Biotest AG

Company Presentation H1 2020

August 2020

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.

Biotest Group: H1 2020 at a glance

- Sales increase of +20.3% to €234.8 m in H1 2020 vs. €195.1 m in H1 2019
- EBIT in H1 2020 at € 0.7 m vs. € -5.5 m in H1 2019
- Adjusted EBIT increased to € 41.1 m in H1 2020 vs. € 29.9 m in H1 2019
- First Albumin sales in China
- Two development projects regarding a therapy for COVID-19 infection started
- Biotest Next Level project progressing; second approval by the Darmstadt Regional Council in mid-June 2020

Corona Virus Special

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Biotest products are safe!

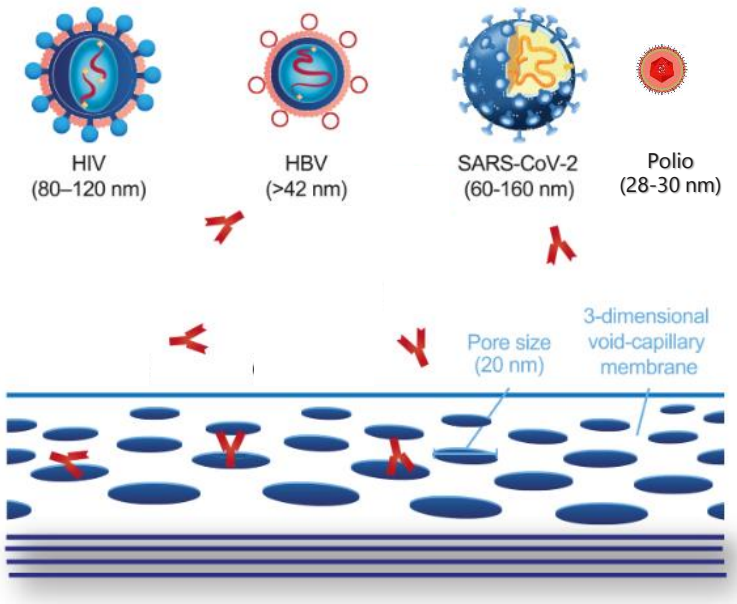
- **FDA** (August 2020): No case of corona virus transmission *via* blood transfusion has been reported
- **Biotest:** persons with diagnosed corona virus infection are not permitted to donate plasma
- **Biotest manufacturing process:** four processing steps for virus inactivation and virus elimination

Manufacturing process ensures inactivation of viruses

- Treatment with octanoic acid
- Use of detergents
- Heat treatment
- Nanofiltration

Virus removal by nanofiltration

- Plasma protein solution must pass an **only 20 nanometers wide** filter opening
- **Viruses** with a larger diameter are **filtered out**
- **Ø corona virus: >120 nanometers**



Protection for plasma donors and Biotest staff

- **Protection of plasma donors**
  - Complying with **distance rules** with respect to donation beds
  - Donations by appointment only: only a few donors present in center, distance rules in waiting area

- **Protection of staff ➡ ensuring uninterrupted business operations**
  - **Working remotely**
  - Additional measures in terms of **hygiene and distancing**
  - Own production of **hand disinfectant**
  - Biotest is **systemically relevant**, emergency day care for children of staff members possible

Biotest - Three COVID-19 activities ongoing

1. Use of “**convalescent” plasma** (Biotest Germany, Hungary collect plasma)

2. Development of a new **Hyperimmunoglobulin**

3. **Trimodulin** (IgM immunoglobulin concentrate)

   a) Submission of a **phase II** study (ESsCOVID study) exclusively in severe COVID-19 patients to competent authority

   b) COVID-19 will be considered in the design of the **phase III** ESsCAPE study

1. Use of „convalescent“ plasma

- Plasma collected from cured corona virus patients (convalescent plasma) is **directly used for therapy** for patients suffering from COVID-19
- “Convalescent” approach pursued in numerous countries
- In Hungary, the Biotest **plasma collection centre at Budapest** collects **plasma of cured COVID-19 patients** in parallel to regular operations by special request of the Health Ministry of Hungary

2. Development of new drug: COVID-19 Hyperimmunoglobulin

- Entirely **new drug: COVID-19 Hyperimmunoglobulin**
- Use of **plasma donations containing COVID-19 antibodies**
- **Biotest** collects plasma containing COVID-19 antibodies in Hungary and Germany
- Processing into **new hyperimmunoglobulin against COVID-19**
- **Global cooperation** with BPL, CSL, LFB, Octapharma, and Takeda amongst others in “CoVIg-19 PLASMA ALLIANCES”

With optimal project progress, drug available end of 2020 at the earliest

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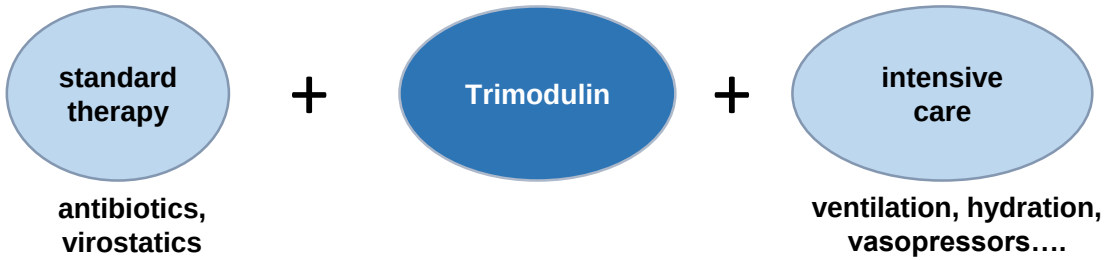
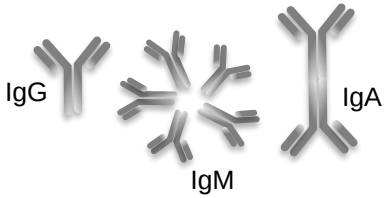
3. Trimodulin: potential for COVID-19 infection

- **Trimodulin** was used in a phase II CIGMA study in **severe pneumonia** (in addition to standard therapy and intensive care)



- **50-70% reduction of mortality** in patients with high inflammation and/or compromised immune system
- **Striking similarity of COVID-19 clinical picture** to this patient group in CIGMA study

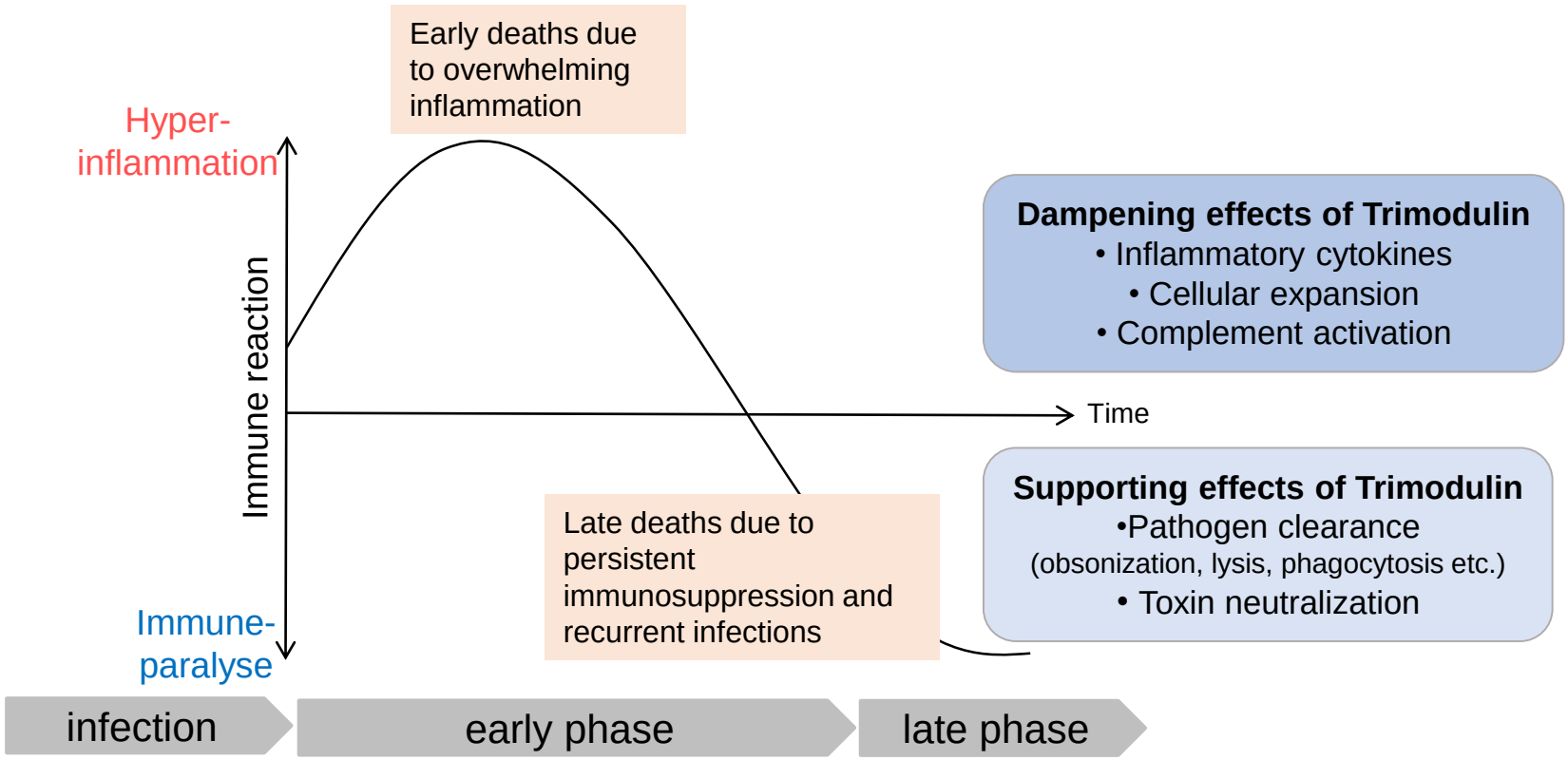
Trimodulin: mode-of-action in sCAP (incl. COVID-19)



Trimodulin

Clearance of causal pathogens, prevention of secondary infections	Neutralization virulence factors, (endo- and exotoxins) and inflammation mediators	Modulation of host immune responses
Bacteria, Viruses, Fungi	Toxin	monocytes, lymphocytes, complement
Pathogen defense	Anti-Inflammation	

Trimodulin in COVID-19



Trimodulin: Status concerning COVID-19

- **ESsCOVID (Escape from severe COVID-19) phase II study** exclusively in severe Covid-19 patients was submitted to Competent Authority and responsible Ethics Committee; study planned in Spain, Brazil and Russia
  - Multinational phase II clinical trial with approx.160 adult patients to be enrolled; Biotest targets an accelerated approval
  - ➢ To offer a fast response during the current outbreak and have a possibility to shorten the time-to-market

- Design of **phase III ESsCAPE study** in sCAP, also accounting for COVID-19 patients in preparation
  - ➢ The goal is to obtain a broad indication in sCAP including COVID-19

Financials H1 2020

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Income statement
(€ million)

	H1 2019	H1 2020
Sales	**195.1**	**234.8**
Operating costs & expenses	-200.6	-234.1
Operating Profit (EBIT)	**-5.5**	**0.7**
Financial result, taxes	7.5	-17.4
Earnings after tax (EAT) Biotest Group	**2.0**	**-16.7**

EBIT regular and adjusted
(€ million)

	H1 2019	H1 2020
EBIT reported	**-5.5**	**0.7**
Biotest Next Level costs*	34.5	40.3
Monoclonal antibodies	0.9	0.1
EBIT adjusted	**29.9**	**41.1**

*: including R&D costs for BNL development drugs

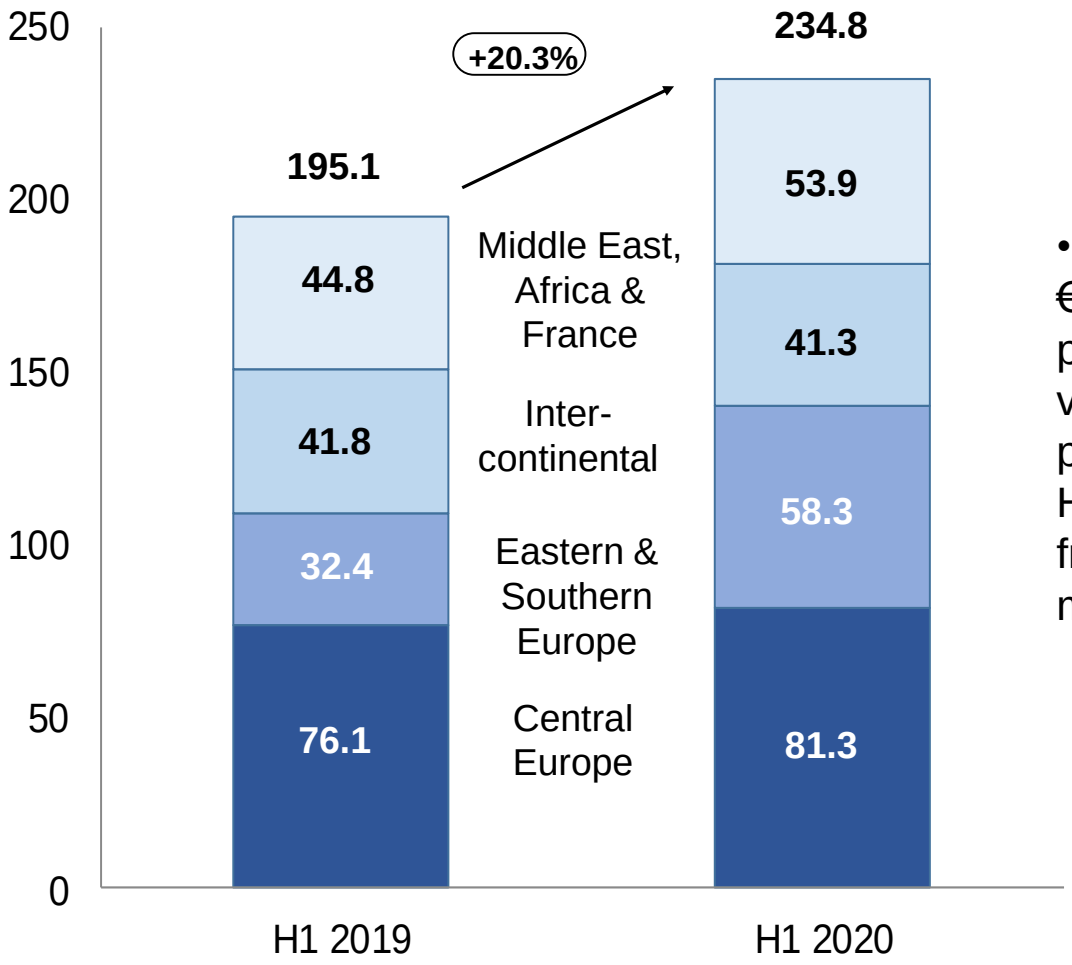
Biotest Next Level (BNL) costs in H1 2020

1. **BNL facility costs**: **€ 19.3 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: **€ 21.0 million**; thereof:
   - € 8.5 million - IgG Next Generation
   - € 7.7 million - Trimodulin (IgM Concentrate)
   - € 4.8 million - Fibrinogen

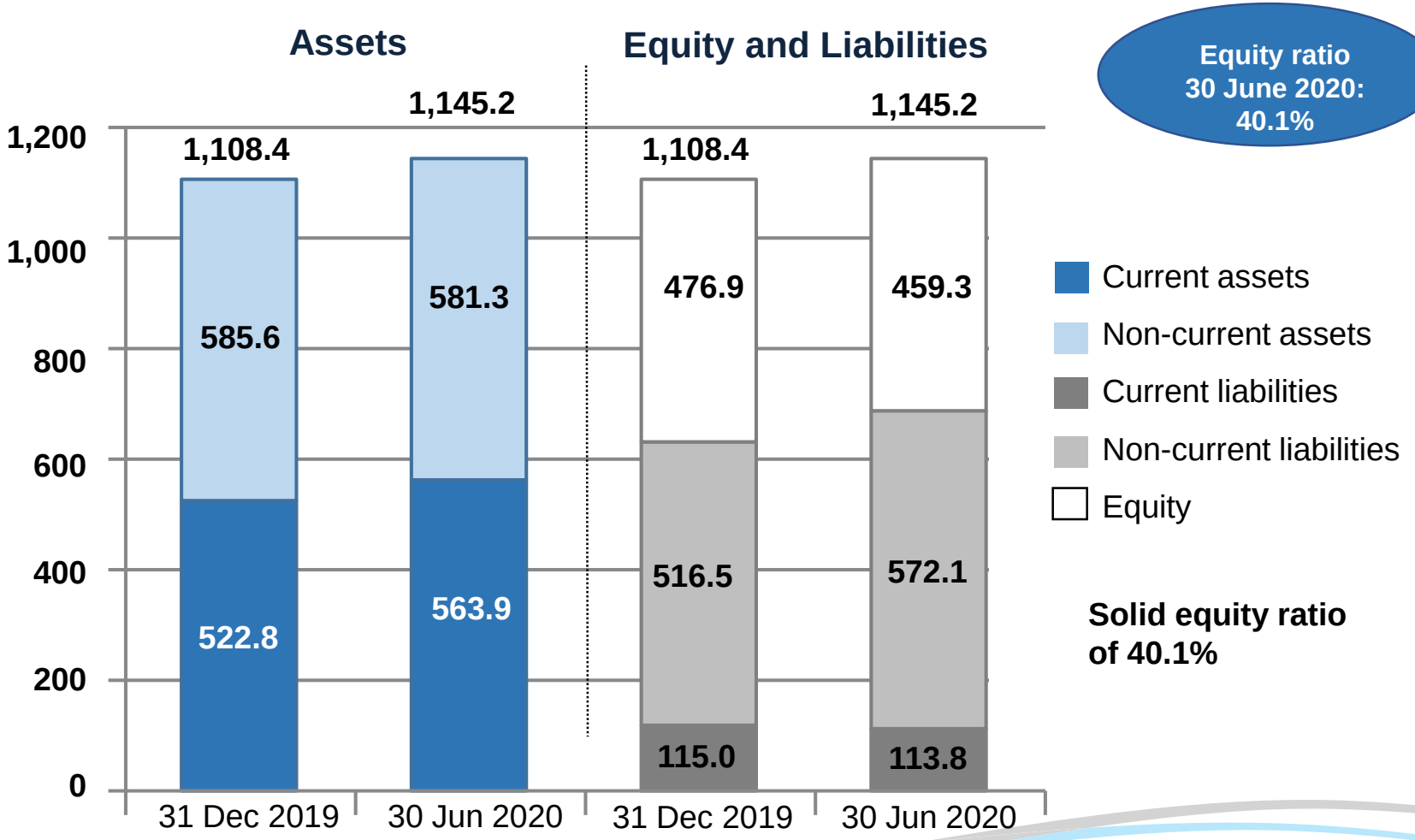
Total BNL costs: **€ 40.3 million** in H1 2020

Sales development
(€ million)



- The sales increase of € 39.7 million resulted in particular from increased sales volumes and higher selling prices for Intratect® and Human Albumin as well as from significantly higher toll manufacturing

Balance sheet (€ million)



Guidance 2020*

Sales: In 2020 sales will increase by 10 percent

EBIT: Earnings will be influenced by various factors in 2020:

- Mainly further BNL expenses (€80 – 90 million)
- Tense situation in the crisis regions, particularly in the Middle East and Asia

EBIT of continuing operations will be **between €-10 m and €-5 m.** Due to two new COVID-19 development projects, management expects earnings to be at the lower end of the range given

* Caveat: Guidance is given without any expected, but not yet assessable negative impact of the Corona virus crisis!

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Market environment & product portfolio

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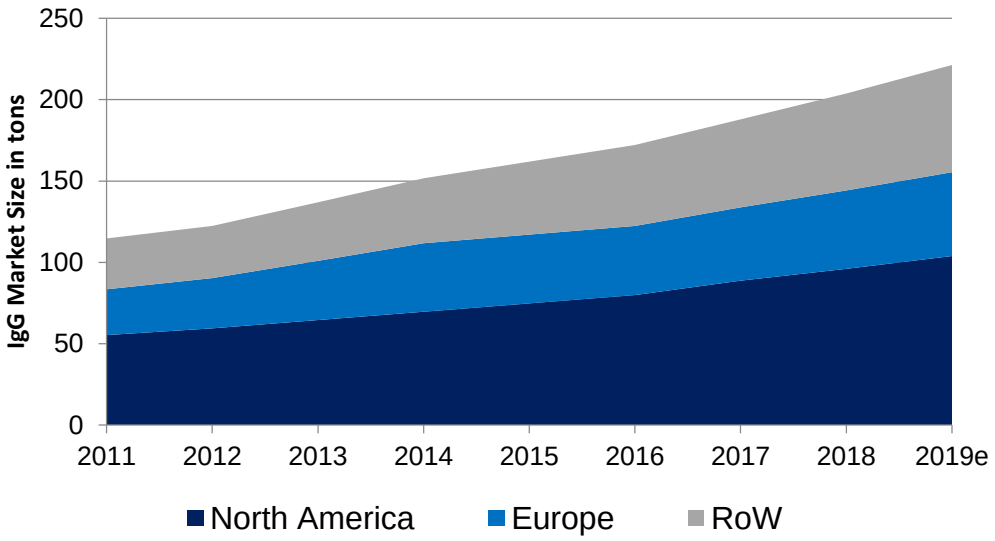
Global IgG (i.v. and s.c.) Market Size Development

IgG Market Size
(Volume in tons)



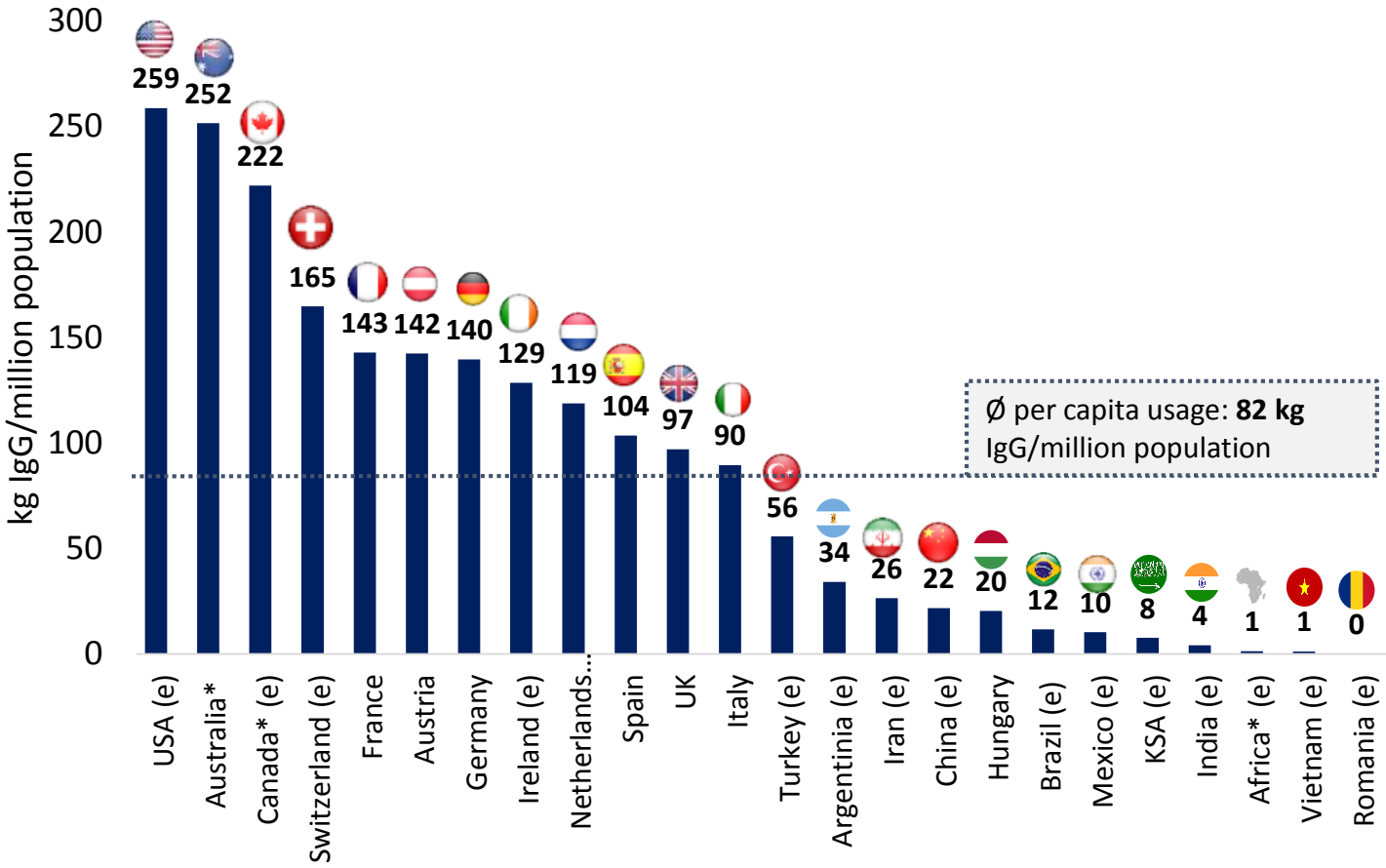
Annual Growth – CAGR 2011 – 2019e

RoW	10%
Europe	8%
North America	8%
World	**9%**

- The global IgG Market reached a size of nearly ~220 tons in 2019.
- In the period 2011 to 2019, the total market grew by ~9% annually (CAGR)

Sources: Biotest Market and Pricing Insights based on MRB (2018, 2019), PPTA (2020), Markets and Markets (2019), Allied Market Research 2018

Global IgG Market – usage per capita 2018



Comments

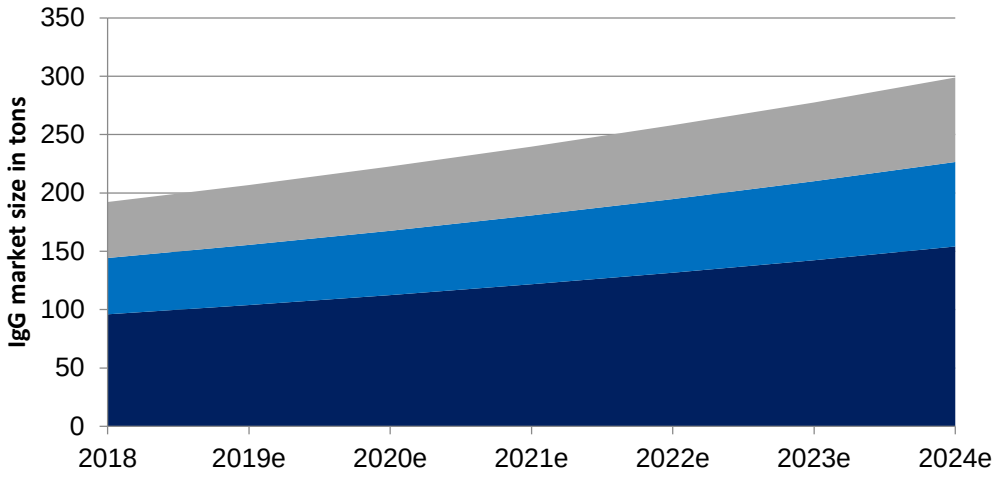
- Increase of new PID patients due to testing requirements in US: Continuous high demand
- Growing use in CIDP in major markets
- Increased need to treat SID due to more aggressive treatments
- Easier reimbursement leads to market growth
- Cost of treatment remains still a barrier to market expansion

*: Primary Immune Deficiency; **: Chronic Inflammatory Demyelinating Polyneuropathy, or other neurological indication; ***: Secondary Immune Deficiency

Sources: Iqvia (2018), PPTA (2018 for EU and USA estimation based on CSL Analyst report May 2019), MRB (2014, 2015, 2016, 2017), NBA Australia 2018, CIA Factbook, except * populationpyramid.net

Immunoglobulins (IgGs) – Forecast to 2024
(Market volume in tons)

IgG Market Size w/o COVID-19 impact
(Volume in tons)



COVID-19 impact

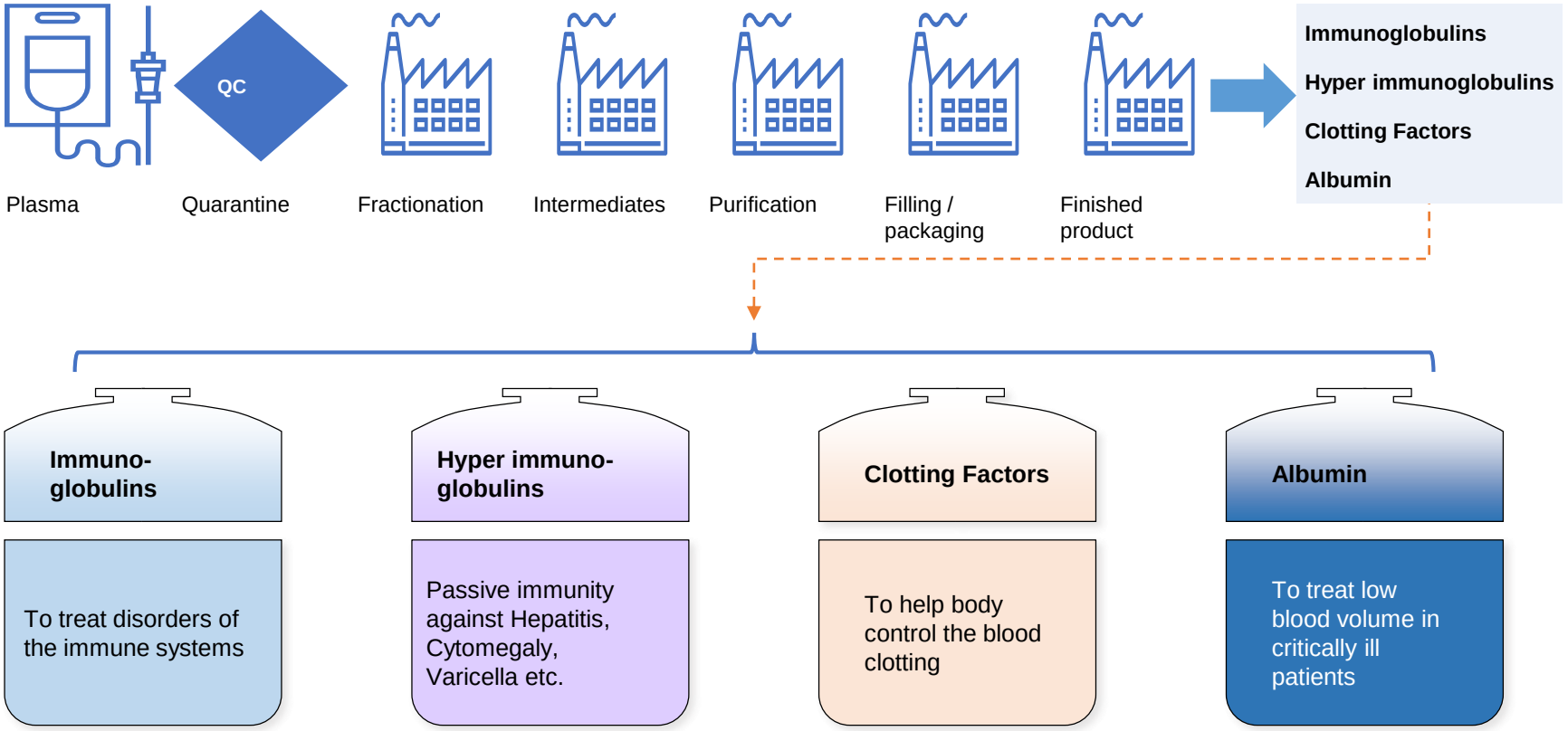
- **2020**: No/ minor impact on global IgG market expected
- **2021**: Slow down in plasma collection volumes in 2020 expected to lead to tight global supply

- The global IgG market is projected to reach > 330 t in 2024 at a CAGR (2018 – 2024) of 9%.
- North America accounted for a share of 47% in 2018 and is estimated to reach 155 t by 2024 from approximately 96 t in 2018, at a CAGR (2018 – 2024) of 8%.

MPI based on MRB (2018, 2019), PPTA (2020), Markets and Markets (2019); Morgan Stanley May 2020, „ A collection of sensitives"; Morgan Stanley June 2020 „Global Plasma Tracker"

Biotest core business overview

Biotest is a vertically integrated business, from plasma collection through production and distribution



Biotest Product Portfolio Overview

Biotest produces and sells

biological medicinal products in three therapeutical areas, that are either obtained from human plasma or manufactured using biotechnological methods

Clinical Immunology	**Haematology**	**Intensive Care Medicine**
Disorders of the immune system	Diseases of the blood and blood-forming system	Acute, mostly life-threatening diseases
Intratect® Hepatect® Zutectra®, Fovepta® Cytotect® Varitect®	Haemoctin® Haemonine® Vihuma ®	Pentaglobin® Human Albumin Biseko® Cofact®

Clinical Immunology

Intratect (IVIG)
- high quality immunoglobulin
- in 5% and 10% concentrations

Unique Hepatitis B hyper-immunoglobulin **portfolio (Hepatect, Zutectra and Fovepta)**:
- Leader in post Transplantation prophylaxis
- Unique subcutaneous solution to meet patient's needs

Cytomegalovirus hyper-immunoglobulin **(Cytotect):**
- Strong development on organ transplant
- New Mutual recognition procedure in EU/ new launch in HSCT*

Varicella Zoster Virus hyper-immunoglobulin **(Varitect):**
- Strong and fast efficacy against herpes zoster virus (shingles)
- Effective reduction of post-herpetic neuralgia

*: HSCT = hematopoietic stem cell transplantation

Biotest offers a broad portfolio of high quality Hepatitis B Immunoglobulins (HBIG)

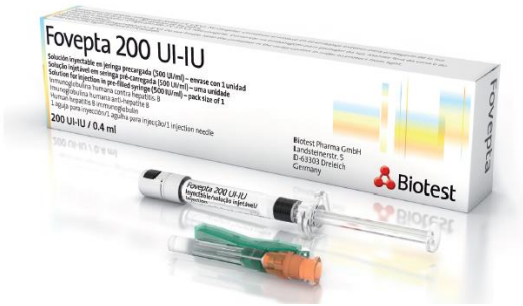
Hepatect®CP

- Good safety profile (no nephrotoxicity)
  and quality formulation (no sucrose)
- Broad indications
- Various sizes
- Ready to use
- Approved since 1982
- Authorized: 42 countries

Zutectra®

- Convenient (ready to use, easy to use, and early use 1 week after Liver Transplantation)
- Only SC HBIG in the market
- Less painful form of administration (compared to IM)
- Provides high quality of life (compare TWINSII study)
- Approved since 2009
- Authorized: 38 countries

Fovepta®



- Only subcutaneous Hepatitis B immunoglobulin for newborns
- Low volume
- Ready to use
- Less painful (compared to i.m./ i.v.)
- Approved since 2012
- Authorized in 10 countries

Haematology

Haemoctin - The Wild Type Factor VIII Concentrate:
- Consists of the natural complex of factor VIII and von Willebrand factor
- Safety, efficacy and low immunogenicity proven by the longest long-term noninterventional study performed so far with a single factor VIII concentrate
- Easy and convenient handling (small injection volume, modern transfer system Mix2Vial, two years storage at room temperature)

Haemonine - The Natural Factor IX Concentrate:
- High specific activity and minimal thrombotic risk
- Excellent recovery and long half-life
- Easy and convenient handling (modern transfer system Mix2Vial, two years storage at room temperature)

Vihuma (recombinant Factor VIII (recFVIII):
- First recFVIII derived from human cell line
- Vihuma is the factor VIII concentrate which is closest to the Wild Type
- Low immunogenicity

Intensive Care Medicine

Pentaglobin:
- >30 years of Immunglobulin M experience
- Pentaglobin reduces mortality in sepsis patients
- Pentaglobin is the only approved (IgM-enriched) immunoglobulin preparation for treatment of severe bacterial infections

Albiomin:
- Biotest Albiomin shows the highest purity (lowest aluminum, lowest salt, no detectable ethanol)
- First sales in China

Prothrombin Complex Concentrate (PCC)/ Cofact:
- FII, FVII, FIX and FX
- Cofact is the only heparin free product

Investment into BNL – strategic development

Today (current factory)

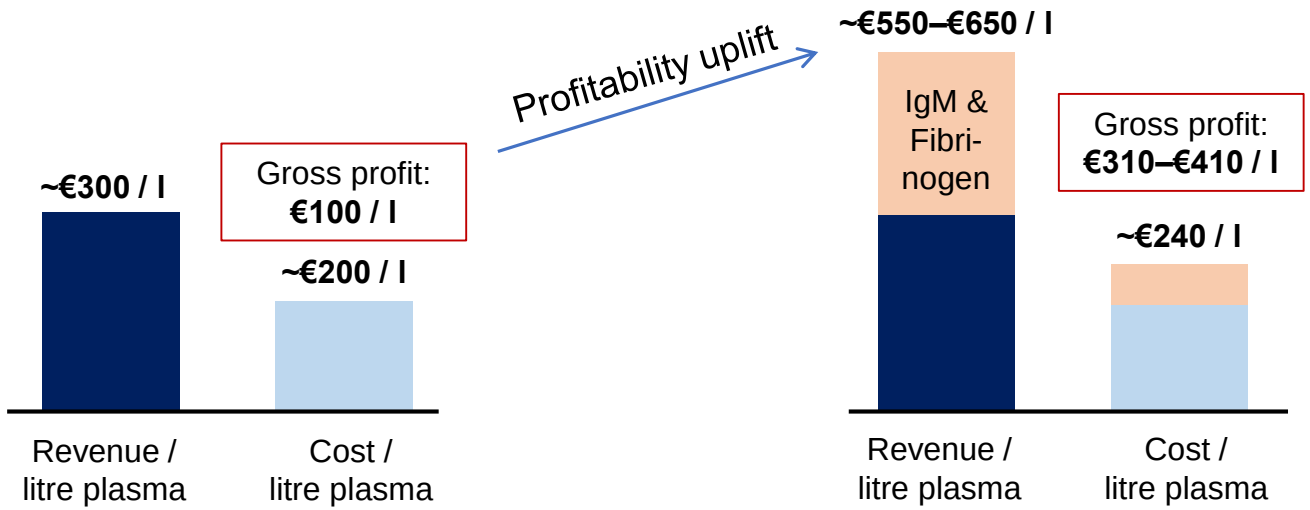
3 products out of **1** litre plasma

Capacity expansion: ~ 6 t

BNL ramped-up

5 products out of **1** litre plasma

~ 12.5 t immunoglobulins



Product portfolio Biotest today / tomorrow

Today		Tomorrow
Polyvalent IgG Intratect 5% Intratect 10 %	+	**Polyvalent IgG** IgG Next Gen
Hyper – IgG/ Specialty products Hepatect (Hep B) Zutectra (Hep B) Fovepta (Hep B) Cytotect (Cytomegaly) Varitect (Varicella-Zoster)	+	**Covid-19** Hyper-Immunoglobulin
Specialty products Pentaglobin (IgM enriched IgG) Cofact	+	**Specialty products** Trimodulin (IgM enriched IgG)
Haemophilia Haemoctin (FVIII) Haemonine (FIX)	+	**Fibrinogen** Acquired Fibrinogen deficiency Congenital Fibrionogen deficiency
Human Albumin Albiomin 5 % Albiomin 20%		

Research & Development

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Strategic pillars of BNL development program

- Globalization of products
- More products out of one litre plasma
- Specialty plasma products (high medical need)

Today

F VIII | Albumin | IgG

BNL

F VIII | Albumin | IgG | Trimodulin | Fibrinogen

Research & development projects to market

2020

- Albumin China
- MRP[1] Cytotect

2021

- **IgG Next Generation**
  - PID[2]
  - ITP[3]
- **Trimodulin (IgM Con.)**
  - Esscovid study
- Albiomin (BNL)
- Haemoctin (BNL)

>2021

- **IgG Next Generation**
  - Subcutaneous (SC)
  - Dermatology
- **Trimodulin (IgM Con.)**
  - sCAP[4]
- **Fibrinogen**
  - congenital
  - acquired
- Haemophilia A Therapeutic

1: Mutual Recognition Procedure; 2: Primary Immune Deficiency;
3: Idiopathic Thrombocytopenic Purpura; 4: severe Community acquired Pneumonia

IgG Next Generation (IVIG, 10%)

- New efficient production process of the “IgG Next Generation” immunoglobulin with high IgG yield established
- One product suitable for worldwide commercialization
- "Master product" for the Biotest Next Level production plant

Clinical development

- **Phase III study in PID* (EU + US; study 991):**
  - Treatment of adults and children completed
  - Evaluation of the study has begun

- **Phase III study in ITP** (EU; study 992):**
  - Treatment of adults and children completed
  - Data shows expected good efficacy and a good safety profile of the product

*: Primary Immune Deficiency; **: Idiopathic Thrombocytopenic Purpura

Fibrinogen

Indication

Congenital fibrinogen deficiency and acquired fibrinogen deficiency in the indication severe spinal surgery

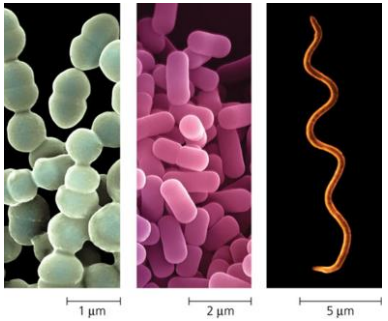
Clinical development

- **Phase I/ III study (study No. 984) in congenital fibrinogen deficiency:**
  - Largest clinical trial in congenital fibrinogen deficiency worldwide
  - Data analysis currently underway
  - Initial results confirm high expectations regarding efficacy and safety
  - Final results expected end of Q4 2020
- **Phase III study (ADFIRST study No. 995) in acquired fibrinogen deficiency:**
  - Recruitment ongoing
  - The ADFIRST study is a prospective, active-controlled, multicenter phase III study in patients who have a high blood loss during elective spinal surgery and Pseudomyxoma peritonei (PMP, tumor)

Trimodulin – IgM-enriched Immunoglobulin

- Neutralization of multiple pathogens
- Binding of toxins and inflammation activators
- Reducing the secretion of immune mediators
- Immune modulation

>> **Broad therapeutic potential in severe infection**



i.e. K. pneumoniae, P. mirabilis, P. aeruginosa, E. sakazakii, Enterococcus sp., Staph. aureus, C. difficile, C. jejuni, C.albicans, E. coli, P. aeruginosa, S. marcescens, Enterobacter sakazakii

Clinical development

- **Phase II "ESsCOVID" study for treatment of patients with severe COVID-19 pneumonia:**
  - Study has been submitted to Competent authority and ethics commission
- **Phase III study "ESsCAPE" and pediatric development plan in sCAP, also accounting for COVID-19 patients:**
  - Coordination with the US Food and Drug Administration (FDA), EMA and Paul Ehrlich Institute has taken place; phase III study and pediatric development plan in preparation

Plasma Donation and Plasma Centres

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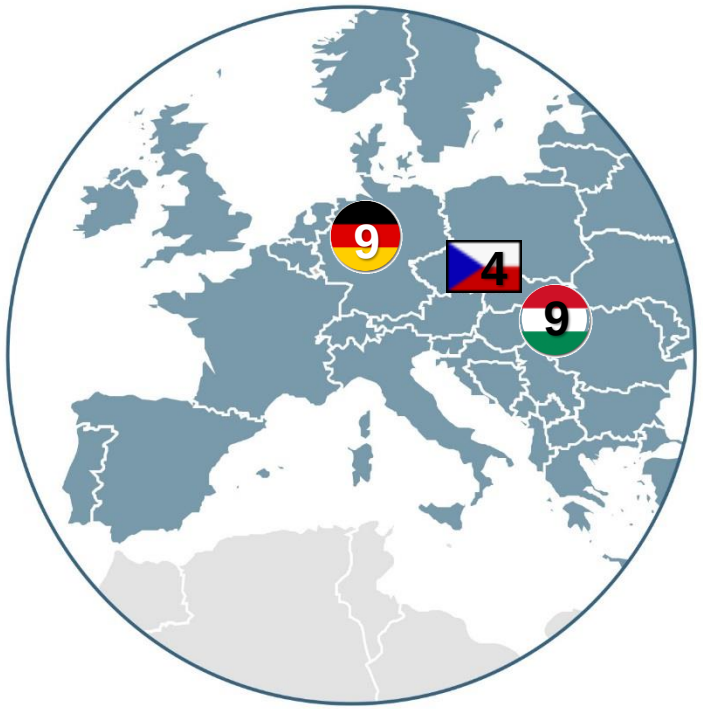
Expansion of plasma collection centres

Europe: 22 centres

- Last centres opened in
  - Hanover, Germany
  - Budapest, Hungary
  - Jihlava, Czech Republik

- Expansion of plasma centres ongoing



Plasma is needed!!!

…more urgent than ever….!!!

- .....particularly in Corona virus times
- Biotest Plasma centres are **open** in Germany, Hungary and Czech Republic
- Worldwide, millions of people need medicines made from plasma, where no other treatment option exists

Plasma donations save lives!!!

Biotest Next Level

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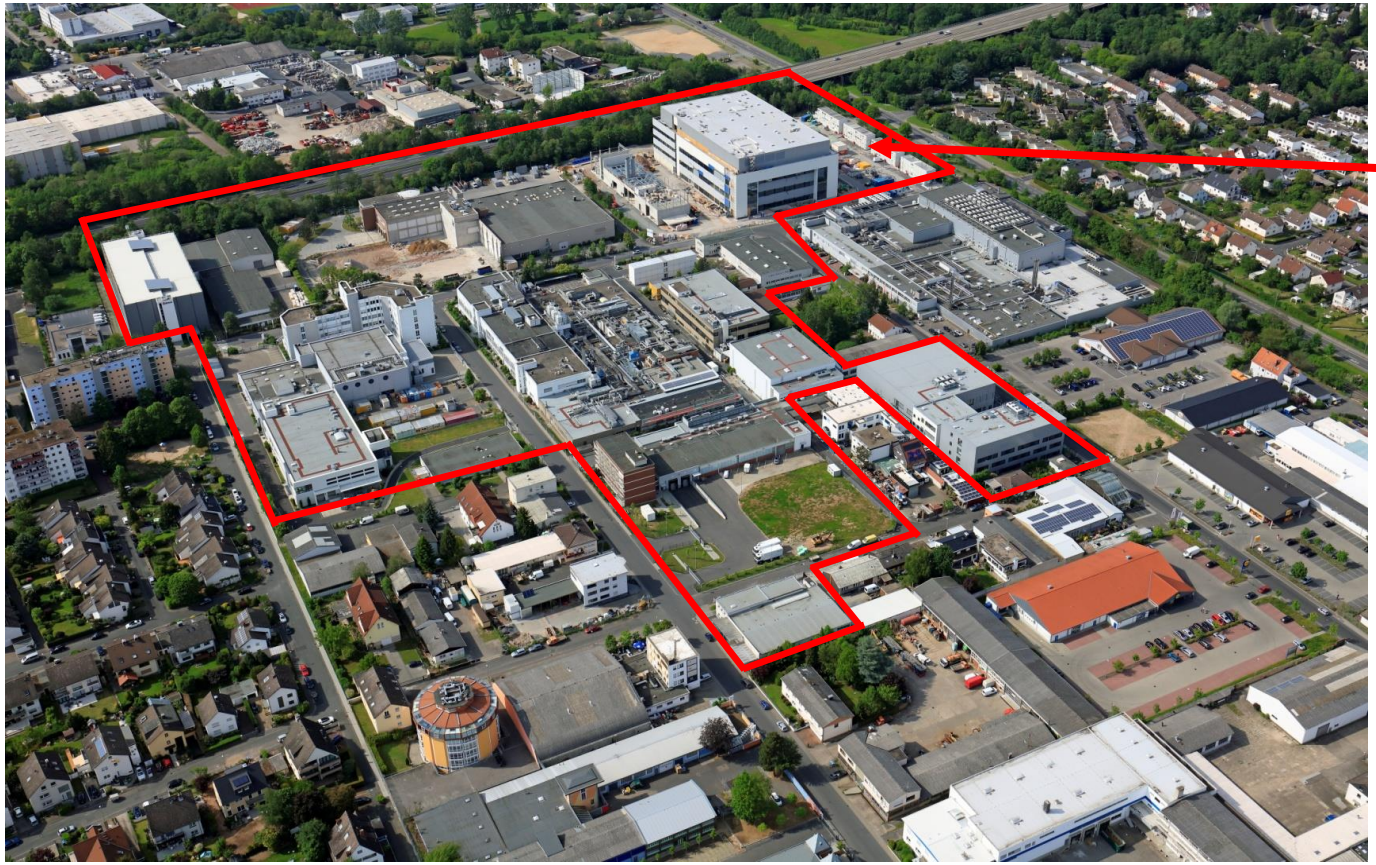
Biotest Next Level

Entire Biotest area



BNL 2019

Preparation of infrastructure (implementation of pressure ranges in clean rooms and locks)

Commissioning & qualification of clean rooms

Performance qualification of sterile media (AP*, WFI**, Pure Steam, Compressed Air)

Inspection of infrastructure by the Darmstadt regional council

5-8 Nov. 2019

OQ completed (production equipment operated by Biotest)

Implementation of manufacturing processes started

*: AP = Aqua Purificata; **: WFI = Water-For-Injection

- Clean rooms and media systems are operated under full GMP conditions

BNL 2020 – Successful second inspection of BNL production plant passed

2nd Inspection of the infrastructure by Darmstadt Regional Council

Period: 23-25. June 2020

Purpose: Inspection of GMP requirements as part of the manufacturing license

Authority: Regional council Darmstadt, Germany

Scope:

Qualification of the actual product-carrying production equipment for the IgG Next Gen process as well as in-process laboratories

Result:

no Critical; no Major; only two Minor findings were recorded.
=> 2 further inspections in 2020/21 to be conducted

Implementation of manufacturing process continues...

1st full scale, overall (Plasma => Drug Substance) Engineering Run completed

=> Further Engineering and Validation Runs are in progress

Summary

Next Steps

- Biotest Next Level progressing
- Clinical trials for new BNL products ongoing:
  IgG Next Gen, Fibrinogen and Trimodulin
- Two development projects regarding a therapy for COVID-19 infection started
- Opening of new plasma collection centres in Europe





Financial Calendar 2020

Contact

Financial Calendar 2020

12 Nov 2020	Q3 Report 2020
11 May 2021	Annual General Meeting

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