Biotest AG

Half year results 2021

12 August, 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.

Facts & Figures H1 2021

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Biotest Group

- Founded 1946, IPO 1987
- 1,963 FTE‘s
- 8 Affiliates in Europe and Brazil
- 25 Plasma Collection Centres in GER, HU and CZ
- 1 Production site in GER (capacity 6 t IVIG) & 1 production site (BNL) in commissioning (6.5 t IVIG)
- Management Board: 2 members (m); Supervisory Board: 6 members (4 m; 2 f)
- H1 2021 Sales: +9.8% compared to H1 2020; H1 2021 adjusted EBIT: € 29.5 million

Financials H1 2021

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Income statement
(€ million)

	H1 2020	H1 2021
Sales	**234.8**	**257.8**
thereof: Therapy	207.4	224.1
Plasma & Services	24.9	29.9
Other Segments	2.5	3.8
Operating costs & expenses	-234.1	-266.4
Operating profit (EBIT)	**0.7**	**-8.6**
Financial result, taxes	-17.4	-9.6
Earnings after tax (EAT) Biotest Group	**-16.7**	**-18.2**

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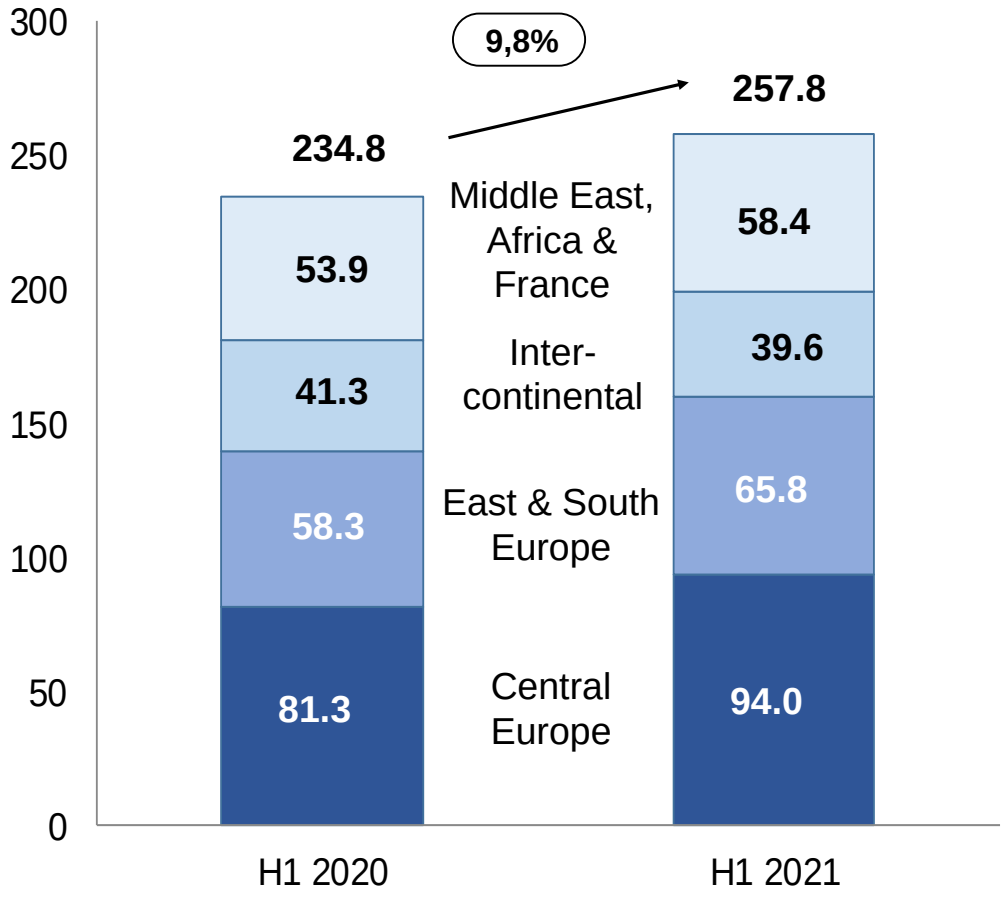
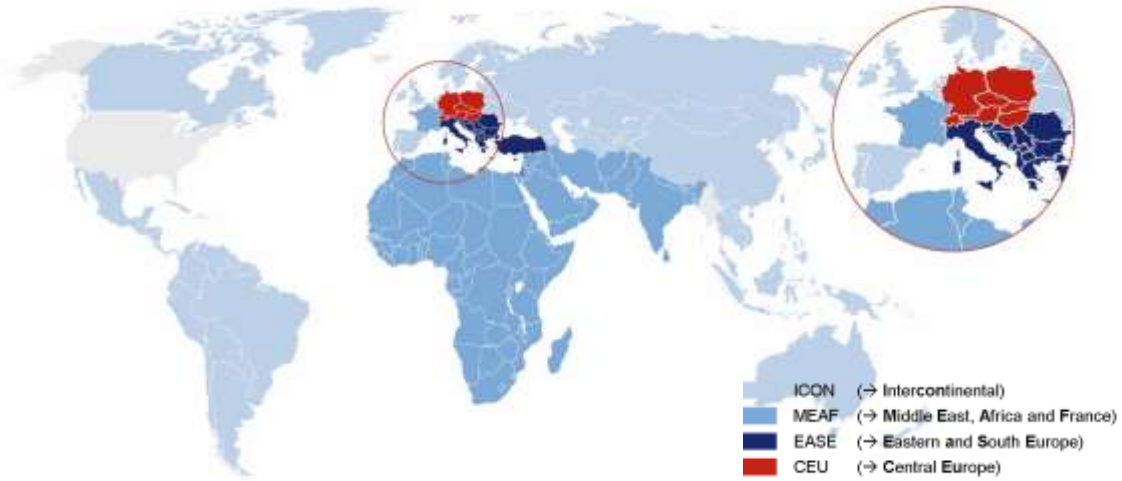
Sales development of sales regions
(€ million)





- **Therapy sales** up +8.1% to € 224.1 million in H1 2021 vs. € 207.4 million in H1 2020
- **Segment Plasma & Services**: growth of +20.1% due to significantly higher toll manufacturing (Middle East)

Reconciliation EBIT H1 2020 – EBIT H1 2021
(€ million)

	€ million*
EBIT H1 2020	**0.7**
Change in Gross Profit (-15.3%)	-10.1
Change in Marketing & Distribution expenses (-0.4%)	0.1
Change in Administrative expenses (-10.2%)	1.7
Change in R&D expenses (-2.6%)	0.8
Change in OOI and OOE (-63%)	-1.7
EBIT H1 2021	**-8.5**

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

EBIT reported and adjusted
(€ million)

	H1 2020	H1 2021
EBIT reported	**0.7**	**-8.5**
Biotest Next Level costs*	40.3	38.0
Monoclonal antibodies	0.1	0.0
EBIT adjusted	**41.1**	**29.5**

*: including R&D costs for BNL development projects

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Biotest Next Level (BNL) costs in H1 2021

1. **BNL facility costs**: **€ 18.8 million**;
   - Facility costs (energy, building costs, security, etc.)
   - Depreciation
   - Personnel costs (for ramp-up, commissioning etc.)
   - Project administration

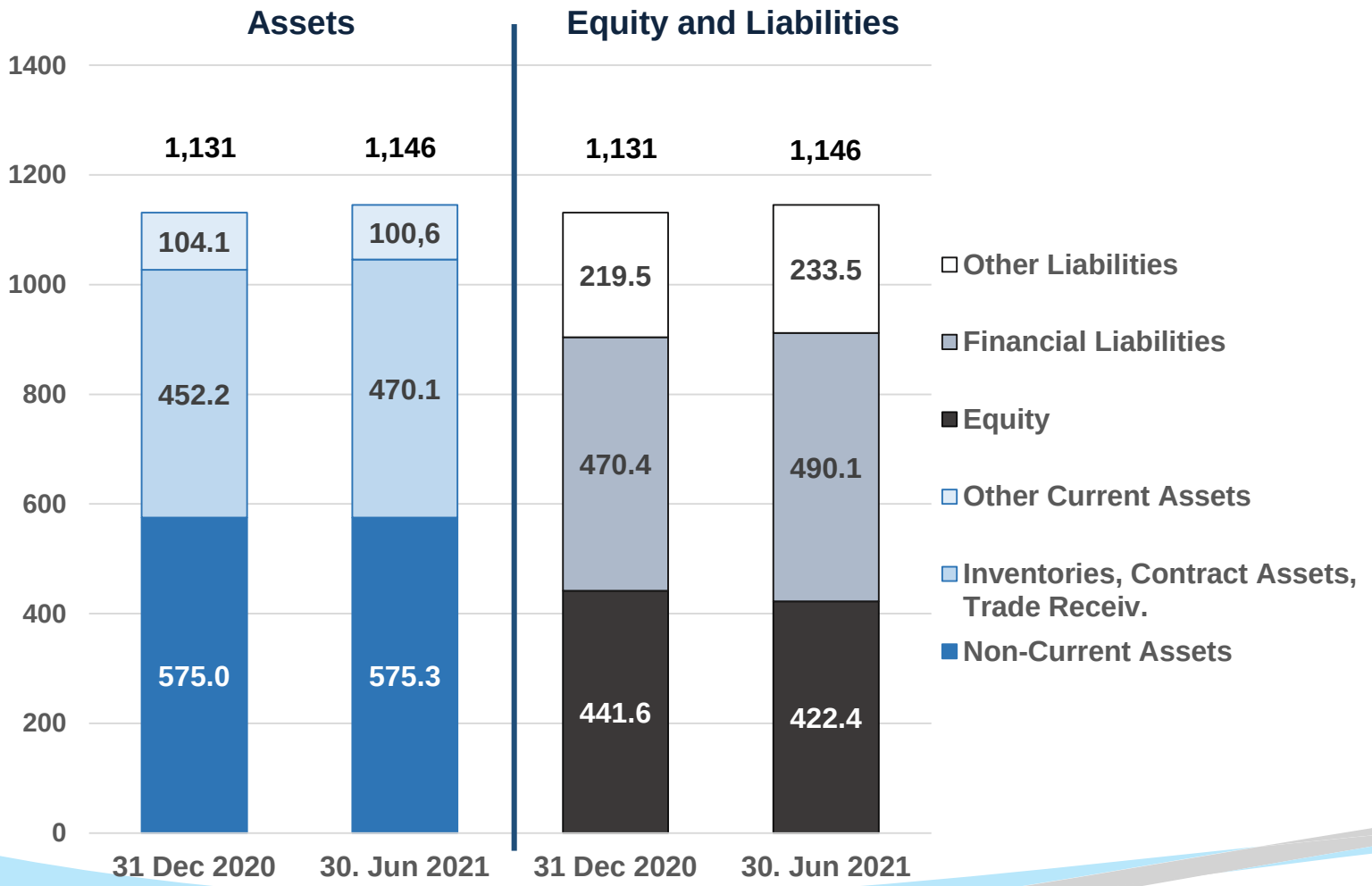
2. **BNL R&D** costs in total: **€ 19.2 million**; thereof:
   - € 6.7 million - IgG Next Generation
   - € 9.3 million - Trimodulin (IgM Concentrate)
   - € 3.2 million - Fibrinogen

Total BNL costs: **€ 38.0 million** in H1 2021

Reconciliation Financial Result H1 2020 – Financial Result H1 2021
(€ million)

	€ million
Financial Result, Taxes H1 2020	**-16.3**
Variation in valuation of ADMA shares held by trustee	+2.4
Higher interest expenses	-1.2
Higher FX / hedging costs	+6.8
Other	-0.9
Financial Result, Taxes H1 2021	**-9.2**

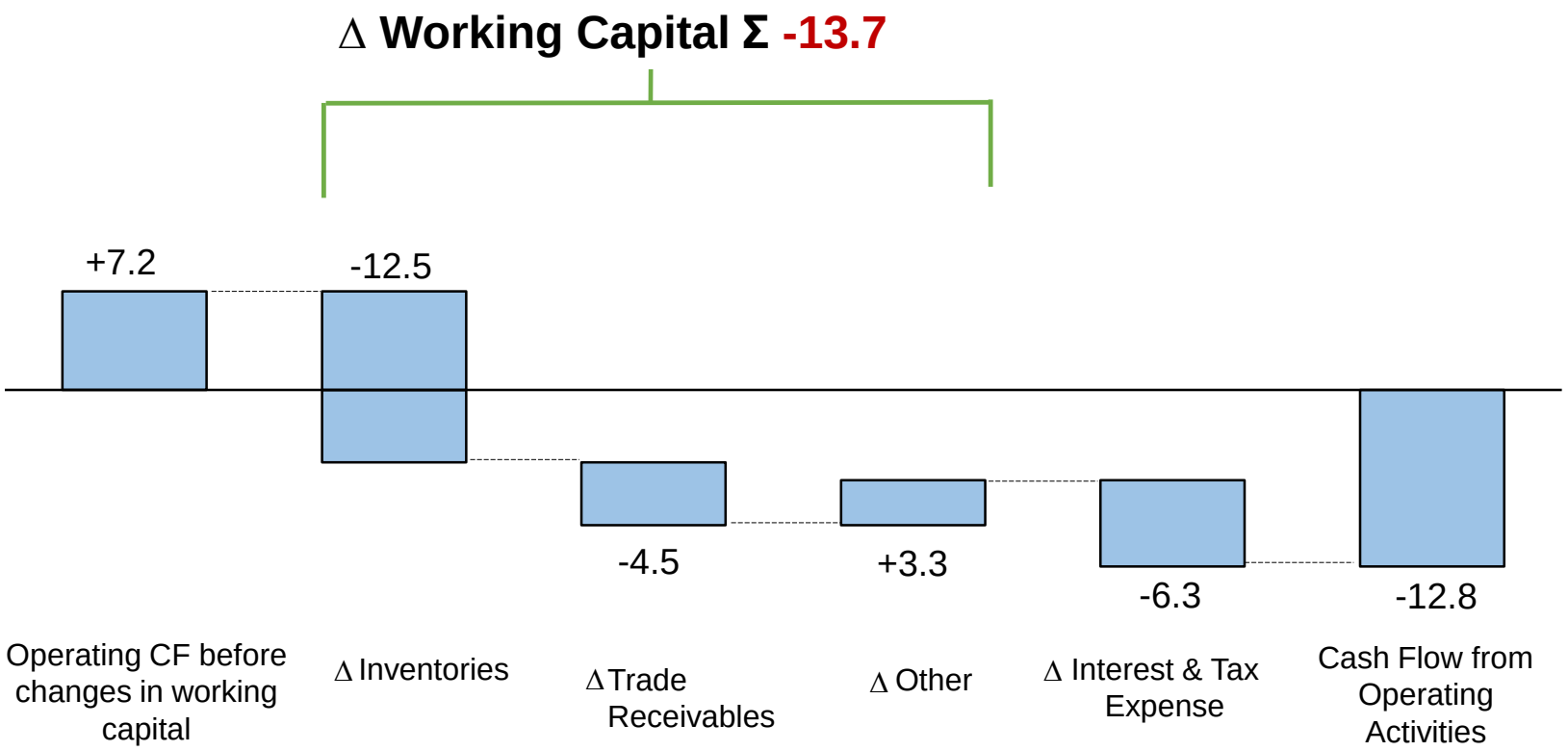
Balance sheet
(€ million)



Net debt:
30 Jun 2021:
€ 425 million

Equity ratio
30 Jun 2021:
41%

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



R&D update
for BNL projects

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BNL: IgG Next Generation

- Immunoglobulin “IgG Next Generation” for patients with immune system dysfunctions and autoimmune disorders

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

➢ First virtual Investigator meeting held with positive feedback on efficacy and safety data by investigators

➢ Abstracts planed in parallel to submission

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

BNL: 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
- Spinal surgery and Pseudomyxoma peritonei (tumor surgery) have been postponed due to Corona

Phase III: ongoing

BNL: Trimodulin

- **Strong medical rationale for Trimodulin (IgM/IgA Concentrate)**
  - 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
  - Convincing mode-of-action in COVID-19 *in vitro* - at the very front of the competitors
- **Phase II study: "ESsCOVID" (Escape from severe COVID-19)**
  - Multinational phase II clinical trial with 166 adult patients
  - Patients with confirmed severe COVID-19 disease with CAP[1] or ARDS[2], receiving non-invasive ventilated (NIV) or high oxygen therapy; signs of inflammation: CRP[3] >50 mg/mL

Work package	Start
Submission CTA[4]	Jul 2020 ✓
First-patient-in	Oct 2020 ✓
Last-patient-out	Q2 2021 ✓
Clinical study report ready for submission	Q3 2021
First sales	Q1 2022*

*Depending on study outcome and acceleration options

[1]: Community acquired Pneumonia [2]: Acute Respiratory Distress Syndrome [3]: C-Reactive Protein [4]: Clinical Trial Application

BNL: Trimodulin - clinical development in phase III – in preparation

Design of **phase III "ESsCAPE" study and pediatric development plan** in sCAP, also accounting for COVID-19 patients:

- Start of study after phase II "ESsCOVID" study, depending on the outcome of this study
- Coordination with US Food and Drug Administration (FDA), EMA and Paul Ehrlich Institute has taken place
- Phase III study preparation ongoing

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

BNL: 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

BNL update

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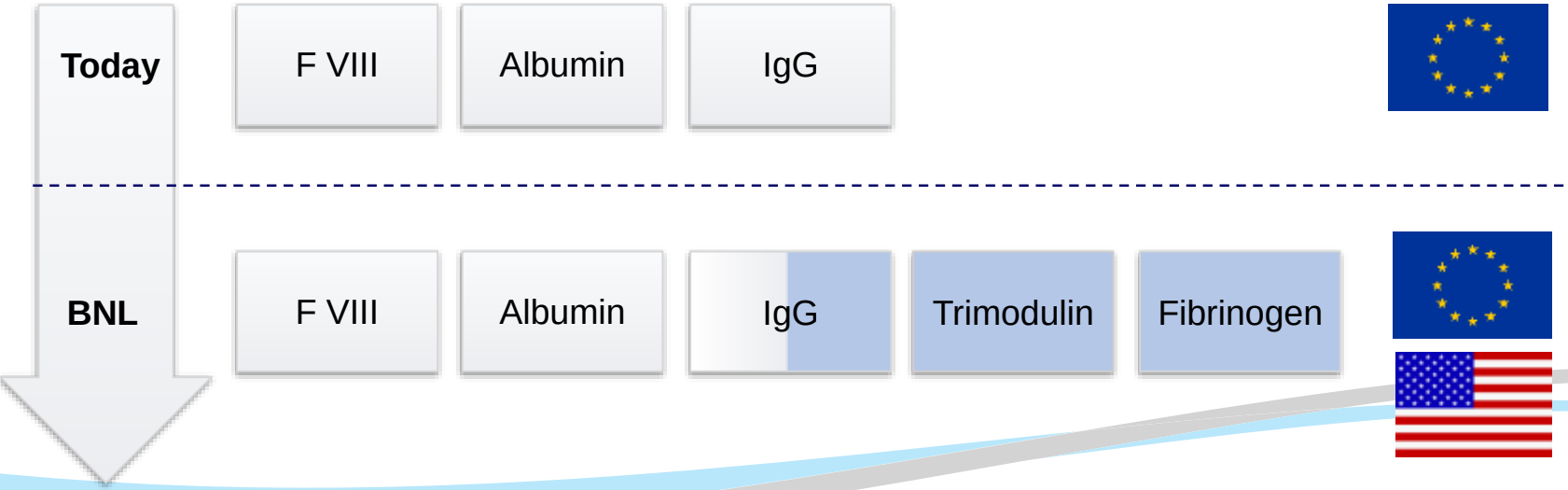
Biotest receives manufacturing license for new production facility

Biotest Next Level site

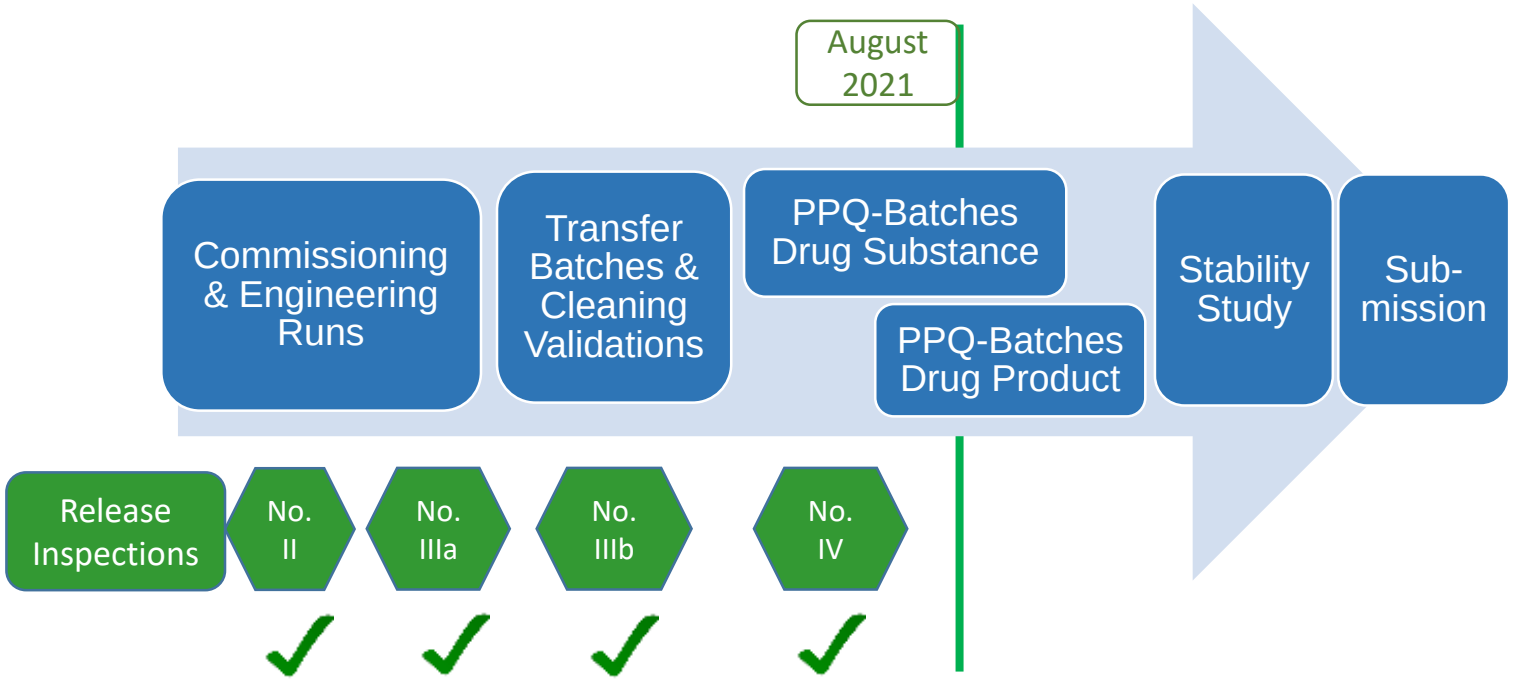
- Final inspection by the Darmstadt Regional Council and the Paul Ehrlich Institute successfully completed
- As a result, the manufacturing license was granted in accordance with §13 AMG (German Medicines Act)
- The final steps for the market approval of our new IgG Next Generation immunoglobulin still need to be completed
- Beginning of 2022, Biotest will apply for approval at the Paul Ehrlich Institute with the data of the first, currently produced batches and subsequently ramp up production in parallel
- Start of routine production and ramp-up of the plants is initiated

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 – IgG Next Generation



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.

Summary

- H1 2021 showed a 10% revenue increase despite the pandemic
- The pandemic will stimulate and motivate us: we will rather be encouraged by chances than frightened by the challenges
- We trust that Trimodulin will become a helpful therapy for severe COVID-19 patients – clinical trial results expected in August 2021
- We will continue to increase the number of our European plasma collection centers





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Financial Calendar 2021/ 2022 and Contact

Financial Calendar 2021

11 Nov 2021	Q1-Q3 Report
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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