Biotest AG

Ninemonth Report 2019

14 November 2019

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 figures reported relate to the Continuing Operations of the Biotest Group, if not specified otherwise. After the transfer of all US subsidiaries incl. our associate ADMA Biologics Inc., these activities are being reported as Discontinued Operations in the previous year.
- All comparative figures relate to the corresponding last year´s period, unless stated otherwise.

Biotest Group: Q1-Q3 2019 at a glance

- Guidance 2019 confirmed
- Sales of Continuing Operations in Q1-Q3 2019 at €294.9 m vs. €289.6 m in Q1-Q3 2018
- EBIT in Q1-Q3 2019 at €-8.2 m vs. €5.1 m in Q1-Q3 2018
- Opening of two new plasma collection centres in Germany and Hungary; Total number to date 21
- Biotest Next Level project progressing; First inspection by Darmstadt Regional Council on qualification of clean rooms and media systems passed on 8 Nov. 2019

Financials
Q1-Q3 2019

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Income statement
(€ million)

	Q1-Q3 2018	Q1-Q3 2019
Sales	**289.6**	**294.9**
Operating costs & expenses	-284.5	-303.1
Operating Profit (EBIT)	**5.1**	**-8.2**
Financial result, taxes	-11.7	5.3
Earnings after tax (EAT) from Continuing Operations	**-6.6**	**-2.9**
Earnings after tax (EAT) from Discontinued Operations	197.5	-
Earnings after tax (EAT) Biotest Group	**190.9**	**-2.9**

EBIT regular and adjusted
(€ million)

	Q1-Q3 2018	Q1-Q3 2019
EBIT reported	**5.1**	**-8.2**
Biotest Next Level costs*	37.8	49.7
Monoclonal antibodies	3.1	1.1
EBIT adjusted	**46.0**	**42.6**

*: including R&D costs for BNL development drugs

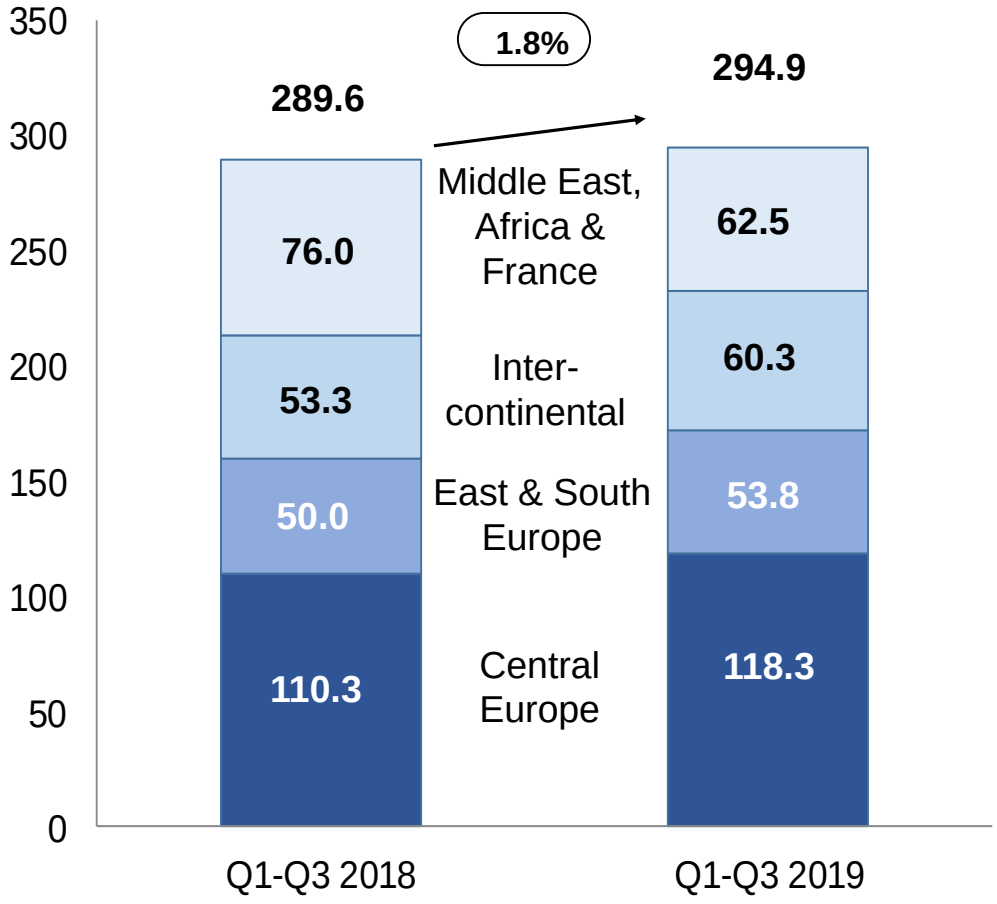
Biotest Next Level (BNL) costs in Q1-Q3 2019

1. **BNL facility costs**: **€ 21.0 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: **€ 28.7 million**; thereof:
   - € 13.2 million - IgG Next Generation
   - € 8.3 million - Trimodulin (IgM Concentrate)
   - € 7.2 million - Fibrinogen

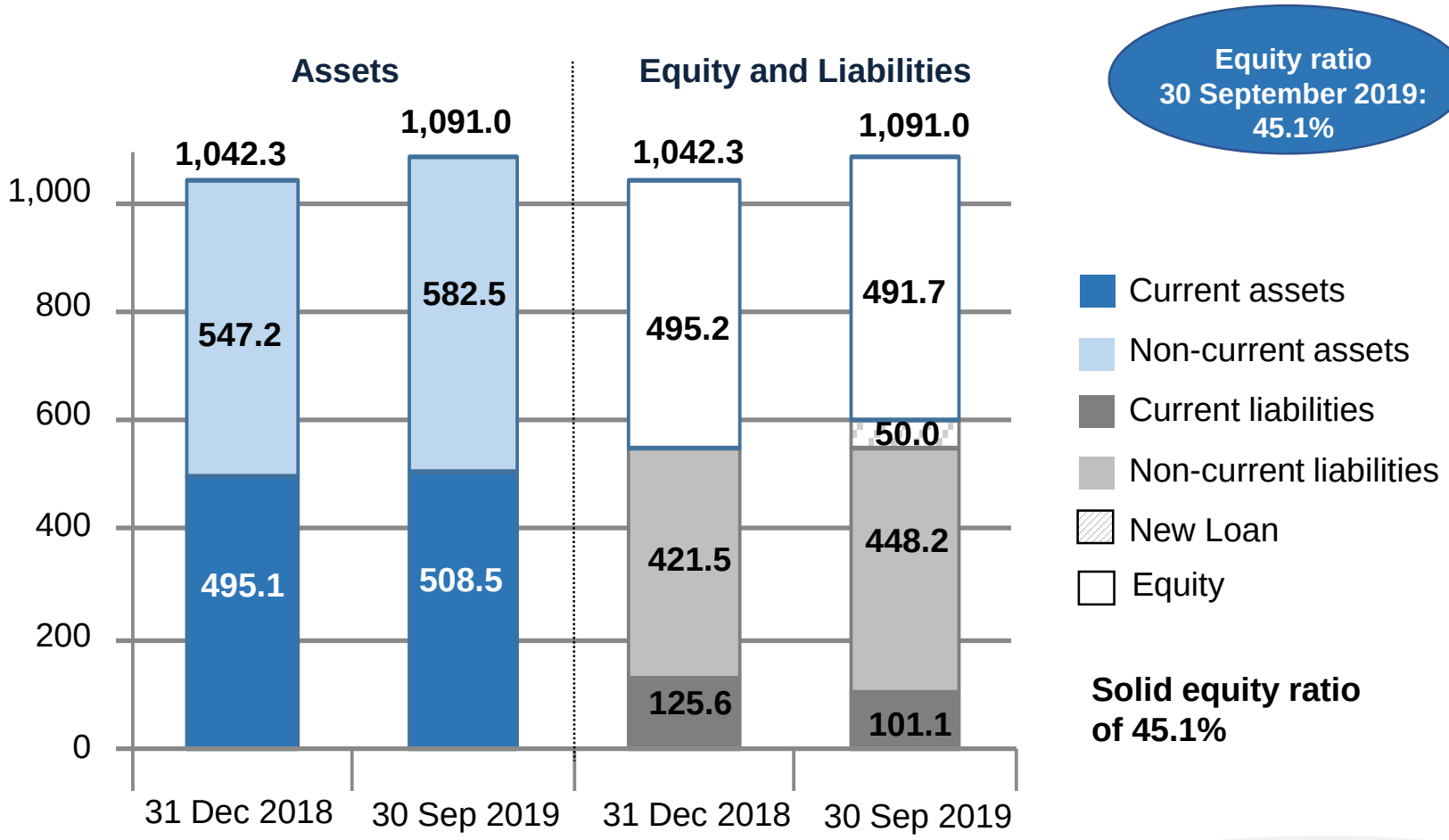
Total BNL costs: **€ 49.7 million** in Q1-Q3 2019

Sales development
(€ million)



- **Therapy sales** up +5.3% to € 266.1 m in Q1-Q3 2019 vs. 252.8 m in Q1-Q3 2018
- **Segment Plasma & Services**: Decline in contract fractionation (Middle East), capacity used for own production

Balance sheet – Solid Equity ration and new financing
(€ million)



Guidance 2019

Sales: In 2019 sales of continuing operations will increase by a mid-single-digit percentage

EBIT: Earnings will be influenced by various factors in 2019:

- Mainly further BNL expenses BNL
- Tense situation in the crisis regions, particularly in the Middle East
- Execution of a partnering agreement

EBIT of continuing operations will be **between €-5 m and € +5 m,** if partnering can be successfully concluded in 2019; otherwise an EBIT of € –15 to –35 million is expected.

Market environment & Development projects

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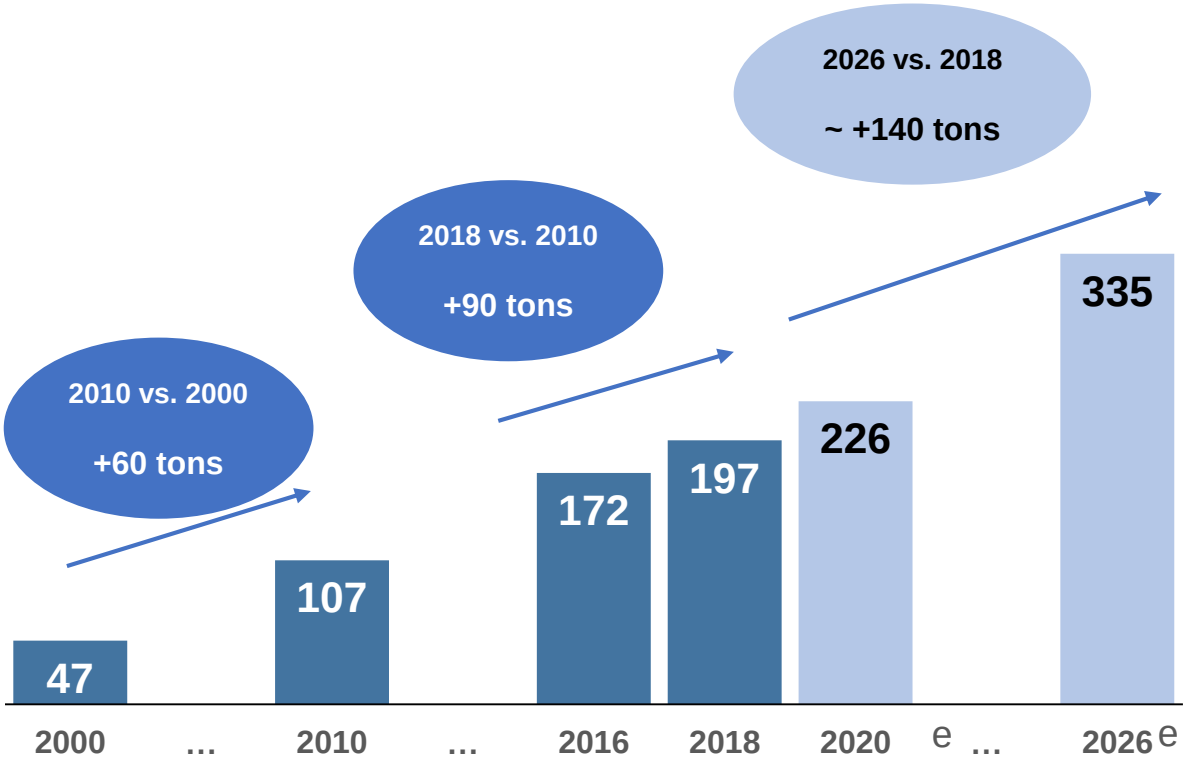
Immunoglobulines (IgGs): Further increase of global market volume expected

(Market volume in tons)



Source: Marketing Research Bureau (March 2019)

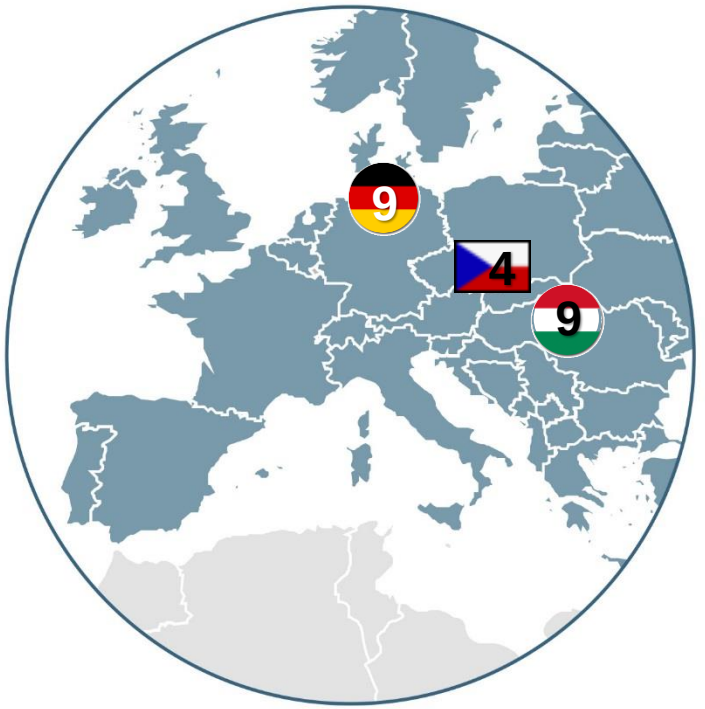
Consequences:

- Industry is expanding production capacity
- In some countries tight IgG supply situation
- Increase in plasma collection

Expansion of plasma collection centres

Europe: 22 centres

- One new centre in Germany (Hanover) and one in Budapest (Hungary) in 2019
- One new center will open in Nov 2019 in Jihlava in the Czech Republik



New plasma donation centre in Brno

Haemoctin® SDH in long-term study

Biotest shows excellent efficacy and tolerability of Haemoctin ® SDH in long-term study of patients with haemophilia A
– 18-year observation period

- Clinical data of the worldwide longest surveillance study on 198 patients representing all age groups (0 - 88 years) published
- 24 patients were followed up for more than 15 years
- No unexpected adverse effects on the health of the patients were documented
- Previously untreated haemophilia A patients scarcely develop antibodies against the product (low inhibitor formation)
- Patients benefit more from prophylactic than from on-demand therapy

Kittler S. et al., Haemostaseologie November 2019

IgG Next Generation (IVIG)

- New efficient production process with high IgG yield established
- "Master product" for the Biotest Next Level production plant

Clinical development

- **Phase III study in PID* (EU + US; study 991): enrollment completed, treatment of children ongoing**
- **Phase III study in ITP** (EU; study 992): study completed**

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

IgG Next Generation: Phase III in ITP* completed

IgG Next Generation:

- Phase III study in Primary Immune Thrombocytopenia (ITP) completed
- Good safety and efficacy expectations confirmed
- The study is one of two pivotal phase III studies in the clinical program for IgG Next Generation, a novel development of our polyvalent immunoglobulin G
- Clinical development in line with progress of new manufacturing facility Biotest Next Level
- IgG Next Generation can be marketed in additional established indications with a sales potential of immunoglobulins in immunomodulatory diseases in Europe in the range of € 1.3 billion (7% thereof in ITP*)**

*: Idiopathic Thrombocytopenic Purpura

**: Sources: Allied Market Research (2018), Markets and Markets (2017), Global MRB report (2016), Iqvia

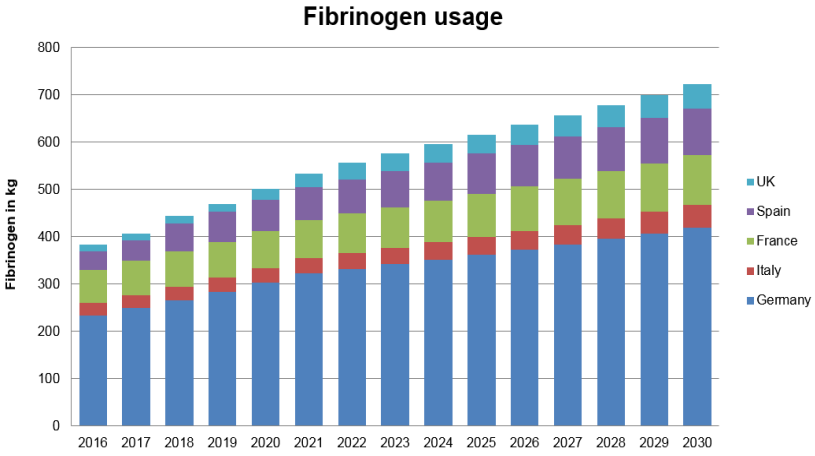
Fibrinogen

Indication:

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

Status:

- Congenital Fibrinogen deficiency study in phase I/III ongoing
- Acquired Fibrinogen deficiency study in phase III ongoing



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

Trimodulin –IgM-enriched Immunoglobulin

Trimodulin:

Broad therapeutic potential in severe infections

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

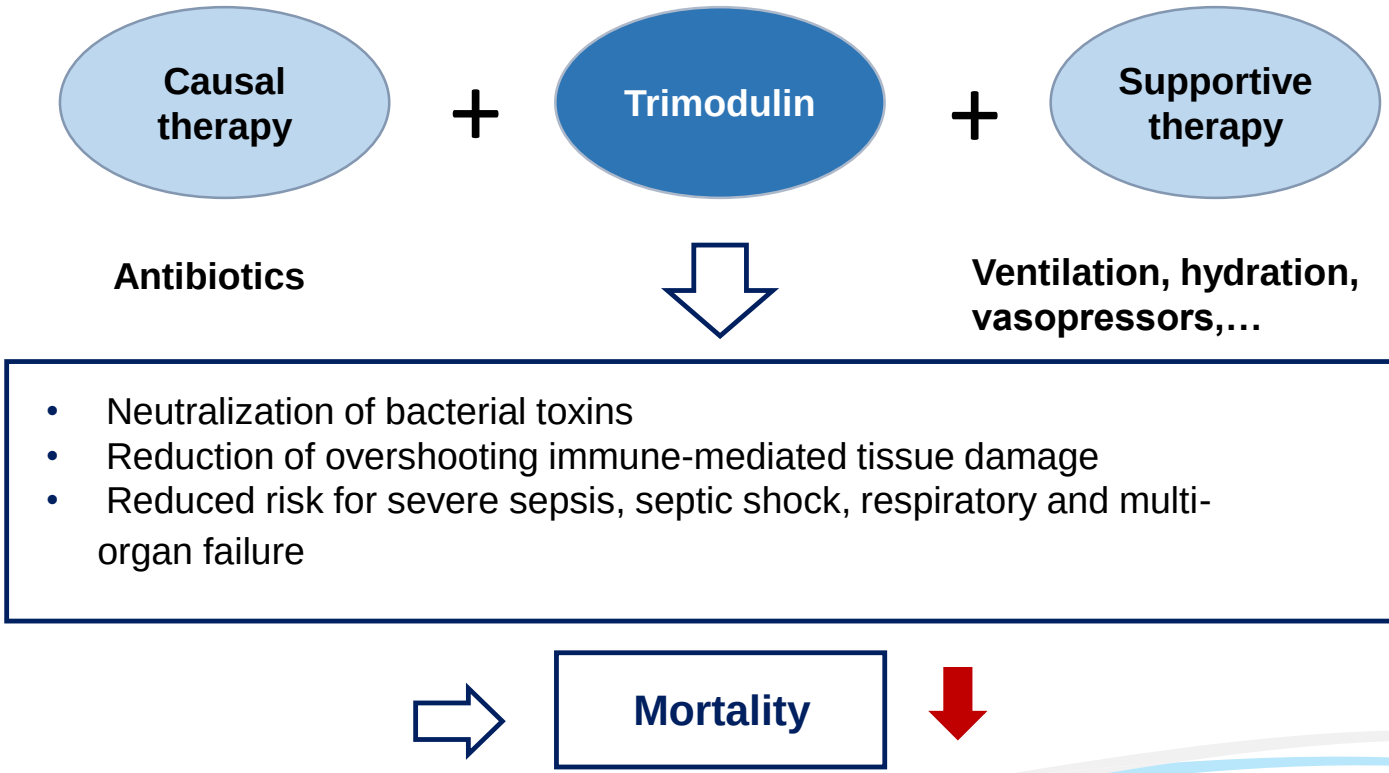
Current Status:

- Coordination with the U.S. Food and Drug Administration (FDA), EMA (European Medicines Agency) and Paul-Ehrlich-Institute took place
- Phase III study and paediatric development plan in preparation

Trimodulin

Trimodulin for treatment of severe community acquired pneumonia (sCAP)

- No comparable adjuvant therapy available



Biotest Next Level

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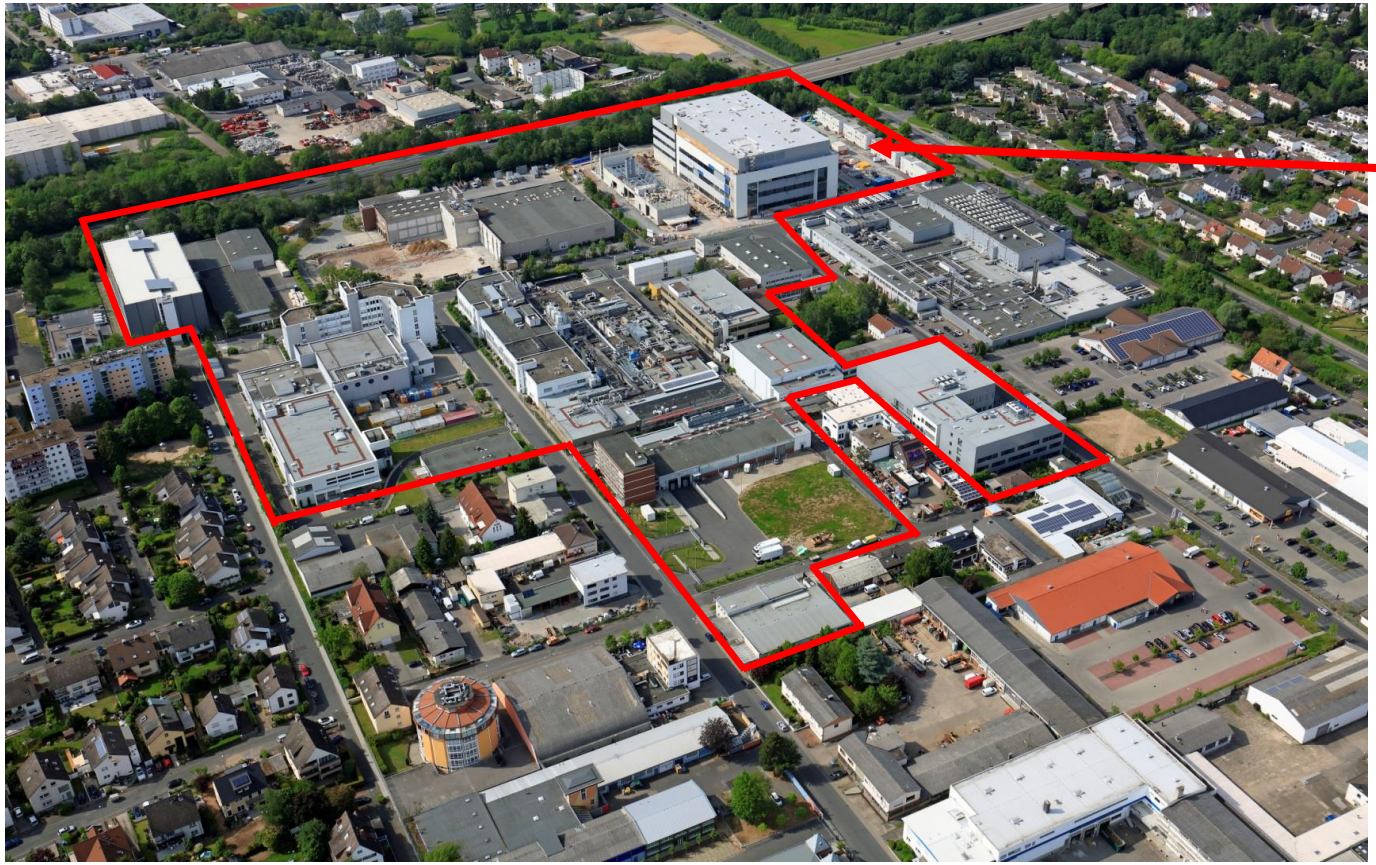
Biotest Next Level

Entire Biotest area



New BNL production site

BNL 2019 – What we have achieved so far...

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

Today

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

BNL Equipment – Qualification
Clean room & media qualification means...

- Clean rooms: 17,000 samples & analytical tests
- Media: 16,000 samples => 88,000 analytical tests

BNL 2019 – First inspection of BNL production plant passed

Inspection of the infrastructure by Darmstadt Regional Council

Period: 05 - 08 November 2019

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

Authority: Regional council Darmstadt, Germany

Scope:

- Qualification of sterile media (AP[1], WFI[2], pure steam, compressed air)
- Clean Rooms
- Support area (autoclaves, washing machines)
- Media support (Ethanol, acid/ alkaline solutions and CIP[3] media)
- Storage rooms (-30°C, +4°C, +18°C)
- Production of acid/ base, ethanol storage, balances for solids (NaCl, etc.)

Implementation of manufacturing process continues...

=> Further test runs with water and written-off plasma and pastes

[1]: AP = Aqua Purificata; [2]: WFI = Water-For-Injection;
[3]: Cleaning In Place

Summary

Next Steps

- Biotest Next Level progressing
- Clinical trials for new BNL products ongoing:
  IgG Next Gen, Fibrinogen; Trimodulin in preparation
- Opening of new plasma collection centres in Europe





Financial Calendar 2020

Contact

Financial Calendar 2020

30 Mar 2020	FY Report 2019
08 May 2020	Q1 Report 2020
08 May 2020	Annual General Meeting
13 Aug 2020	Q2 Report 2020
12 Nov 2010	Q3 Report 2020

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