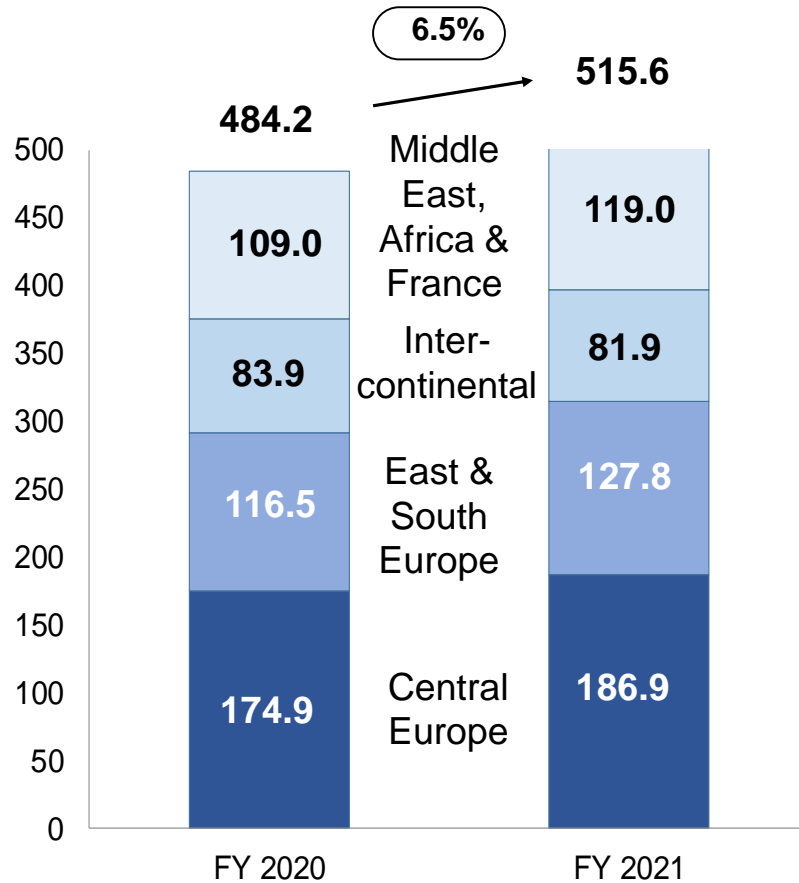
# Income statement

(€ million)

	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2021 w/o FVIII one-time effect</b>
<b>Sales</b>	<b>484.2</b>	<b>515.6</b>	<b>515.6</b>
<u>thereof:</u> Therapy	430.5	461.6	
Plasma & Services	46.7	46.7	
Other Segments	7.0	7.3	
Operating costs & expenses	-485.5	-562.7	-522.6
<b>Operating profit (EBIT)</b>	<b>-1.3</b>	<b>-47.1</b>	<b>-7.0</b>
Financial result, result from joint ventures, taxes	-30.1	-16.3	-16.3
<b>Earnings after tax (EAT) Biotest Group</b>	<b>-31.4</b>	<b>-63.4</b>	<b>-23.3</b>



# Sales development of sales regions\* (€ million)



- ICON (→ Intercontinental)
- MEAF (→ Middle East, Africa and France)
- EASE (→ Eastern and South Europe)
- CEU (→ Central Europe)

- **Therapy sales** up +7.2% to € 461.6.8 million in FY 2021 vs. € 430.5 million in FY 2020

\*: In Q1 2021, Poland and the Czech Republic were reclassified from the Central Europe region to the Eastern Southern Europe region. The previous year's figures have been adjusted accordingly.



# Reconciliation EBIT FY 2020 – EBIT FY 2021

(€ million)

	€ million*	FY 2021 w/o FVIII one-time effect
<b>EBIT FY 2020</b>	<b>-1.3</b>	<b>-1.3</b>
Reduced Gross Profit (-38.0%)	-49.5	-9.4
Higher Marketing & Distribution expenses	-0.9	-0.9
Higher Administrative expenses	-1.9	-1.9
Lower R&D expenses	3.6	3.6
Others (Other operating income and Other Oper. Expense)	2.9	2.9
<b>EBIT FY 2021</b>	<b>-47.1</b>	<b>-7.0</b>

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

# EBIT reported and adjusted

(€ million)

	<b>FY 2020</b>	<b>FY 2021</b>	<b>FY 2021</b> w/o FVIII one-time effect
<b>EBIT reported</b>	<b>-1.3</b>	<b>-47.1</b>	<b>-7.0</b>
Biotest Next Level costs*	79.6	76.5	76.5
Monoclonal antibodies	0.1	0.0	0.0
<b>EBIT adjusted</b>	<b>78.4</b>	<b>29.4</b>	<b>69.5</b>

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

# Biotest Next Level (BNL) costs in FY 2021

## 1. BNL facility costs: € 38.3 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: € 37.5 million\*; thereof:

- € 13.5 million - IgG Next Generation
- € 16.6 million - Trimodulin (IgM Concentrate)
- € 7.4 million - Fibrinogen

**Total BNL costs: € 76.5 million** in FY 2021

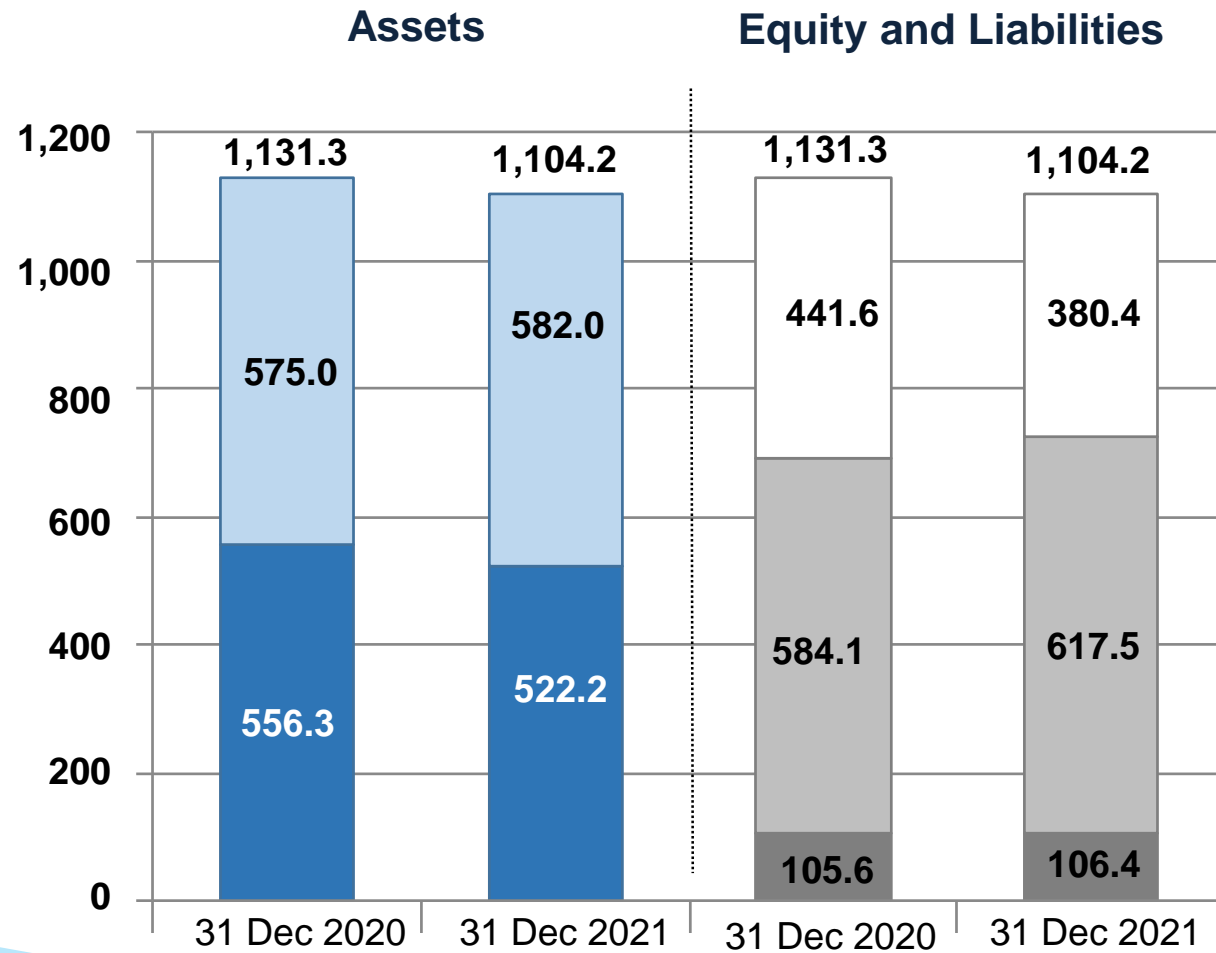
\*: including external vendor cost (e.g. CRO) and internal cost of personnel and infrastructure

# Reconciliation Financial Result FY 2020 – Financial Result FY 2021 (€ million)

	€ million
<b>Financial Result FY 2020</b>	<b>-28.2</b>
Variation in valuation of ADMA shares held by trustee	+5.4
Higher interest expenses	-0,1
Positive effect of FX / hedging	+6.1
<b>Financial Result FY 2021</b>	<b>-16.8</b>

# Balance sheet

(€ million)



- Current assets
- Non-current assets
- Current liabilities
- Non-current liabilities
- Equity

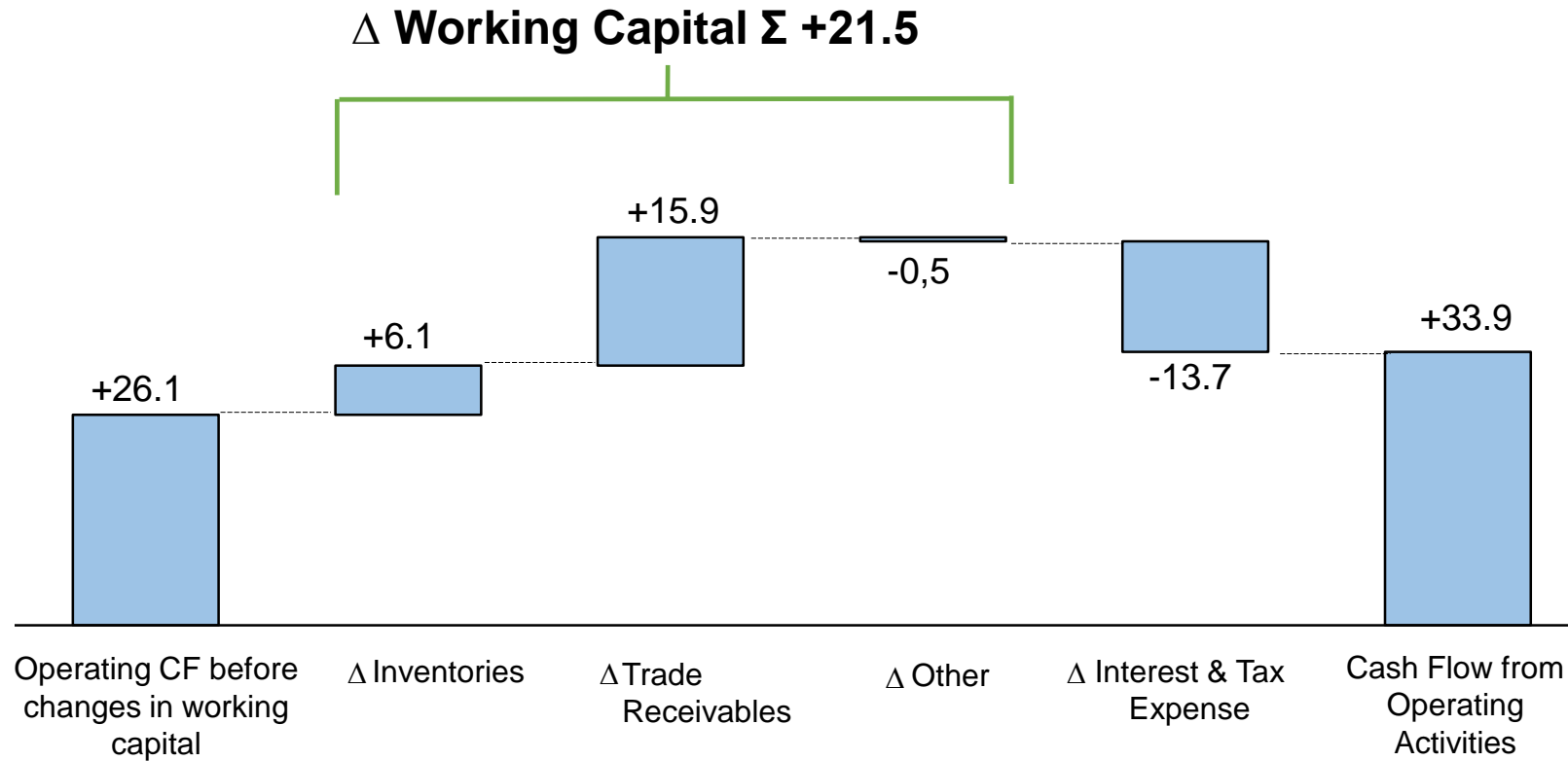
**Net debt:**  
31 Dec 2021:  
€ 393 million

**Equity ratio**  
31 Dec 2021:  
34.4%



# Cash flow from operating activities

January – December 2021 (€ million)





**R&D update  
for BNL projects**

# R&D Opportunities - Biotest with Grifols

1. Grifols to be new major shareholder
2. New strategic options for R&D developments with significant increase of market expectations due to complementary expertise and strengths
3. Wider commercial reach
4. Acceleration of R&D projects with higher R&D spending

## Clinical development

- **Phase III study in PID<sup>1</sup> (EU + US; study 991):** ✓
    - Treatment of adults and children completed
    - All clinical endpoints met
  - **Phase III study in ITP<sup>2</sup> (EU; study 992):** ✓
    - Treatment completed
    - Data shows expected good efficacy and a good safety profile of the product
  - **Phase III study for high dose indication (EU, US; study 999):**  
Planned to be started in 2022
- *Results in EU Clinical Trials Register published*
- *Preparation of submission documents for Marketing Authorization for spring 2022*



<sup>1</sup> Primary Immune Deficiency; <sup>2</sup> Idiopathic Thrombocytopenic Purpura

# BNL: Fibrinogen Concentrate - development for congenital and acquired fibrinogen deficiencies

## Phase I/III study fibrinogen deficiency:

- **Congenital** fibrinogen deficiency is a very rare, inherited bleeding disorder in which the body's ability to form blood clots is impaired

**Phase I/III: completed**



## Phase III study **acquired** fibrinogen deficiency:

ADFIRST

- In acquired fibrinogen deficiency body's own coagulation factor fibrinogen is lost i.e. due to major bleeding
- Replacement of lost fibrinogen is critical to restore effective haemostasis
- Patients undergoing spinal surgery or tumor surgery (Pseudomyxoma peritonei) are treated with fibrinogen

**Phase III: ongoing**





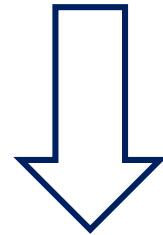
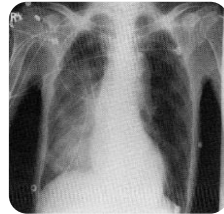
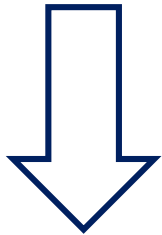
# Trimodulin – Clinical development program Phase III

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

Caused by **SARS-CoV-2**

Clinical trial:  
**CIGMA Phase II**  
completed

Clinical trial:  
**ESsCOVID Phase II**  
completed



Clinical trial:  
**ESsCAPE Phase III**  
Start 2022

Clinical trial:  
**TRICOVID Phase III**  
Start 2022

- Paul-Ehrlich-Institut (PEI) recommended to continue COVID-19 development of Trimodulin in a phase III trial
- **TRICOVID** development is supported by a **€ 29 million grant** by the German Government

## Trimodulin Status update

- In **both phase II clinical trials**, the ESsCOVID trial for COVID-19 and the CIGMA trial for severe Community Acquired Pneumonia (sCAP) Biotest identified patient populations that markedly benefited from treatment with Trimodulin compared to placebo treated patients

➤ The **Phase III program** for Trimodulin will start with two trials in 2022:

- a) **TRICOVID trial** targeting hospitalized COVID-19 patients:  
First study, preparation ongoing



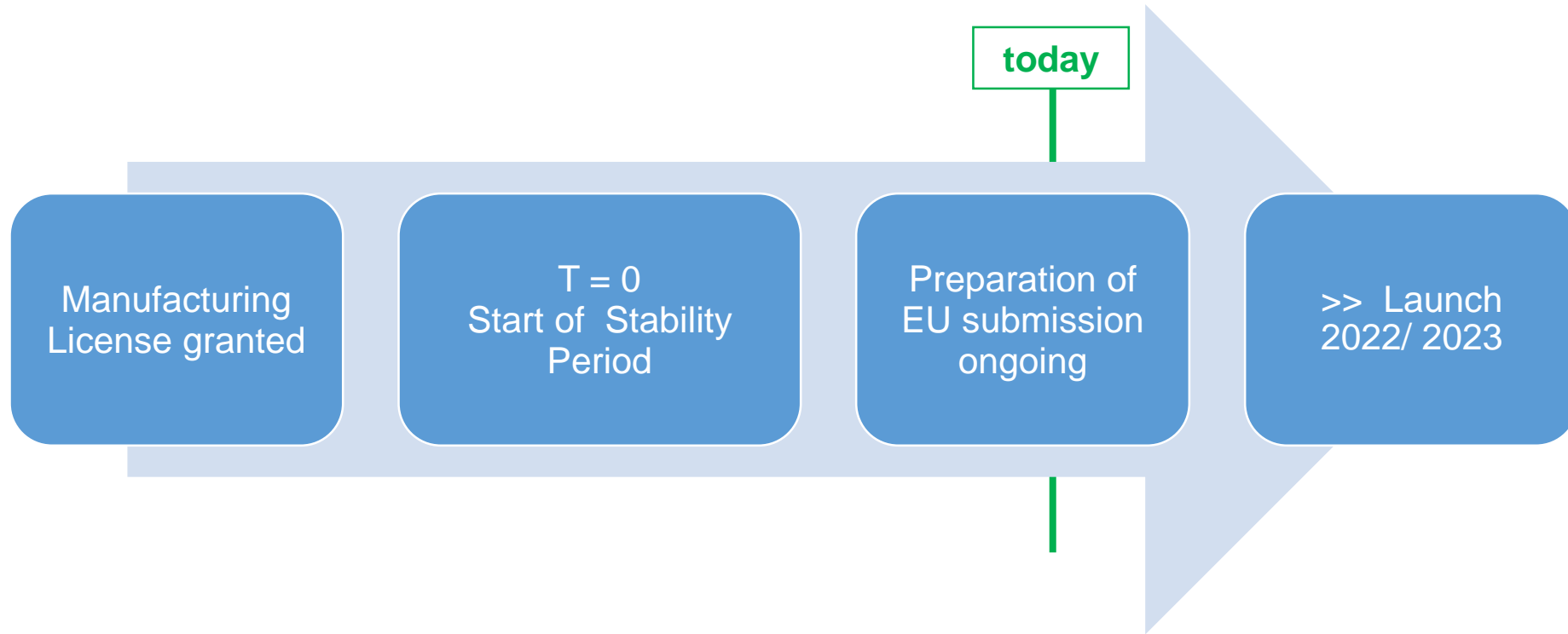
- b) **ESsCAPE trial** targeting patients with sCAP:  
Second study, preparation ongoing





**Biotest Next Level update**

# BNL achievements 2021 – IgG Next Generation



- The last **Process Performance Qualification (PPQ) batch** was manufactured in August 2021; herewith all prerequisites for successful commercial production of IgG Next Generation have been established
- All data collected will be compiled as part of preparing the dossier; **submission of the dossier** to the competent authorities planned for spring 2022
- Approval/ **marketing authorization** for IgG Next Generation is expected at the end of 2022
- Start of validation & commissioning of **Trimodulin** and **Fibrinogen plant**





# Next Steps

## Ramp-up IgG Next Generation



### Continue Commissioning

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







## Plasma collection

# Expansion of plasma collection centers ongoing – now 29 centres



## Europe: 29 centres

Five centres opened in **2021**

Two centres opened in Jan and Mar **2022**

- **Czech Republic:**

- Brno
- Budweis
- Strakonice
- Kolin
- Ostrava

- **Hungary:**

- Sopron
- Szombathely



# Expansion of plasma collection centres ongoing

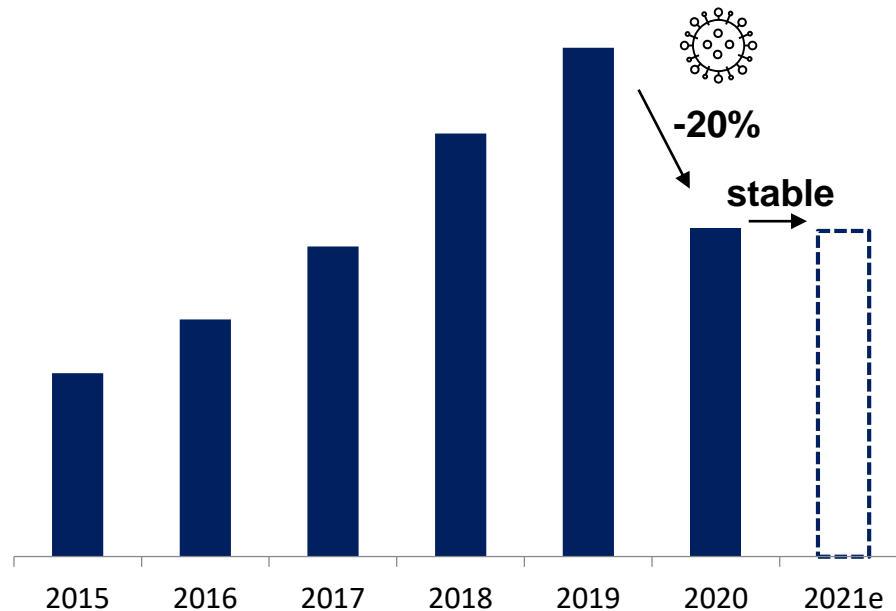


**Cara Plasma, Strakonice, Czech Republic – 11/ 2021**

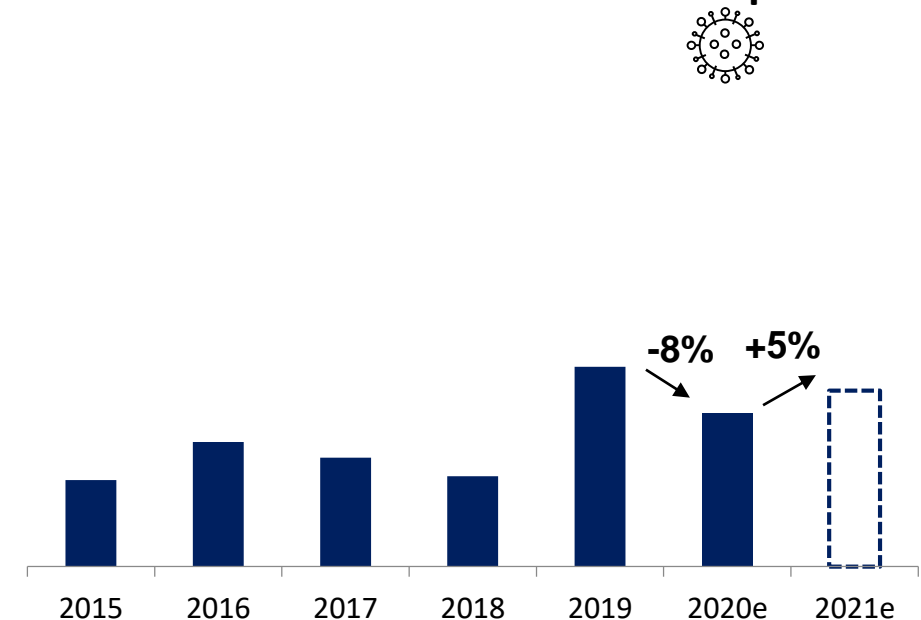
**PDU, Sopron, Hungary – 7/ 2021**

# Impact of COVID-19 on US and EU Commercial Plasma Collections

## US Plasma Collection Volume Development



## EU Plasma Collection Volume Development



- Strong and persisting impact of COVID-19 on US source plasma collections in 2021; >60% of global plasma for fractionation collected in the US
- EU (DE, HU, CZ, AT) collections less impacted and recovering faster, but with minor share of global plasma supply
- Global shortage of plasma and, consequently, shortage of IgG ongoing in 2022

Source: PPTA, Biotest internal analysis; charts not to scale





**Outlook 2022**

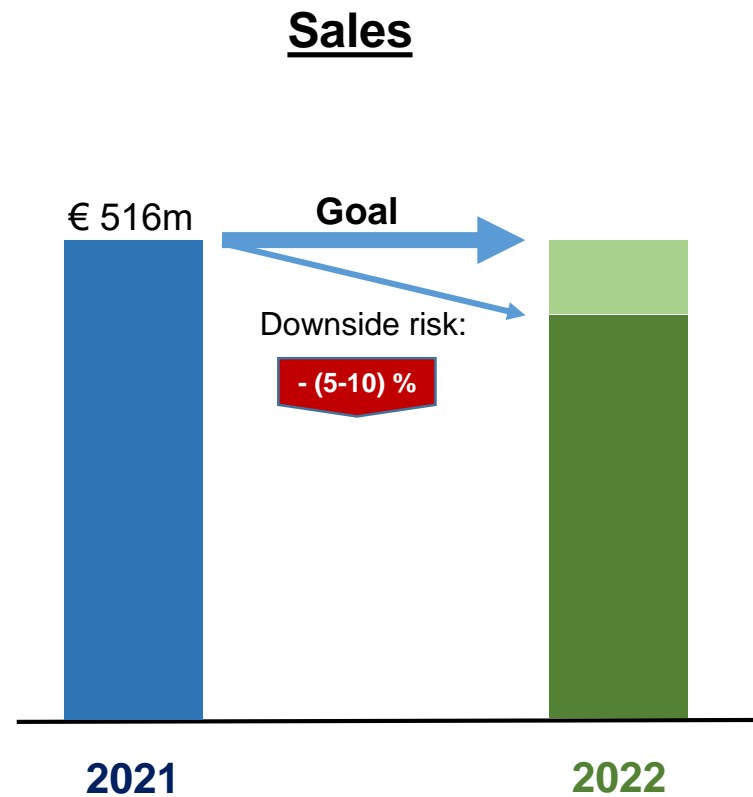
## Forecasting capability for 2022 impaired by

- Weakening of the economy expected due to Russian Ukraine war
- Strong increase of energy costs: gas, electricity, oil etc. > 20%
- Significant increase of costs for other operational materials and supplies > 15%
- Supply difficulties expected: i.e. for Ethanol (alcohol), plasma and other operating materials
- Increased operational risks due to prolonged delivery times (spare parts, filters etc.)
- COVID-19 related staff shortages
- Potential production interruption





# Guidance 2022: Sales & Risks



➤ No general demand or medical need issue

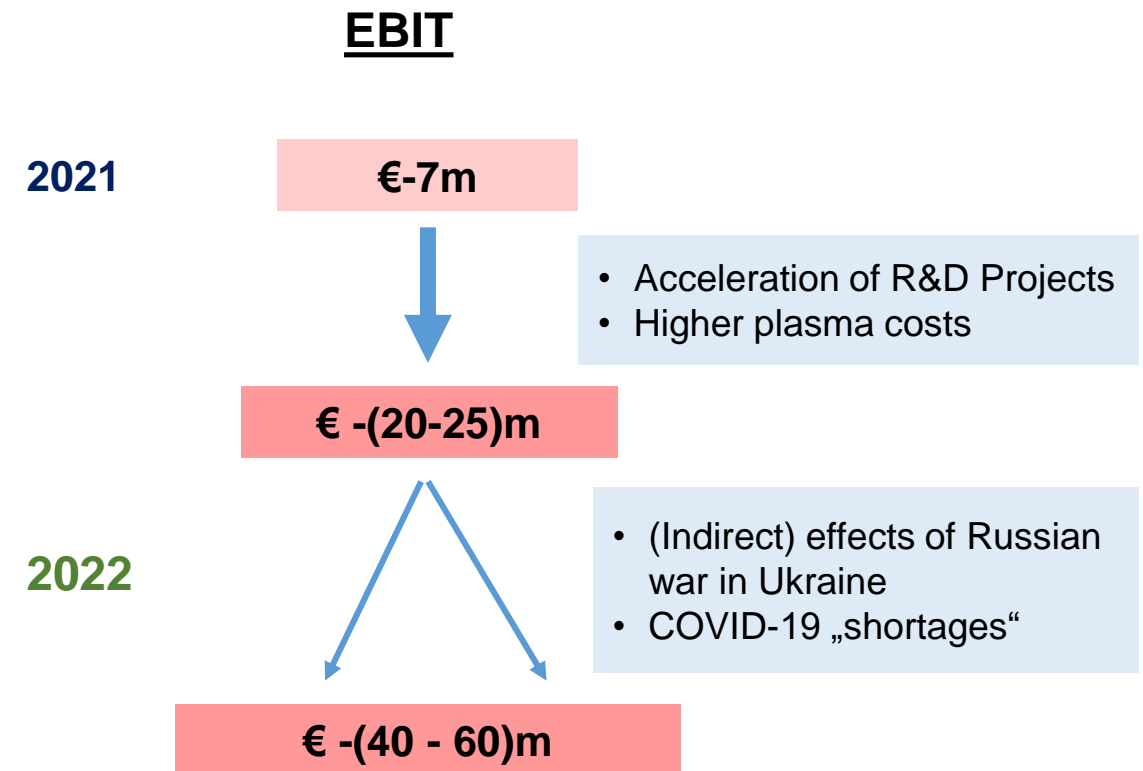
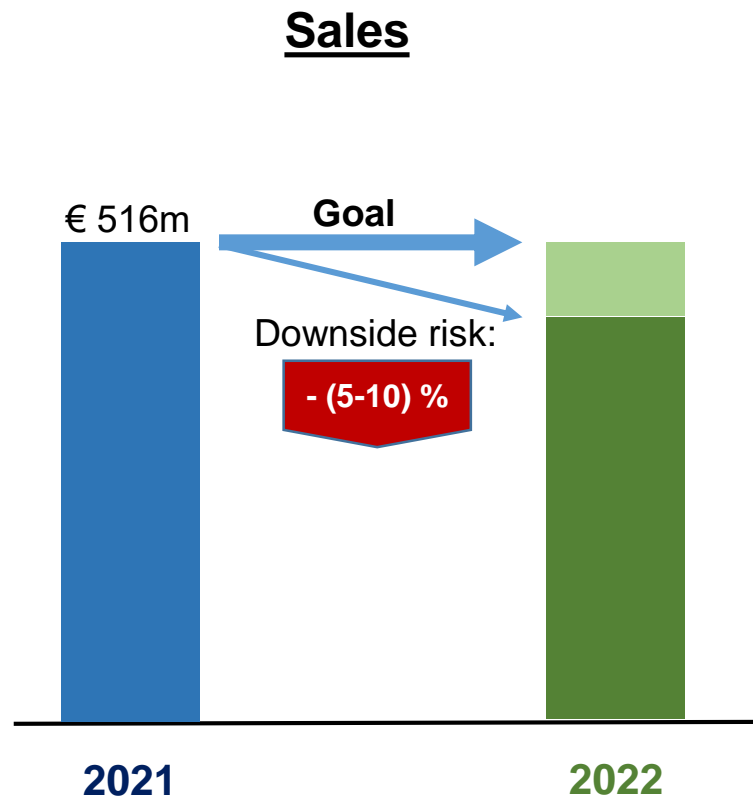
**But:**

➤ Overall economic situation may reduce „purchase power“ of health systems

**More risky:**

- Production slow down or interruption
  - COVID-19 induced staff shortage
  - Delayed delivery of plasma
  - Postponed inspections of new plasma centers
  - Limited availability of spare parts, important supplies
  - Energy shortages

# Guidance 2022



# Financial Calendar 2022 and Contact

## Financial Calendar 2022

05 May 2022	Q1 Report
05 May 2022	AGM
11 Aug 2022	H1 Report
14 Nov 2022	Q1-Q3 Report

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