Biotest AG

Nine Month 2021 Results
Conference call

November 11, 2021

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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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Facts & Figures Q1-Q3 2021

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Biotest Group – Overview Q1-Q3 2021

- **Voluntary takeover offer** by Grifols, S.A. on Oct. 26, 2021
- **Expansion** of plasma collection centres ongoing: now 26 centres
- **R&D pipeline projects** are progressing:
  - IgG Next Generation (IVIG)
  - Fibrinogen (congenital and acquired Fibrinogen deficiency)
  - Trimodulin (IgM Concentrate)
- **Sales** in Q1-Q3 2021: **+8.7%** compared to Q1-Q3 2020;
  Adjusted EBIT in Q1-Q3 2021: **€ 46.3 million**
- **Manufacturing licence granted** for BNL (Biotest Next Level) facility
- **Renate & Hans Schleussner Scientific Award** for innovative research on (hyper)-immunoglobulins
- **Guidance confirmed**

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

- On October 26, 2021 Grifols S.A. published a voluntary public takeover offer for all outstanding ordinary and preference shares of Biotest AG

  Ordinary shares: Offer price: € 43.00

  Preference Shares: Offer price: € 37.00

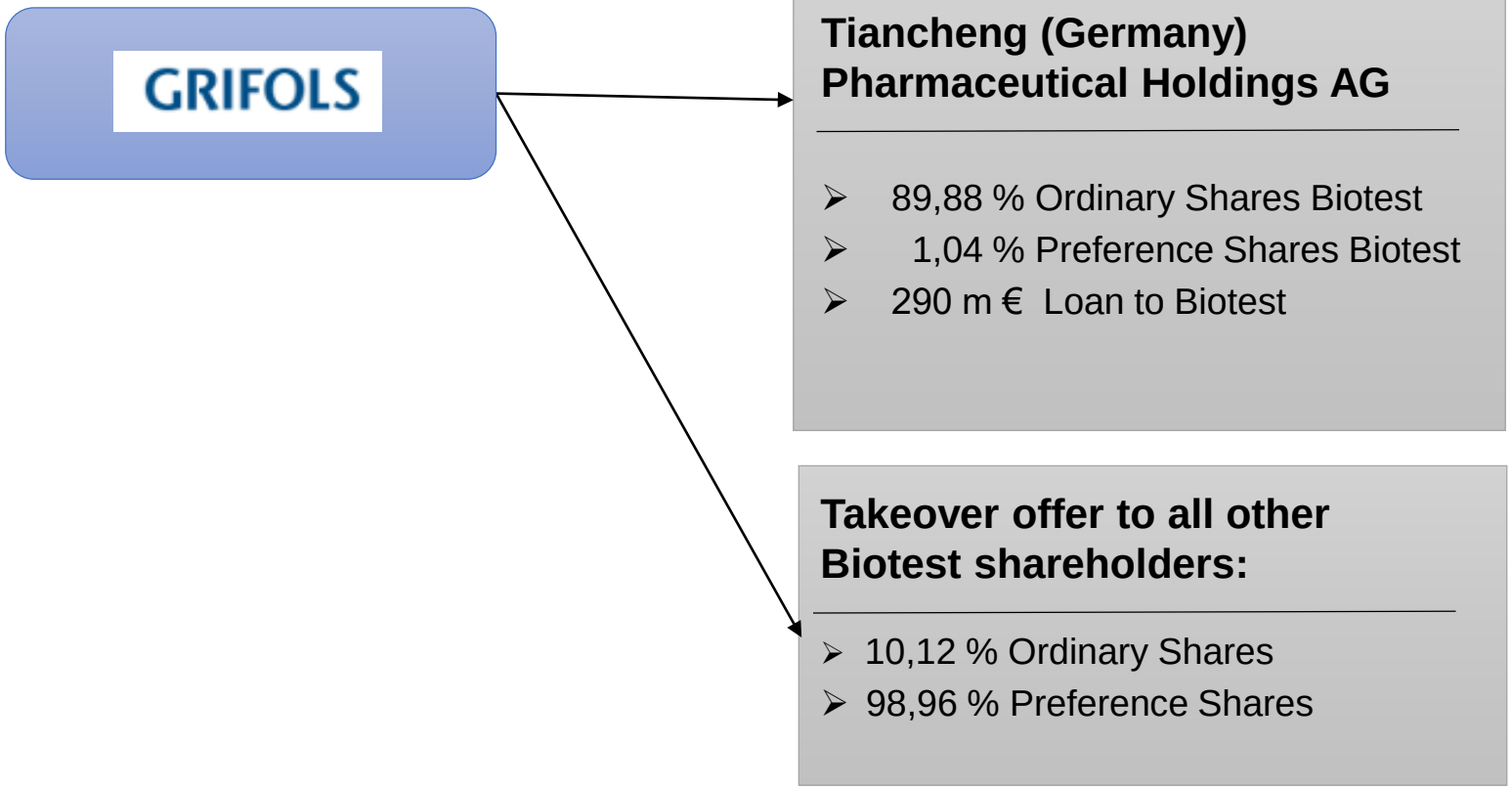
- In a „Joint reasoned statement“ Supervisory Board and Management Board of Biotest AG recommend to accept the takevover offer by Grifols, S.A.

- Joint reasoned statement“ has been published on November 5, 2021

Strategic considerations

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

Agreement CREAT – Grifols/ Grifols Offer Document



CREAT- Grifols Agreement
signed on September 17, 2021

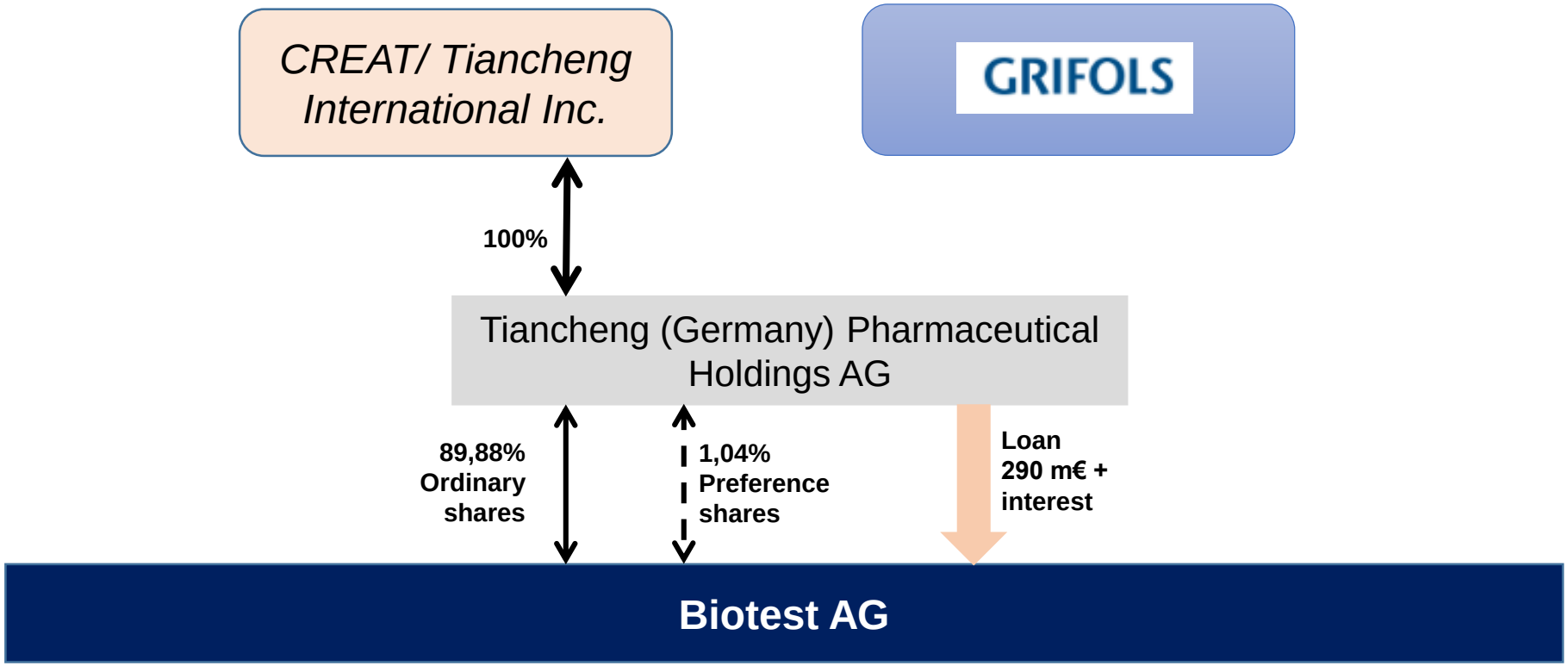
43 € / Ordinary Share
37 € / Preference Share

Closing is subject to Merger Control clearance

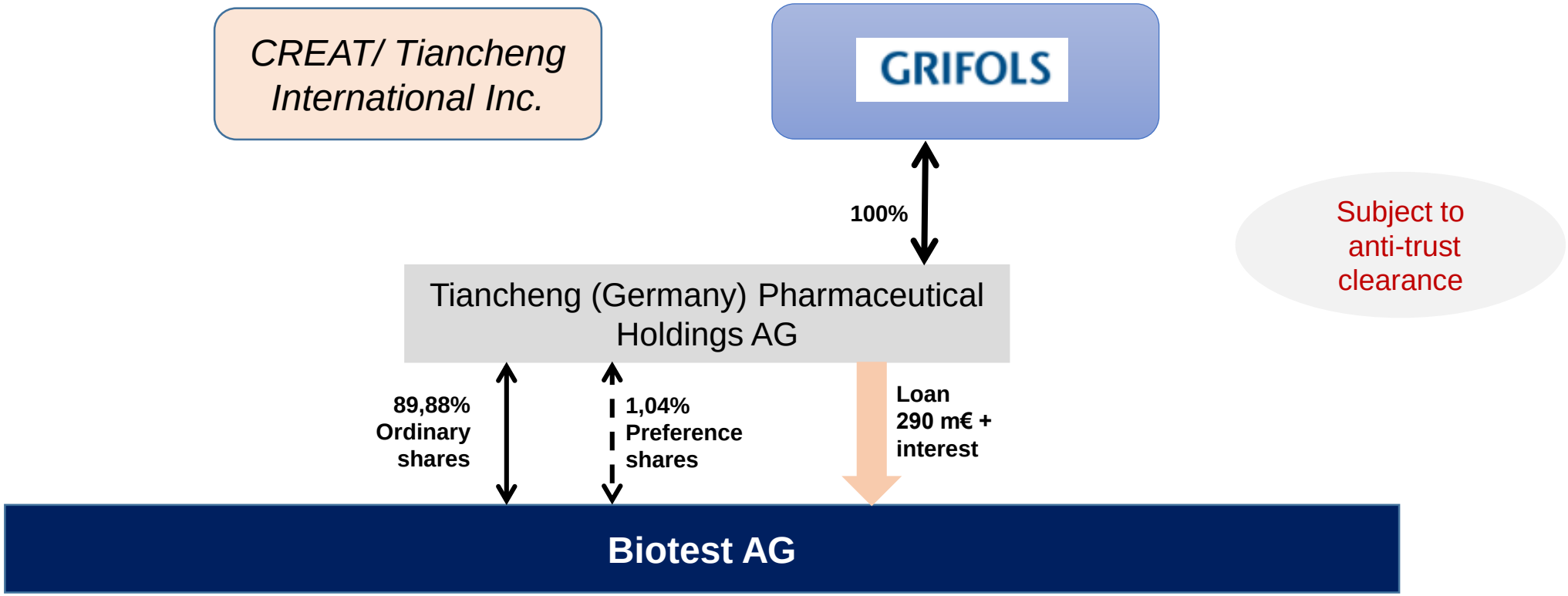
Grifols Offer Document
published on October 26, 2021

Offer price:
43 € / Ordinary Share
37 € / Preference Share

Situation with CREAT as major shareholder



Agreement Grifols – CREAT as of September 17, 2021

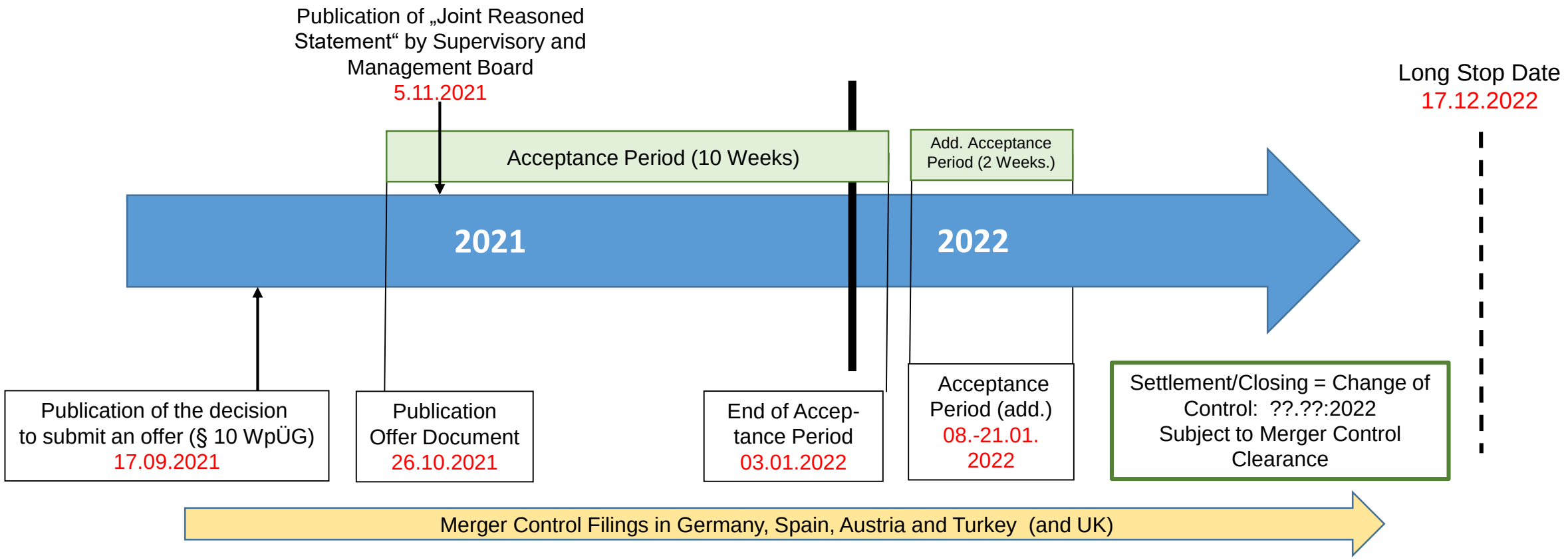


Takeover Offer activities ongoing

As a consequence of Grifols- CREAT Agreement:

- Grifols has published the “Offer Document” incl. assurances to keep name, headquarters’ site and employees and to support our R&D projects and ramp-up of BNL
- Anti-trust/merger control filings in Germany, Spain, Austria, Turkey and UK
- Publication of „Joint Reasoned Statement“ by Supervisory and Management Board of Biotest AG: offer is fair and acceptable
- After expiry of the acceptance period and after clearance by anti-trust authorities the settlement of the takeover offer will take place:
  Grifols will receive the shares and the (former) shareholders the purchase price

Timeline



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Financials Q1-Q3 2021

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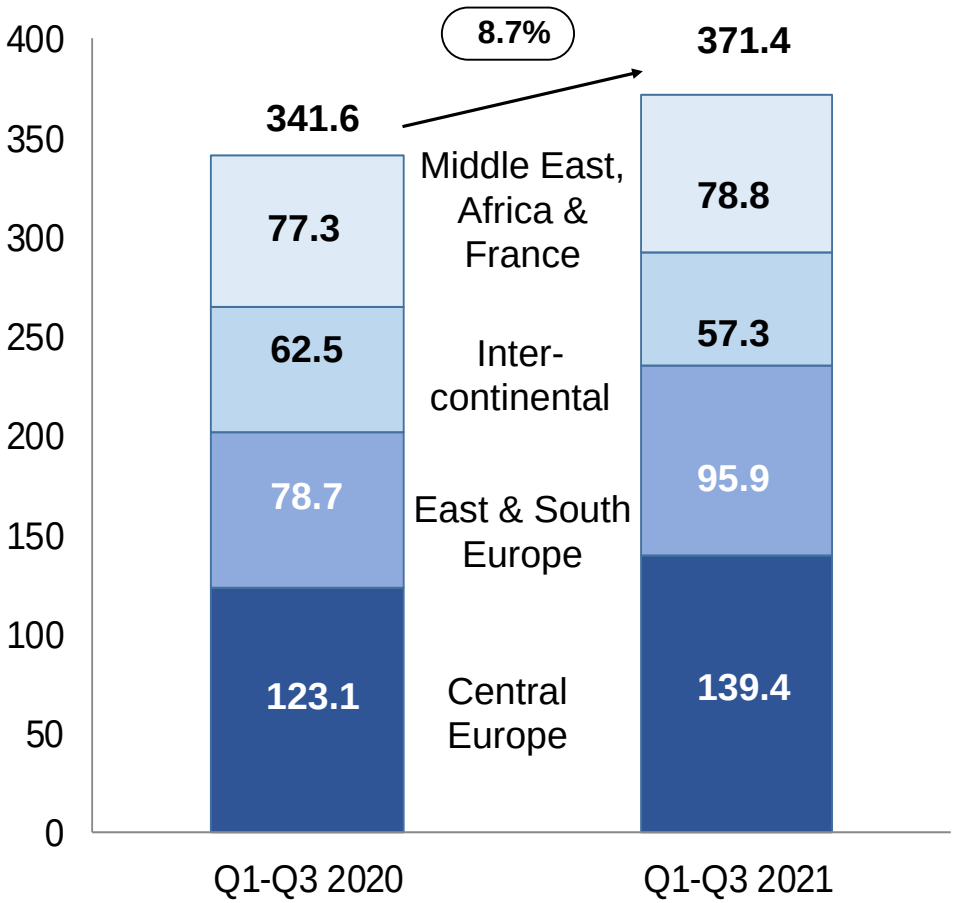
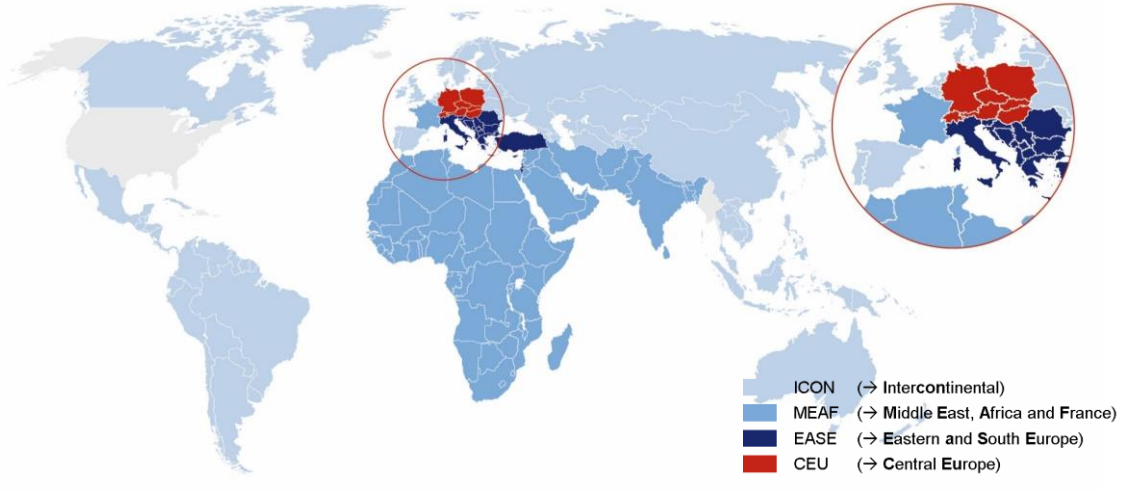
Income statement
(€ million)

	Q1-Q3 2020	Q1-Q3 2021
Sales	**341.6**	**371.4**
thereof: Therapy	303.7	329.8
Plasma & Services	33.8	36.3
Other Segments	4.1	5.3
Operating costs & expenses	-349.4	-382.6
Operating profit (EBIT)	**-7.8**	**-11.2**
Financial result, taxes	-24.0	-17.1
Earnings after tax (EAT) Biotest Group	**-31.8**	**-28.3**

Sales development of sales regions*
(€ million)



*: 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.



- **Therapy sales** up +8.6% to € 329.8 million in Q1-Q3 2021 vs. € 303.7 million in Q1-Q3 2020
- **Segment Plasma & Services**: growth of +7.1% due to higher toll manufacturing (Middle East)

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Reconciliation EBIT Q1-Q3 2020 – EBIT Q1-Q3 2021
(€ million)

	€ million*
EBIT Q1-Q3 2020	**-7.8**
Reduced Gross Profit (-11.4%)	-10.5
Lower Marketing & Distribution expenses	1.4
Lower Administrative expenses	0.8
Lower R&D expenses	1.3
Others (Other operating income and Other Oper. Expense)	3.6
EBIT Q1-Q3 2021	**-11.2**

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

EBIT reported and adjusted
(€ million)

	Q1-Q3 2020	Q1-Q3 2021
EBIT reported	**-7.8**	**-11.2**
Biotest Next Level costs*	59.3	57.5
Monoclonal antibodies	0.1	0.0
EBIT adjusted	**51.6**	**46.3**

*: including R&D costs for BNL development projects

Biotest Next Level (BNL) costs in Q1-Q3 2021

1. **BNL facility costs**: **€ 27.7 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: **€ 29.3 million***; thereof:
   - € 10.9 million - IgG Next Generation
   - € 12.9 million - Trimodulin (IgM Concentrate)
   - € 5.5 million - Fibrinogen

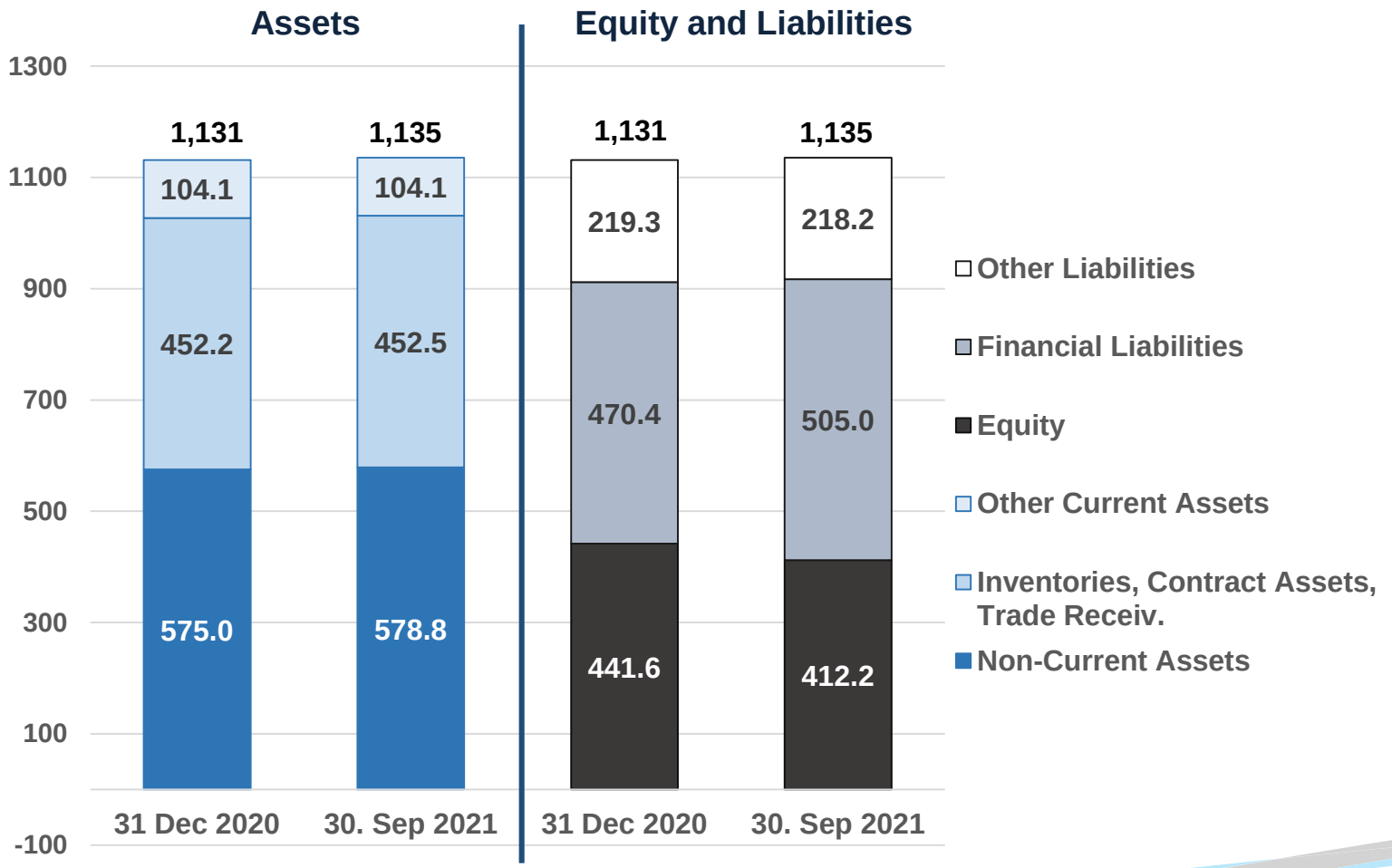
Total BNL costs: **€ 57.5 million** in Q1-Q3 2021

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

Reconciliation Financial Result Q1-Q3 2020 – Financial Result Q1-Q3 2021
(€ million)

	€ million
Financial Result, Taxes Q1-Q3 2020	**-22.7**
Variation in valuation of ADMA shares held by trustee	+2.5
Higher interest expenses	-2.6
Positive effect of FX / hedging	+6.3
Financial Result, Taxes Q1-Q3 2021	**-16.5**

Balance sheet
(€ million)



Net debt:
30 Sep 2021:
€ 424 million

Equity ratio
30 Sep 2021:
36%

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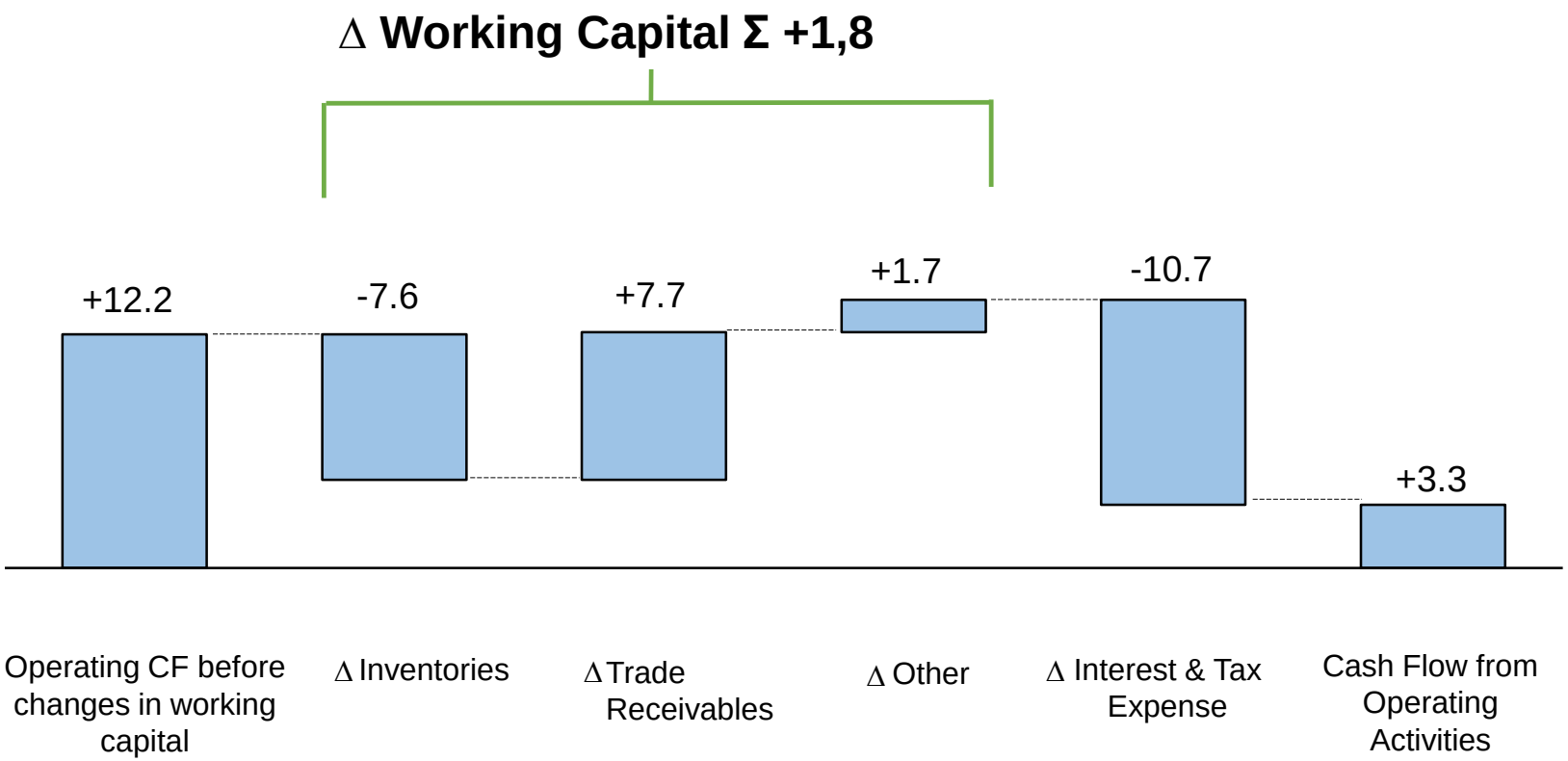
Cash flow from operating activities
January – September 2021 (€ million)



R&D update
for BNL projects

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BNL: IgG Next Generation Overview

10% IVIg manufactured with a new production process, i.e. for highest quality product

IgG Next Generation is intended to become Biotest's world-wide IVIg with a focus on high price markets in EU, US market and RoW

Master product for the planned Biotest Next Level (BNL) production plant

- Increase in IgG yield to 4.5 g/l plasma
- Process suitable for manufacturing of IgG Next Generation and Trimoduline (IgM Concentrate)
- Optimization of product quality (e.g. low IgA and dimer content, low isoagglutinine content by additional column)

BNL: IgG Next Generation

Clinical development

- **Phase III study in PID[1] (EU + US; study 991):**
  - Treatment of adults and children completed
  - All clinical endpoints met
- **Phase III study in ITP[2] (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

➢ *Preparation of submission documents for Marketing Authorization ongoing*

➢ *Results in EU Clinical Trials Register published*

[1] Primary Immune Deficiency; [2] Idiopathic Thrombocytopenic Purpura

BNL: Fibrinogen Concentrate Overview

Abundant complex protein that can be purified from plasma and can be produced at competitive costs

Broad applications: For treatment of severe acute bleeding due to congenital and acquired fibrinogen deficiency

Targeted therapy and diagnostics:
First coagulation factor deficient during acute blood loss

Growing demand expected

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

Fibrinogen plays an essential role in blood clotting; a sufficient plasma fibrinogen level is critical for effective haemostasis

Phase I/III study fibrinogen deficiency:

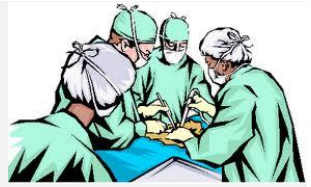
- Congenital fibrinogen **congenital** deficiency is a very rare, inherited bleeding disorder in which the body's ability to form blood clots is impaired

Phase I/III: completed

Phase III study acquired fibrinogen deficiency:

- 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**

ADFIRST



BNL: Trimodulin Overview

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

- Severe COVID-19 or
- Severe community acquired pneumonia (sCAP)
- Relevant upside potentials

Composition of product:
5% protein solution for infusion, approx. **23% IgM, 21% IgA, 56% IgG**

Trimodulin acts via **three potential mechanisms**:
1) Targeting of the host inflammatory response
2) Opsonization (elimination) of causal pathogens
3) Neutralizing of microbial pathogens and their virulence factors

High medical need, high patient benefit and high commercial potential

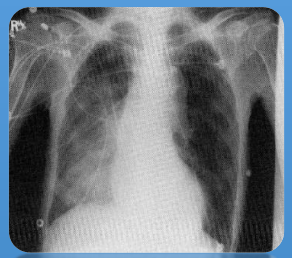
Trimodulin – Clinical development program in different types of pneumonias

Clinical trial:
CIGMA Ph II - completed

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

„bacterial sepsis“

Infectious lung diseases



Clinical trial:
ESsCOVID Ph II - completed

Caused by SARS-CoV-2

„viral sepsis“

Gong et al., 2018; doi: 10.21037/jtd.2018.10.50

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ESsCOVID Design: Phase II trial with Trimodulin in COVID-19

Study objective

Demonstrate the efficacy and safety of trimodulin in severe hospitalized COVID-19 patients

France, Spain, Russia, Brazil

15 active sites

166 patients

Duration: FPI* 06 OCT 2020
LPO* 29 JUN 2021

*FPI=First Patient In, LPO = Last Patient Out

Composite primary endpoint

- The clinical deterioration rate (score =6-7) between day 6 and day 29
- 28-day all-cause mortality rate (score =8) between day 1 and day 29

Adapted 9-category ordinal scale

Patient status	Description	Score[1]
Non-hospitalized	Discharged, cured	0
Non-hospitalized	Discharged, limited activities, not returned to pre-disease health status	1
Hospitalized	Meets discharge criteria defined as clinical recovery with fever, respiratory rate and oxygen saturation returned to normal and with relief of cough and fatigue. Or hospitalized due to sequelae of COVID-19 infection	2
Hospitalized, mild disease	Not requiring supplemental oxygen	3
	Requiring supplemental oxygen	4
Hospitalized, severe disease	On non-invasive ventilation (NIV) or high flow oxygen devices, or both	5
Hospitalized, critical disease	On invasive mechanical ventilation (IMV) or extracorporeal membrane oxygenation (ECMO), or both	6
	Respiratory failure with MODS, MOF, sepsis and/or septic shock	7
Death	All-cause mortality	8

[1] Highest score per calendar day is to be reported.

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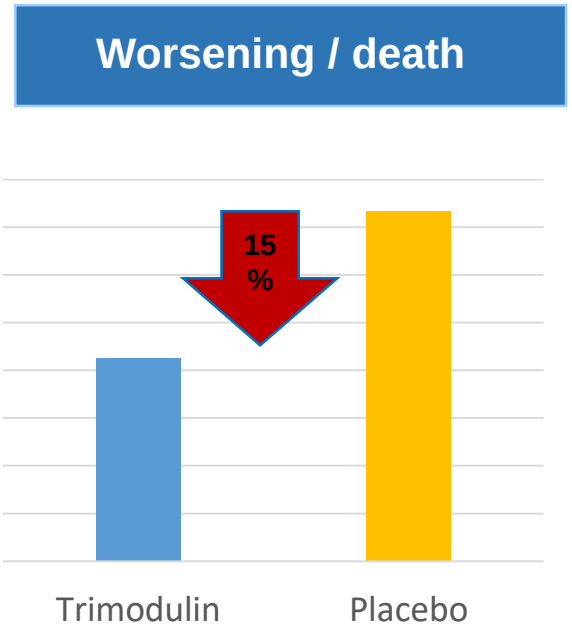
ESsCOVID Phase II trial - Results

Study objective
Demonstrate the efficacy and safety of Trimodulin in severe hospitalized COVID-19 patients

Result
- Primary endpoint in total trial population (n=166) not met
- The good safety profile of Trimodulin was confirmed

- Relevant subgroup of hospitalized COVID-19 patients with **early** systemic inflammation (n=96) identified which benefitted from Trimodulin treatment

- **Deterioration and 28-day mortality rate was 15% lower** in Trimodulin treated patients compared to placebo.



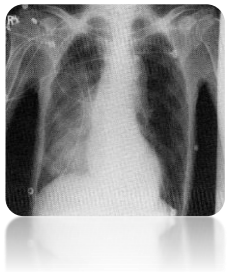
Trimodulin – Clinical development program Phase III

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

Caused by SARS-CoV-2

Clinical trial:
CIGMA Ph II - completed

Clinical trial:
ESsCOVID Ph II - completed



Clinical trial:
ESsCAPE Ph III - planned

Clinical trial:
TRICOVID Ph III - planned

- Paul-Ehrlich-Institut (PEI) recommended to continue COVID-19 development of Trimodulin in a phase III trial

Cytotect Phase III trial - prevent transmission of Cytomegalovirus infection

- Approval of Phase III clinical trial to prevent transmission of Cytomegalovirus (CMV) infection to the unborn child (“PreCyssion” - Prevention of maternal-foetal Cytomegalovirus transmission after primary maternal infection)
- Cytomegalovirus (CMV) infection of the foetus is one of the most common congenital infections and may cause severe developmental retardation, hearing loss and neurological late damage in new-borns
- High unmet medical need due to large amount of new-borns born with CMV-related disorders:
  In EU/ USA > 50,000 babies are born with CMV infection p.a. Currently, there is no approved therapy for this indication
- Significant reduction in CMV transmission from mother to foetus expected with treatment with CMV hyperimmunoglobulin
- With successfully completed trial, Biotest is seeking to extend the market authorisation for Cytotect CP Biotest®

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Biotest Next Level update

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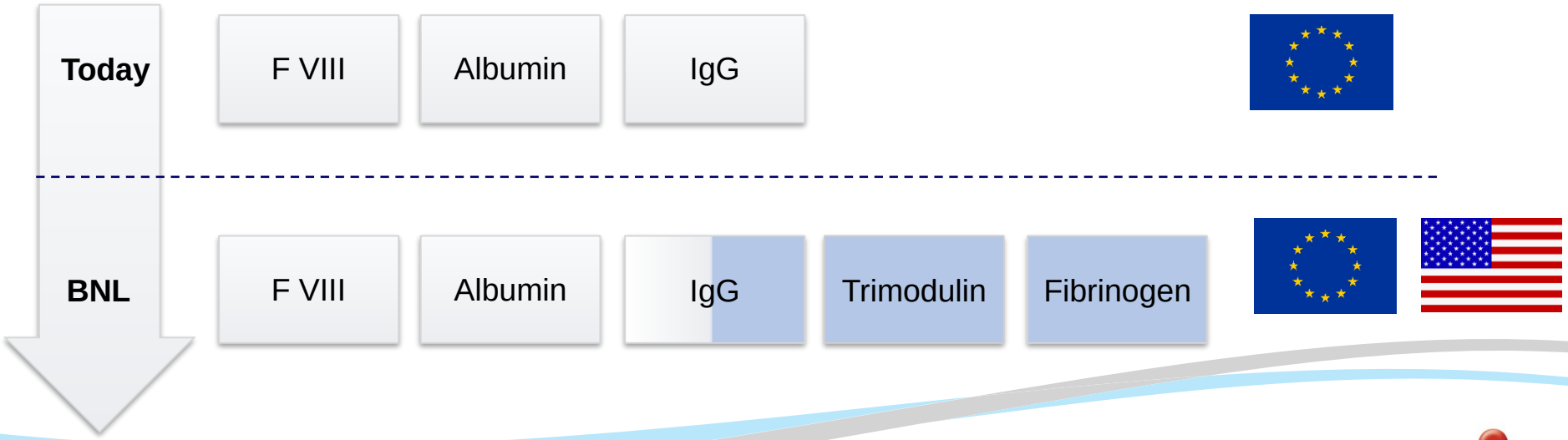
Strategic pillars of BNL development program

- Capacity increase
- Globalisation of products
- More products out of one litre plasma
- Improved yield
- Specialty plasma products (high medical need)



BNL achievements 2021 – IgG Next Generation

today

Manufacturing License granted

T = 0
Start of Stability Period

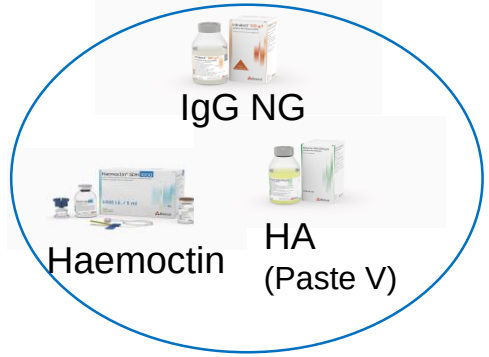
Preparation of EU submission ongoing

>> Launch 2022/ 2023

Next steps

IgG Next Gen.	• Dossier preparation • Process optimization • Implementation of Anti A/B • Ramp-up for commercial production
Human Albumin	• Commissioning
IgG Next Gen.	• Preparation of market launch of IgG Next Generation
Recruit-ment & Training	• Hiring and training of employees

2021 → 2022 → 2023

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Plasma collection

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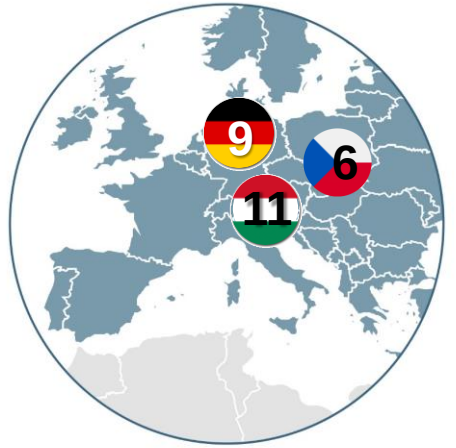
Expansion of plasma collection centers ongoing

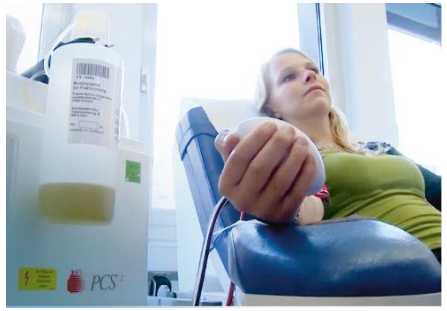
Europe: 26 centres

- Four centres opened in 2021

  - Brno, Czech Republic
  - Budweis, Czech Republik
  - Sopron, Hungary
  - Szombathely, Hungary

- Expansion of plasma collection centres ongoing





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Outlook 2021

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Guidance 2021 confirmed

Sales: Sales growth in mid-single-digit percentage

EBIT: EBIT will be between **€ -5 and € -10 million**

Earnings 2021 will be influenced by expected expenses of € 75 – 85 million due to BNL project incl. R&D costs, tense situation in the crisis regions as well as global impact of COVID-19 pandemic.

Financial Calendar 2022 and Contact

Financial Calendar 2021

30 Mar 2022	FY 2021
03 May 2022	Q1 Report
11 Aug 2022	H1 Report
14 Nov 2022	Q1-Q3 Report

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