Biotest AG

Company Presentation Q1-Q3 2020

November 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: Q1-Q3 2020 at a glance

- Sales increase of +15.8% to € 341.6 m in Q1-Q3 2020 vs. € 294.9 m in Q1-Q3 2019
- EBIT in Q1-Q3 2020 at € -7.8 m vs. € -8.2 m in Q1-Q3 2019
- Adjusted EBIT increased to € 51.6 m in Q1-Q3 2020 vs. € 42.6 m in Q1-Q3 2019
- Two development projects regarding a therapy for COVID-19 infection continued
- Biotest Next Level project progressing; third partial approval by the Darmstadt Regional Council in October 2020

Biotest - Corona update

- **Covid-19 R&D projects**
  - Covitect 10% - Hyperimmunoglobulin by plasma alliance
  - Trimodulin phase II „ESsCOVID“ study
- **Sales & Marketing**
  - Very limited (physical) access to customers
  - Increase of digital sales & marketing activities
  - Again: increasing number of Covid-19 patients in ICU therefore postponement of other surgeries
- **Production**
  - Slightly reduced output as result of COVID-19 protection measures
- **Plasma supply**
  - Reduced plasma collection in March & April
  - Currently, in Germany, Hungary and Czech Republic plasma collection almost on pre-Corona level again

Financials Q1-Q3 2020

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Income statement
(€ million)

	Q1-Q3 2019	Q1-Q3 2020
Sales	**294.9**	**341.6**
Operating costs & expenses	-303.1	-349.4
Operating Profit (EBIT)	**-8.2**	**-7.8**
Financial result, taxes	5.3	-24.0
Earnings after tax (EAT) Biotest Group	**-2.9**	**-31.8**

EBIT regular and adjusted
(€ million)

	Q1-Q3 2019	Q1-Q3 2020
EBIT reported	**-8.2**	**-7.8**
Biotest Next Level costs*	49.7	59.3
Monoclonal antibodies	1.1	0.1
EBIT adjusted	**42.6**	**51.6**

*: including R&D costs for BNL development projects

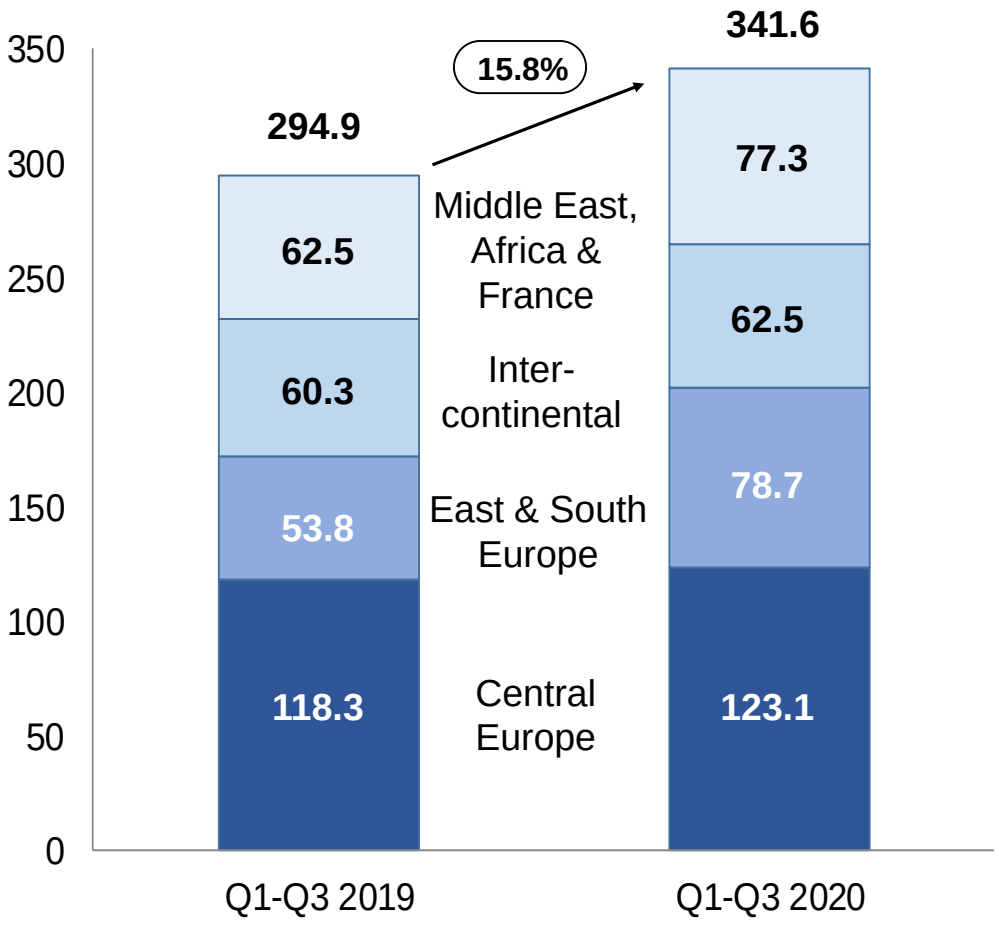
Biotest Next Level (BNL) costs in Q1-Q3 2020

1. **BNL facility costs**: **€ 27.8 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: **€ 31.5 million**; thereof:
   - € 11.3 million - IgG Next Generation
   - € 12.4 million - Trimodulin (IgM Concentrate)
   - € 7.8 million - Fibrinogen

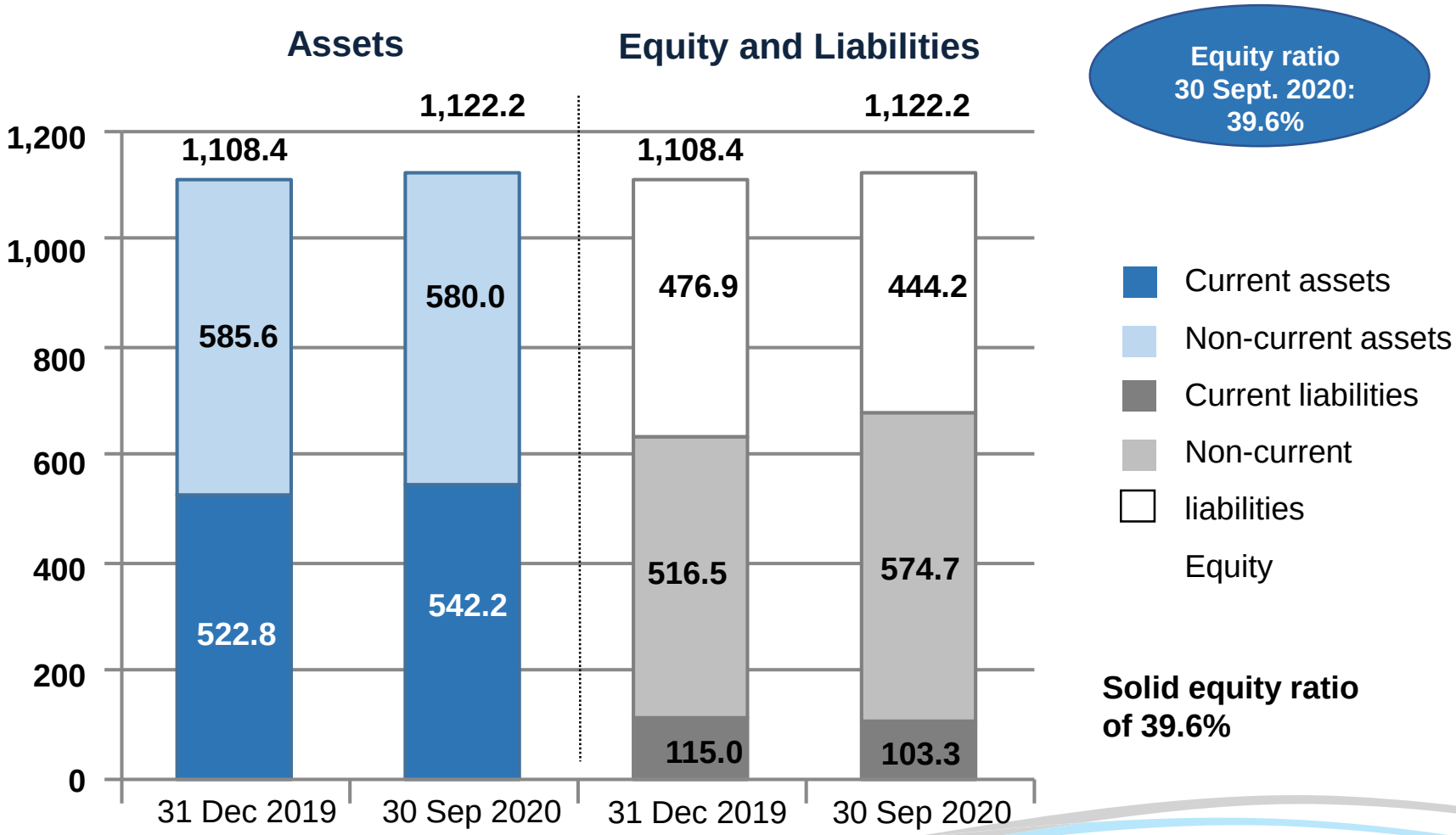
Total BNL costs: **€ 59.3 million** in Q1-Q3 2020

Sales development
(€ million)



- **Therapy sales** up +14.1% to € 303.7 m in Q1-Q3 2020 vs. 266.1 m in Q1-Q3 2019
- **Segment Plasma & Services**: growth of +43.8% due to significantly higher toll manufacturing (Middle East)

Balance sheet (€ million)



Equity ratio 30 Sept. 2020: 39.6%

Solid equity ratio of 39.6%

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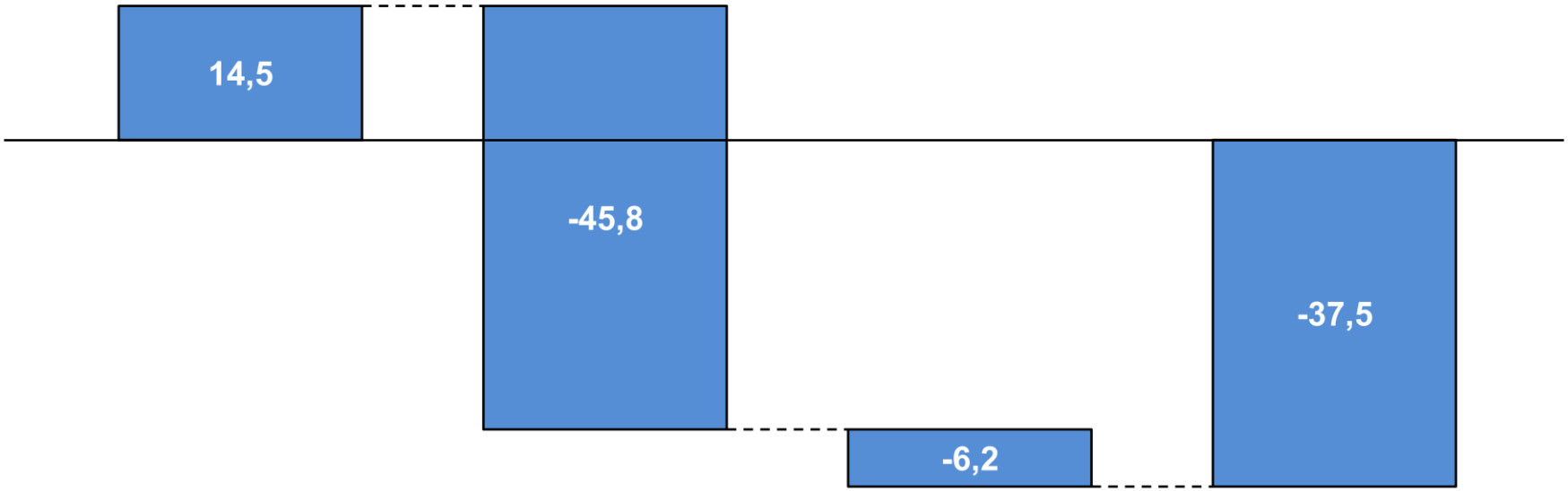
Cash flow from operating activities 2020 (€ million)

Operating cash flow before changes in working capital + Cash flow from changes in working capital + Interest & tax expense = Cash flow from operating activities



Guidance 2020*confirmed

Guidance of 30 March and 12 August 2020 confirmed:

Sales: In 2020 sales will increase by 10 percent compared to 2019

EBIT: EBIT will be at approx. **€-10 million**

* provided, no increase of negative Corona effects in the remaining weeks

COVID-19 activities, Research & Development

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Biotest - Three COVID-19 activities ongoing

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

2. Development of a new **Hyperimmunoglobulin “CoviTect 10%”**

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. COVID-19 Hyperimmunoglobulin

CoVIg-19 PLASMA ALLIANCE
Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

- Entirely new drug: COVID-19 Hyperimmunoglobulin “CoviTect 10%”
- Use of plasma donations containing COVID-19 antibodies
- Global cooperation within “CoVIg-19 PLASMA ALLIANCES”
- All stakeholders put their expertise in common but work using their own funds
- Solid evidence generation in NIH-sponsored world-wide INSIGHT 013 clinical trial with 500 patients
- Hyperimmunoglobulins will be prepared using each proprietary formulas and industrial processes

With optimal project progress, drug available beginning of 2021 at the earliest

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2. COVID-19 Hyperimmunoglobulin

CoVIg-19 PLASMA ALLIANCE

Working Together to Fight COVID-19 with Immunoglobulin (Ig) Therapy

1. FOUNDERS

CSL Behring

Takeda

2. MEMBERS

Biotest

LFB S. A.

octapharma

3. CONTRIBUTORS

ADMA BIOLOGICS

biopharma

GC Pharma

Sanquin

Liminal BioSciences

bpl Bio Products Laboratory

National Bioproducts Institute NPC

Silanes

4. SUPPORTERS

Bing

Edelman

facebook

Google

Microsoft

msn

PALL

Uber Health

SURVIVOR CORPS

IgNS Immunoglobulin National Society Advancing Ig Therapy Practice

AsahiKASEI

3. Trimodulin - background for development in COVID-19

Strong medical rationale

- 50-70% reduction of mortality in similar patient population: Mechanically ventilated patients with severe Community Acquired Pneumonia (sCAP) and high inflammation markers and/or low IgM levels
- No major advance in medical practice in this indication in last 40 years
- Convincing mode-of-action in COVID-19 *in vitro* - at the very front of the competitors

Strong strategic rationale for Biotest

- Great opportunity for Biotest to gain market approval for Trimodulin before large phase III study in sCAP will be finished (approx. 4 years earlier)
- Additional plasma product from Biotest Next Level facility
- Attractive positioning in addition to standard-of-care
- Additional costs for COVID-19 activities including the ESsCOVID trial can be balanced by postponement of the much larger phase III trial (ESsCAPE)
- Change in patient population for phase III will be addressed in ESsCOVID trial

3. Trimodulin - clinical development and timeline overview

New phase II ESsCOVID study exclusively for severe COVID-19 patients submitted after feedback from EMA.

To offer a fast response during the current outbreak, gain experience in COVID-19, and leverage the big opportunity to significantly shorten the time-to-market (conditional approval).

Work package	Start
Submission CTA	Jul 2020 ✓
First-patient-in	Oct 2020 ✓
Last-patient-out	Q1 2021*
Clinical study report ready for submission	Q2-Q3 2021
First sales	Q4 2021 – Q1 2022**

* Based on different pandemic scenarios **Depending on study outcome and acceleration options

3. Trimodulin - clinical development in phase II

- **Phase II study "ESsCOVID" (Escape from severe COVID-19) study** exclusively in severe COVID-19 patients:

  - Submission of study to Competent Authority and responsible Ethics Committee;
  - Study planned in France, Spain, Brazil and Russia in 10 sites; first patient-in in Spain
  - Multinational phase II clinical trial with approx.160 adult patients to be enrolled; Patients with confirmed severe COVID-19 disease with CAP or ARDS, receiving noninvasive ventilated (NIV) or high oxygen therapy; signs of inflammation: CRP ≥50 mg/mL
  - Biotest targets a conditional market authorization

  ➢ To offer a fast response during the current outbreak and have a possibility to shorten the time-to-market (conditional approval)

3. Trimodulin - clinical development in phase III

- Design of **phase III "ESsCAPE" study and pediatric development plan** in sCAP, also accounting for COVID-19 patients:
  - Start of study will be after phase II "ESsCOVID" study
  - Coordination with US Food and Drug Administration (FDA), EMA and Paul Ehrlich Institute has taken place
  - Phase III study and pediatric development plan in preparation

➢ **The goal is to obtain a broad indication in sCAP including COVID-19**

3. Trimodulin – commercial aspects

➢ **COVID-19 and severe Community Acquired Pneumonia (sCAP)**

- >80 000 patients/year in initial target population already exceeds current manufacturing capacity
- Market size in sCAP alone approx. 350,000 patients worldwide[1]
- Sales potential min. €300 million p.a.
- Good clinical outcomes (mortality reduction) can further drive value
- Significant upside due to higher price depends on data of clinical trials

➢ **Several upside indications**

1 Source: Biotest market research

IgG Next Generation

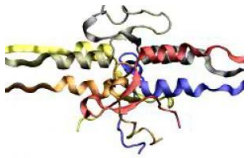
- Immunoglobulin “IgG Next Generation” for patients with immune system dysfunctions and autoimmune disorders
- New efficient production process of “IgG Next Generation” immunoglobulin with high IgG yield established (4.5 g/l)
- One product suitable for worldwide commercialization
- "Master product" for the Biotest Next Level production plant

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

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

Fibrinogen - 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

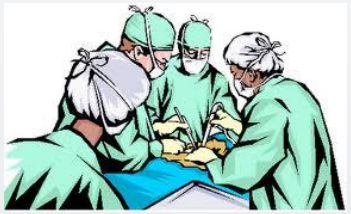
Phase I/III study
congenital fibrinogen deficiency

- 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

- 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
- **Phase III: ongoing**



Fibrinogen – clinical development

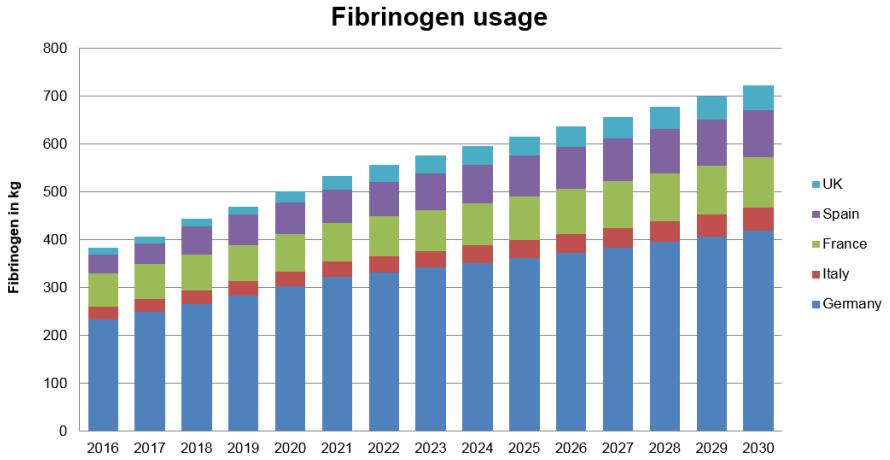
Clinical development

- **Phase I/ III study (study no. 984) in congenital fibrinogen deficiency:**
  - Treatment of adults and children completed
  - Largest clinical trial in congenital fibrinogen deficiency worldwide
  - 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 in the indication severe spinal surgery:**
  - 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 (tumor surgery)

Fibrinogen market

- Growing market due to increasing use of point of care diagnostic and changing treatment concepts
- State-of-the-art process with low processing costs due to UVivavtect® technology



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

Plasma Donation and Plasma Centres

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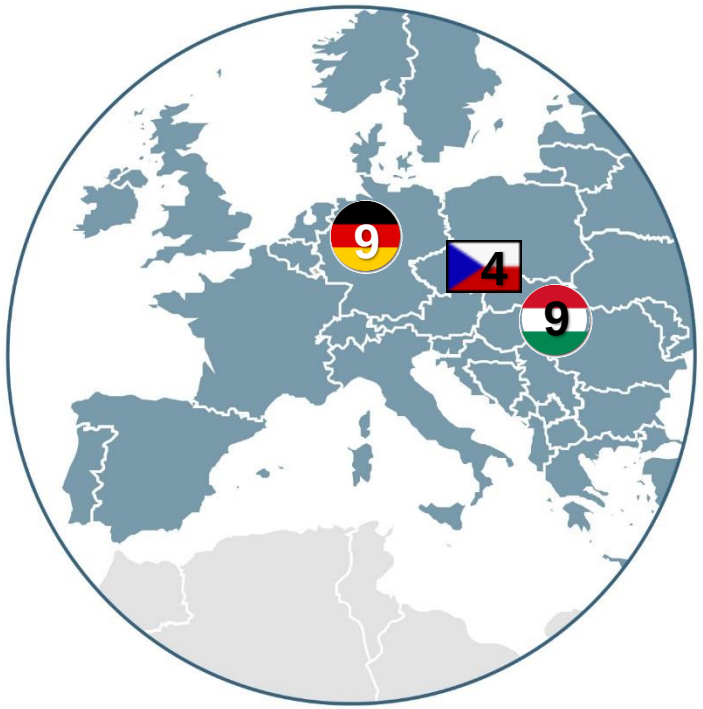
Expansion of plasma collection centres

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

➢ **COVID-19 & the plasma donation**:
To all cured corona patients: Your plasma can save lives.

Plasma donations save lives!!!

Biotest Next Level

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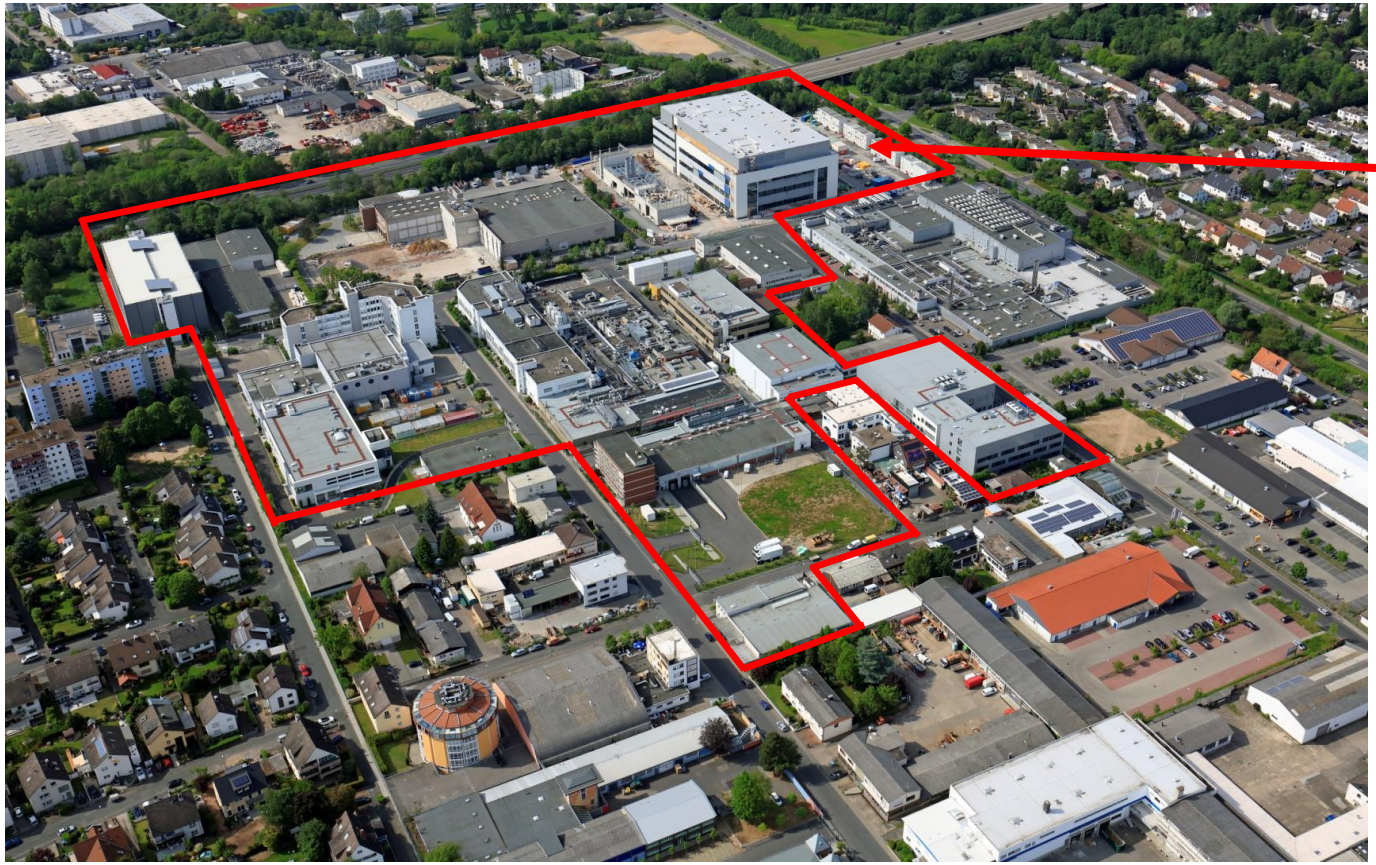
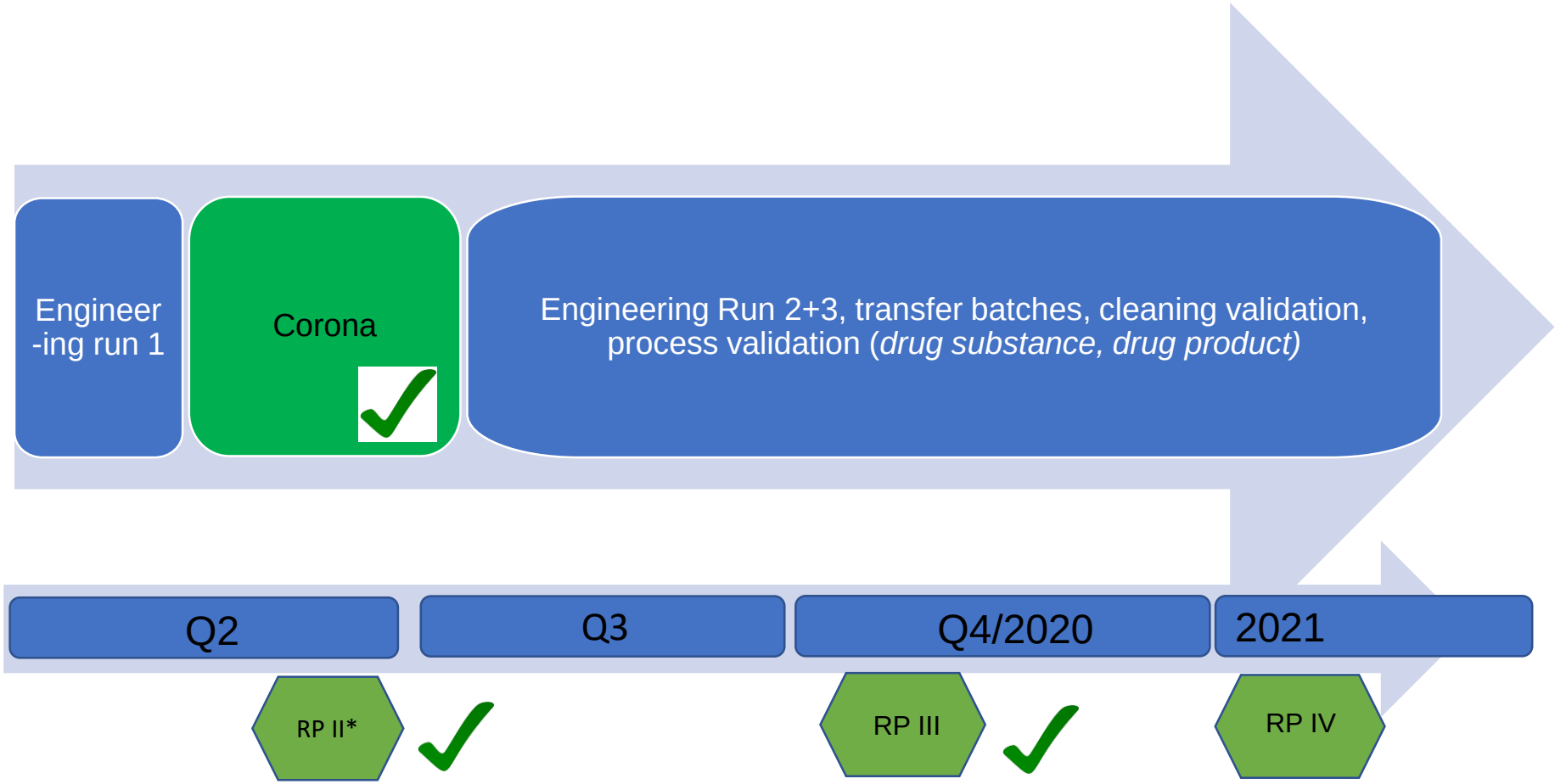
Biotest Next Level

Entire Biotest area



BNL – path to operation



* Inspection by the Darmstadt regional council (Regierungspräsidium Darmstadt)

Summary

Next Steps

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





Financial Calendar 2021 and Contact

Financial Calendar 2021

31 Mar 2021	Q1 Report
11 May 2021	Annual General Meeting
11 May 2021	Q1 Report
12 Aug 2021	H1 Report
11 Nov 2021	Q1-Q3 Report

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