Biotest

From Nature for Life

Biotest AG

Company Presentation

March 2017

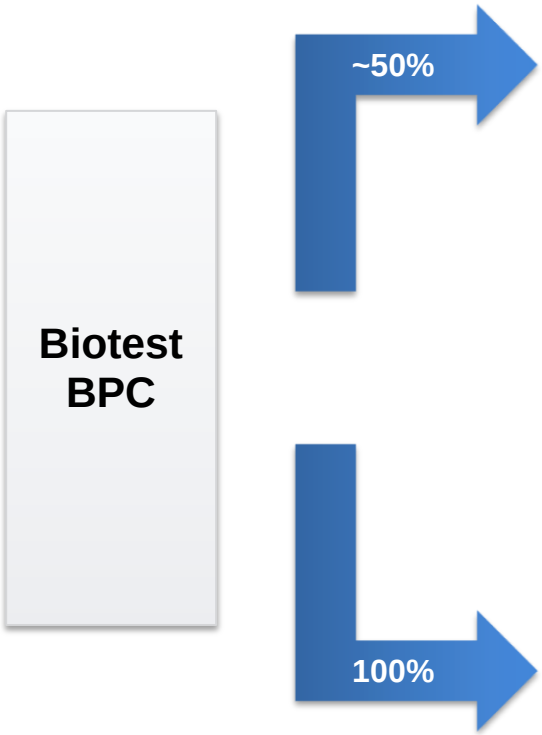
Disclaimer

- 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: FY 2016 at a glance

- Biotest restructures US therapy business: Focus on plasma collection and its extension in the US
- Sales of Continued Operations in FY 2016 up by 3.5% to €553.1 m
- Continued EBIT in FY 2016 up by 73% to €64.4 m
- Opening of six plasma collection centres in the US (4) and Hungary (2) to date
- "Biotest Next Level" project is on track

Re-alignment of US business



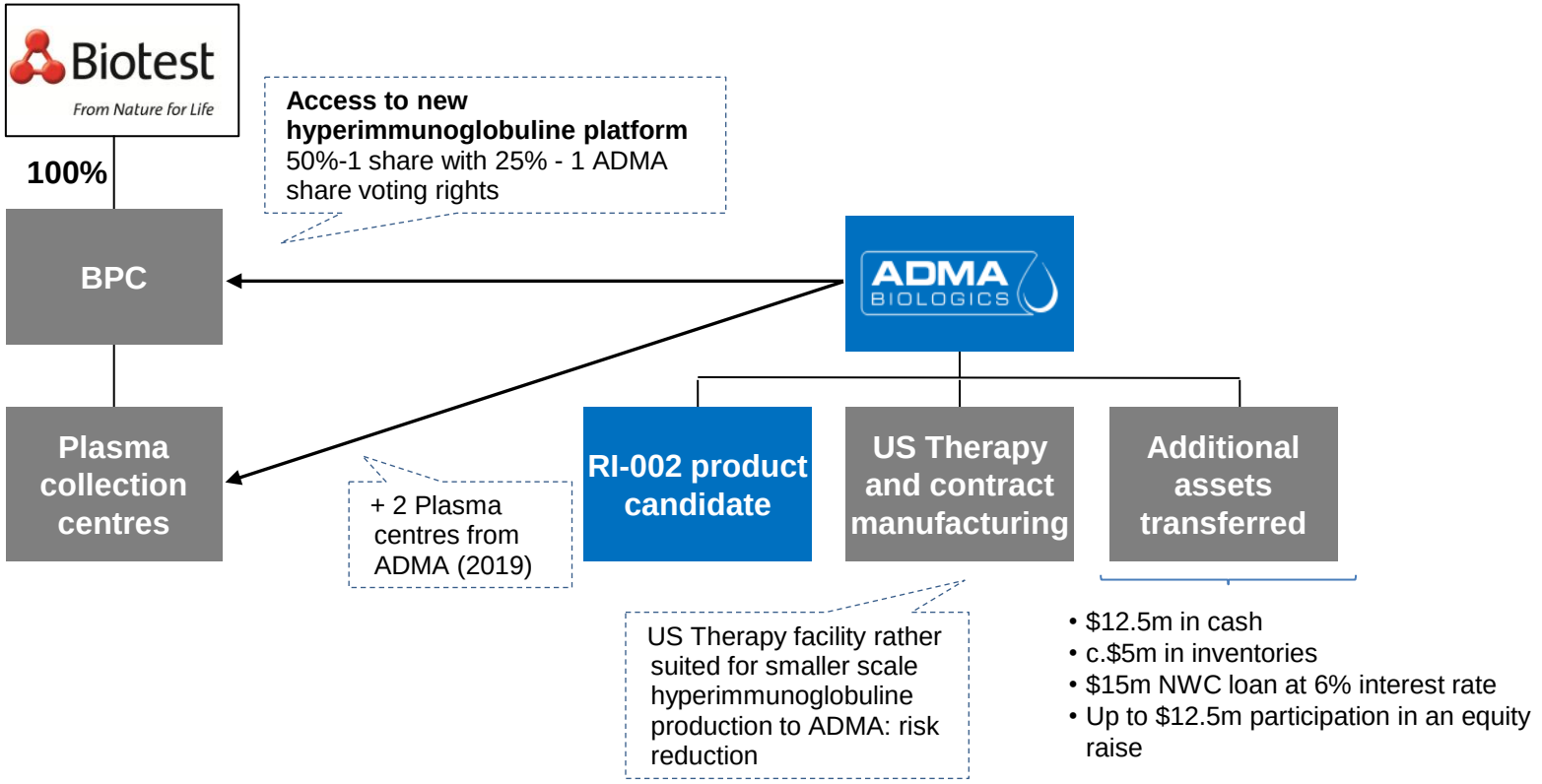
Re-inforcing hyperimmunoglobuline strategy

- Transferring Boca facility rather suitable for smaller scale hyperimmunoglobuline production to ADMA: risk reduction
- Access to new hyperimmunoglobuline platform
- Potential future sales & distribution partner

Strengthening of plasma collection business

- 22 + 2 new collection centers from ADMA

Re-alignment of US operations to de-risk business and create optionality



Source: Company information.
Note: Restriction of voting rights to 25%-1 ADMA shares permits Biotest to deconsolidate earnings / cash flows of the US Therapy business without consolidating stake in ADMA.

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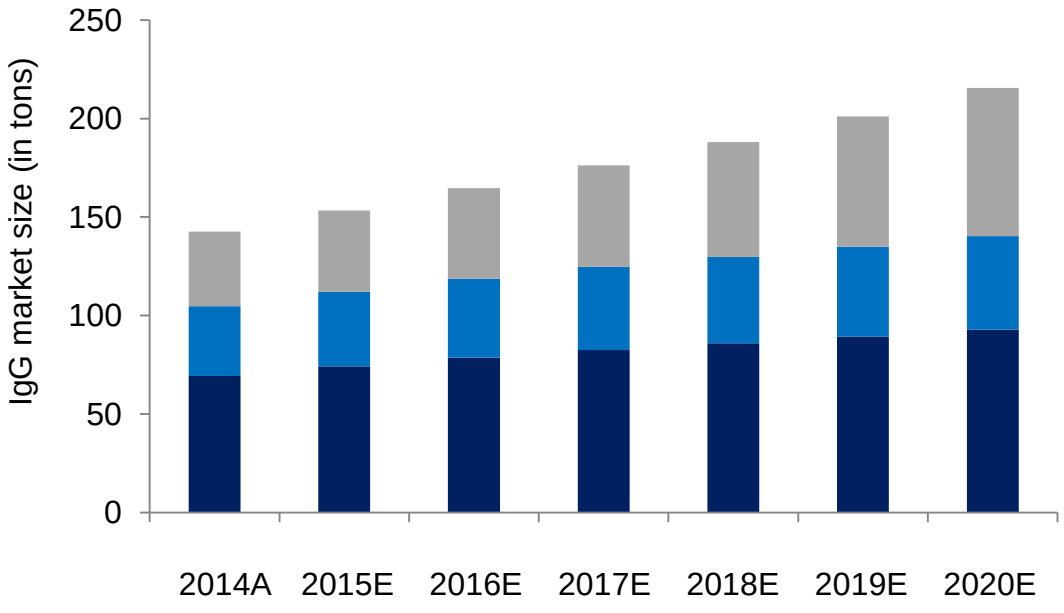
Market environment & Strategy

Global IgG (i.v. + s.c.) market forecast



Expected annual growth
CAGR 2014–2020E

RoW	12%
Europe	5%
North America	5%
World	7%

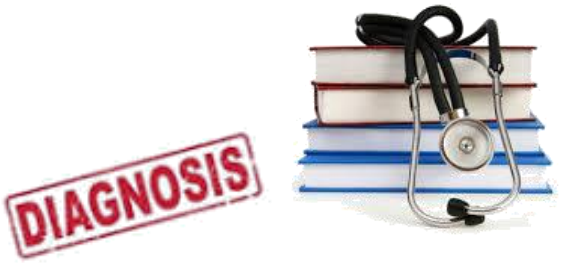
- Worldwide demand for plasma proteins is growing

Sources: Biotest Market Research based on MRB (2016), PPTA (2016).

Factors supporting growth of IgG

Market expansion

- Improvements in wealth and therapy reimbursement
- Improving access to care

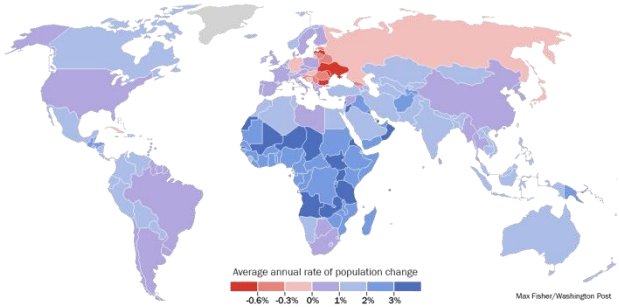


Physicians' awareness

- Awareness of treatment options and indications still low
- Many patients are still undiagnosed

Demographic development

- Growth of population
- Weight gain

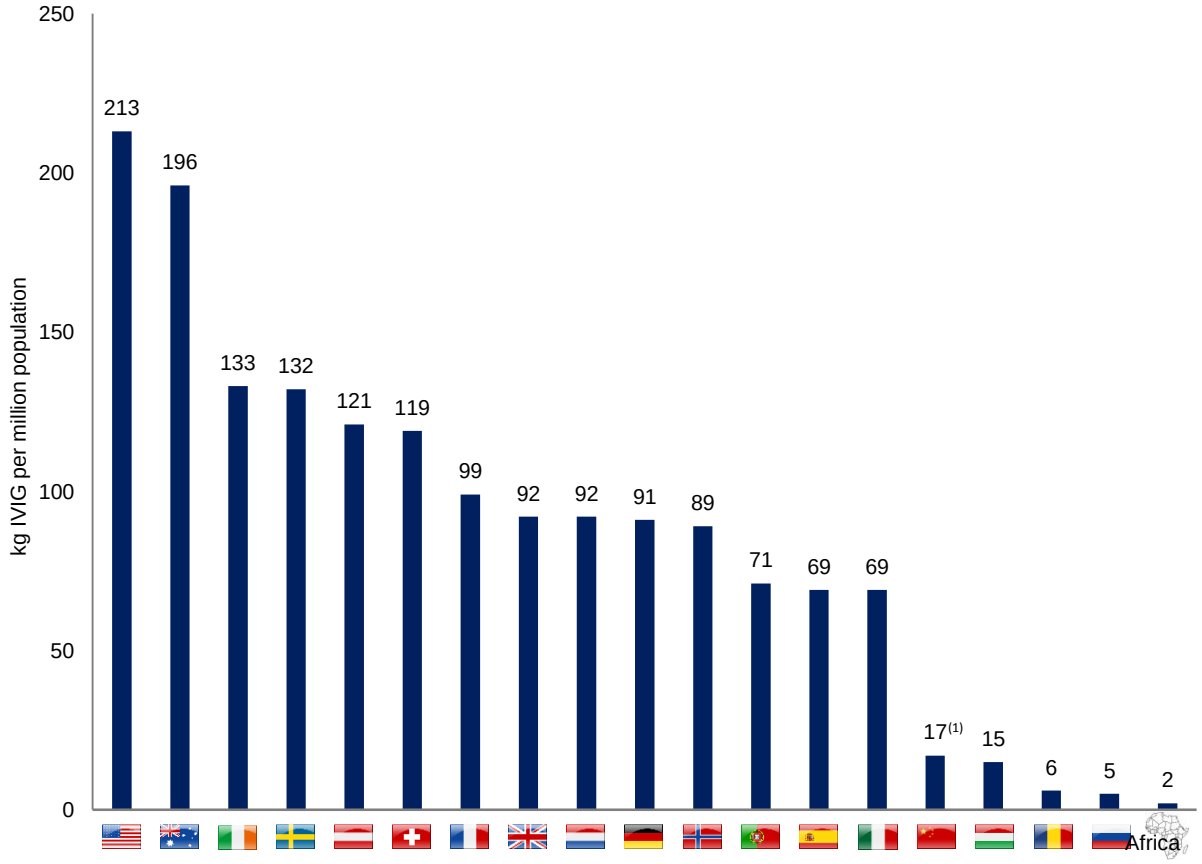


Indications / usage areas

- Use of IgG in a broader set of indications
- Regular treatment of patients with chronic conditions
- Limited success of conventional treatment options increase demand for plasma-derived products

IVIG usage per capita 2015

Consumption

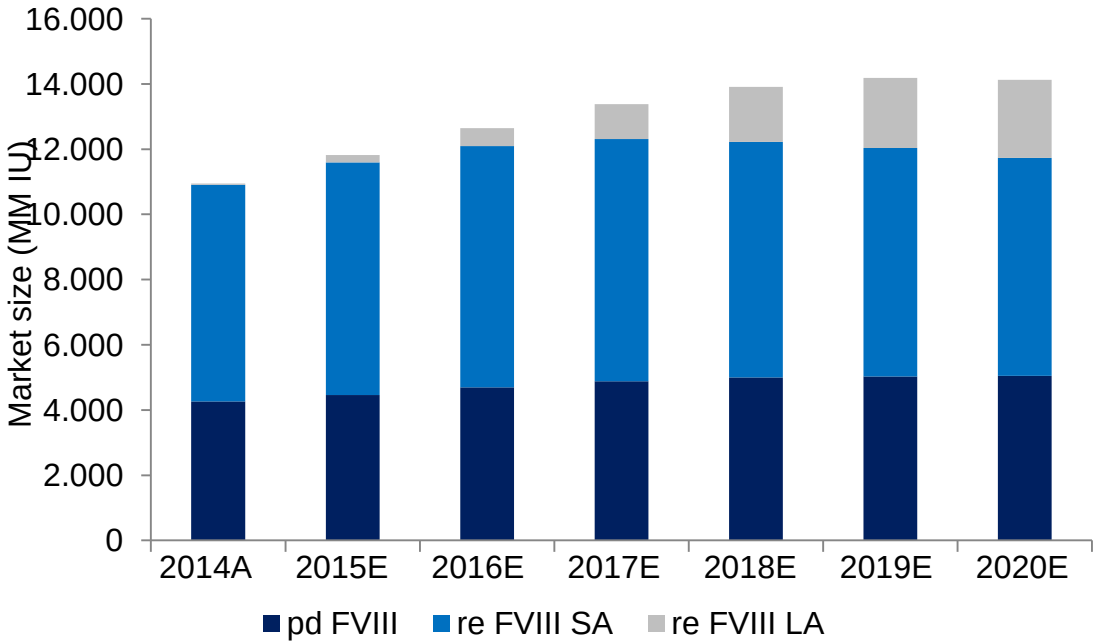


- Catch-up of consumption in major markets
- Availability of raw material limits growth
- Regulatory barriers restrict global exchange
- Improved reimbursement outlook will support market growth

Source: Biotest Market Research based on PPTA (2016), MRB (2016), NBA Australia (2016), IMS Midas (2016), CIA World Factbook (2016).
(1) Based on 2014 data.

Global FVIII market forecast

Volume perspective



Expected annual growth
CAGR 2013–2020E

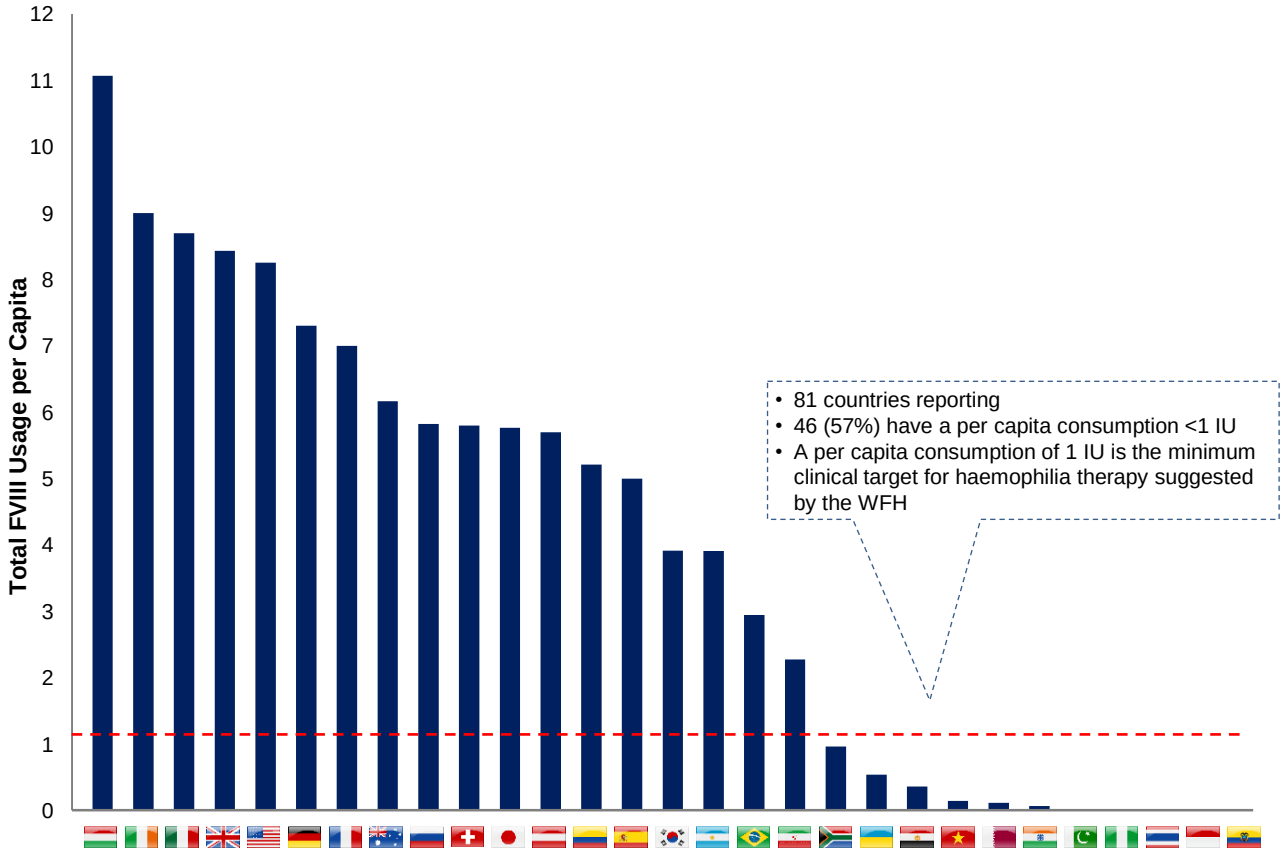
Recombinant total	5%
Recombinant SA	0%
Plasmatic	3%
Total FVIII	4%

- The global FVIII volume is expected to grow by 4% p.a. from 2014 to 2020
- The plasmatic segment will grow by 3% p.a. in volume until 2020
- In the recombinant market, growth will exclusively come from long-acting preparations

Note: SA = short-acting, LA = long-acting.
Source: Biotest Market Research based on MRB (2016), Company Reports, Analyst Reports.

FVIII usage per capita 2014 / 2015

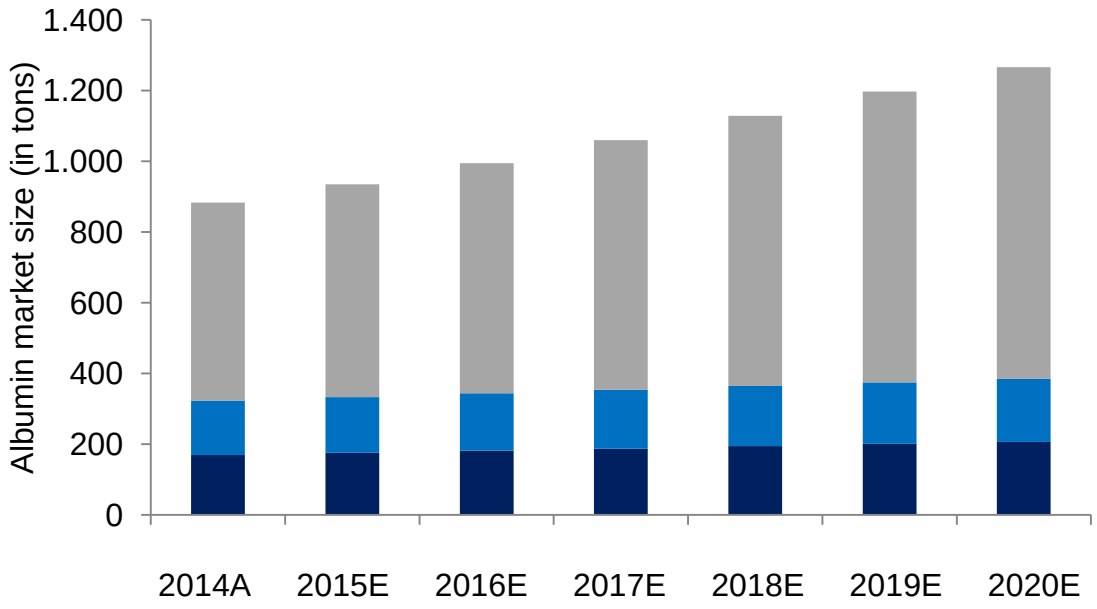
Consumption



- Catch-up of consumption in major markets expected
- Availability of raw material limits growth and regulatory barriers restrict global exchange
- Improved reimbursement outlook will support market growth

Source: Biotest Market Research based on MRB (2016), WFH (2016),CIA World Factbook (2016).

Global albumin market forecast



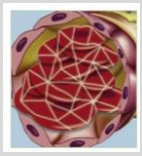
Expected annual growth CAGR 2014 – 2020E	
RoW	8%
Europe	3%
North America	3%
World	6%

- The global Albumin market is expected to grow to ~1,260 t by 2020
- This is equivalent to a global annual growth expectation of ~6% p.a. in the period between 2014 and 2020
- Increasing demand in emerging markets and launch of new products

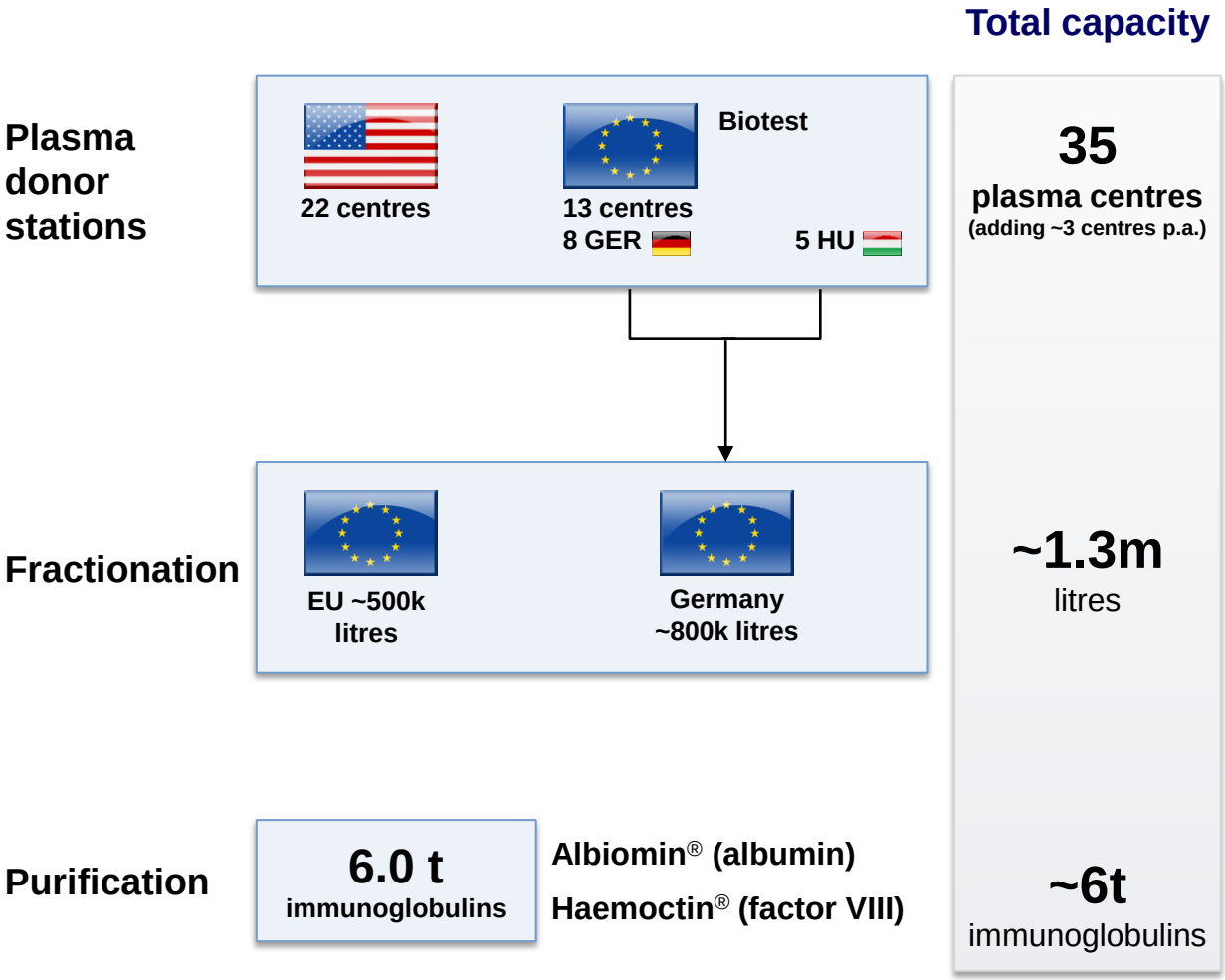
Source: MRB (2015).

Focus of Biotest

Biotest is a pharmaceutical company which develops, produces and sells **biological medicinal products**, obtained from human plasma or manufactured using biotechnological methods.

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

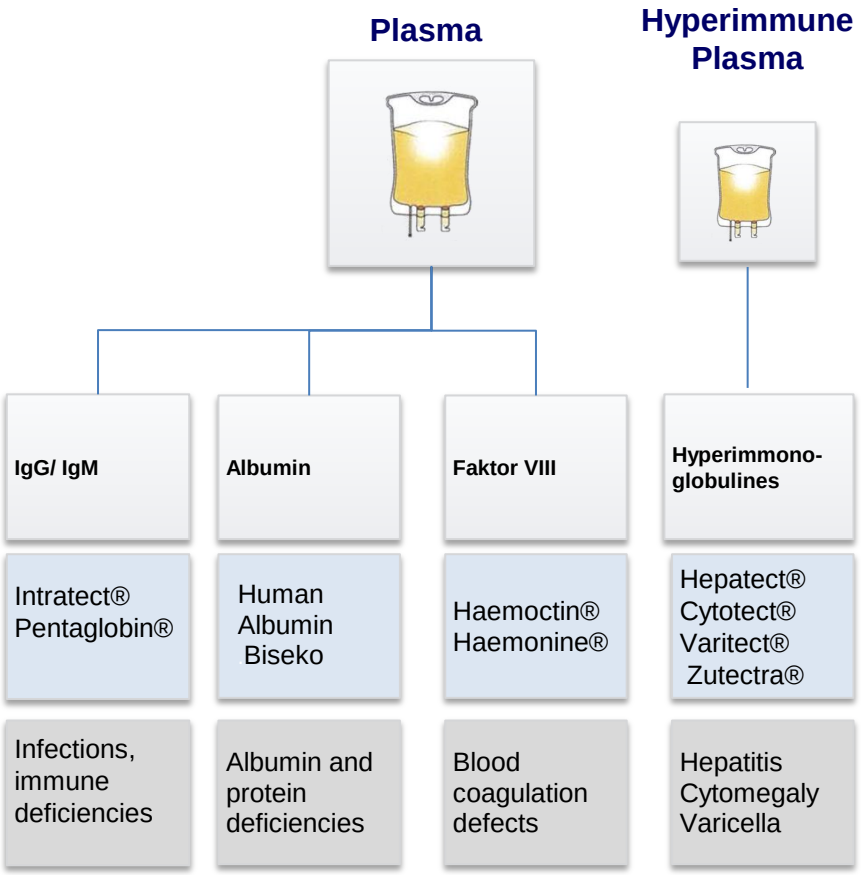
Plasma proteins – Efficient production



- Level of self-sufficiency:
  60% for standard plasma
- 100% sufficiency for special products plasma

Plasma fractionation overview

Today



- Intratect® (IVIG) market share in (GER + AUT + CH) = ~12%
- World market leader with Varitect® and Pentaglobin®; European market leader with Cytotect®
- Leading position with Hepatect® in Europe
- Biotest covers full value creation chain: plasma sourcing, R&D, production and distribution
- Vertical integration leads to rationalisation and higher productivity

Key pillars of Biotest's strategy

- **Drive organic growth with significant capacity and process investment**
  - Broadening of product portfolio
  - Doubling of production capacity
  - Improved yield
  - Additional products from every litre of Plasma
- **Capitalise on new product opportunities with strong in-house R&D capabilities**
  - Focus on IgG Next Gen, IgM Concentrate, Fibrinogen
- **Further leverage existing platform via value-enhancing partnering**
  - Partnering strategy in selected R&D areas to leverage products beyond own production capacity
  - 50% - 1 share ADMA ownership

Biotest

From Nature for Life

Research & Development projects

Biotest product and R&D portfolio

BNL programme

- IgG Next Generation
- IgM Concentrate
- Fibrinogen
- Albumin

Early development

- Haemophilia A Therapeutic

Partnering projects

- BT-061
- BT-062
- BT-063
- Civacir

IgG Next Generation

- Development of successor of Intratect® and Bivigam® helps patients with immune system dysfunctions and some autoimmune disorders
- Global commercialisation planned
- New efficient production process with high Ig yield established
- "Master product" for the Biotest Next Level production plant

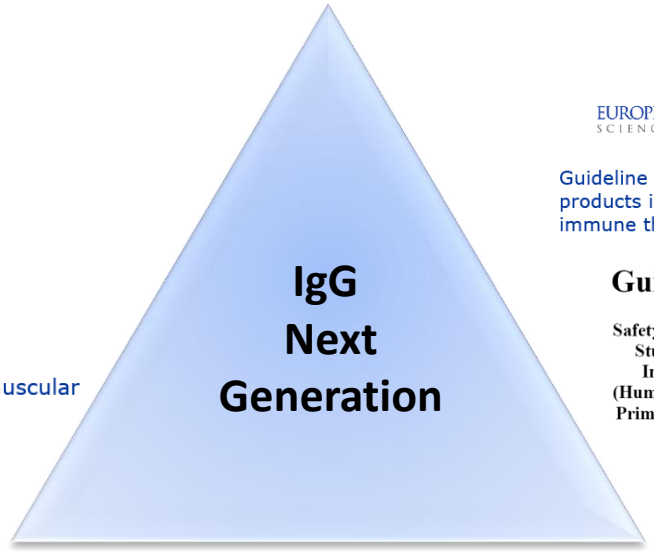
Clinical development

- Phase III clinical development (EU / US) started in Q4 2016 in two indications
- An additional phase III study in a neurological indication is currently under evaluation - study design discussed with FDA in 2016

IgG Next Generation (IVIG)

Study 991 PID* ★ First patient in 11-2016

50 evaluable patients



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia

Guidance for Industry

Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency

DEPARTMENT OF HEALTH & HUMAN SERVICES • USA
FDA

Study 993 CIDP* US under evaluation** ★

Study 992 ITP** ★ First patient in 1-2017

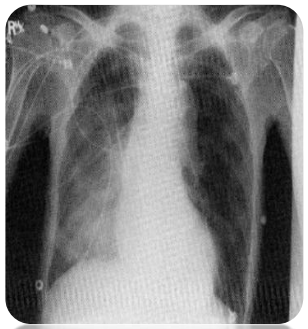
(Ideopathic Thrombocytopenic Purpura)

40 evaluable adult patients

*: Primary Immune Deficiency
**: Immune Thrombocyto Penia
***: Chronic Inflammatory Demyelinating Polyneuropathy

IgM Concentrate: Severe community acquired pneumonia (sCAP)

- Community acquired pneumonia (CAP) is a leading cause of illness and death worldwide[1]
- CAP is an infection of the lungs occurring in people who have not been recently hospitalized
- Severe CAP (sCAP) is usually defined as CAP that requires admission to the intensive care unit (ICU)
- sCAP is a progressive disease often leading to life-threatening sepsis and multiple organ failure



Chest radiograph

High unmet medical need

- Mortality of sCAP patients admitted to ICUs usually ranges from 23-58% depending on time and admission to hospital[2],[3]
- Mortality rates have not changed significantly over the past several decades despite the availability of improved broad-spectrum antibiotics

(1) Wunderink 2014, N Engl J Med 370;6.
(2) Woodhead, 2006, Critical Care 10:S1, p3.
(3) Sirvent et al. 2013, Med. Intensiva 37:308e 15.

IgM Concentrate: CIGMA study (phase II) – Objectives & endpoints

Objectives

- Evaluation of the efficacy and safety of IgM Concentrate in patients with sCAP

Primary endpoint / Key secondary endpoints

- Increase of ventilator free days (VFDs)
- 28-day all cause mortality

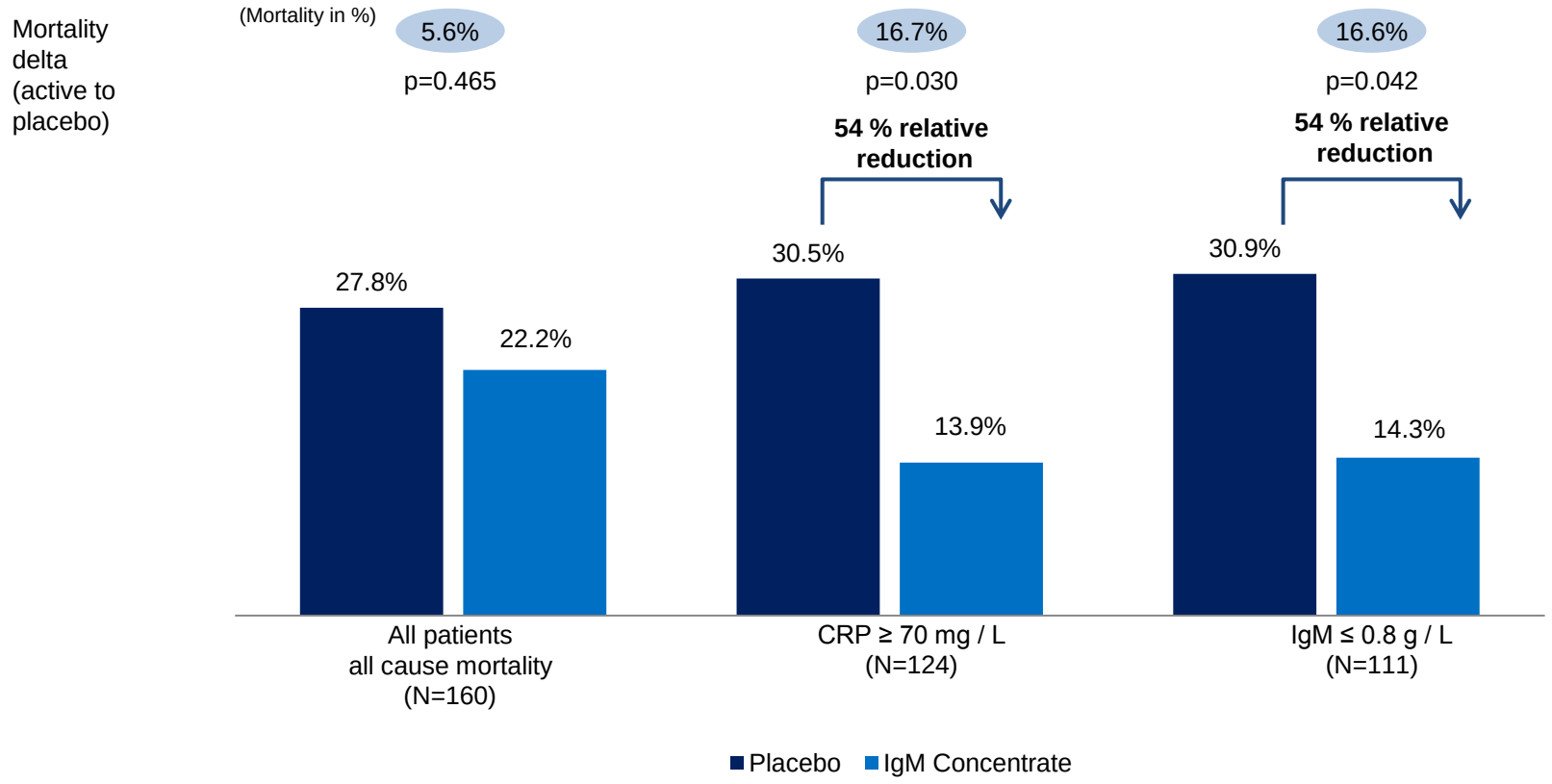
Key inclusion criteria

- Pneumonia has been acquired outside the hospital or diagnosed within 72 hours after hospital admission
- Patient receiving adequate antibiotic treatment for pneumonia
- Major sCAP criterion: need for invasive mechanical ventilation

Markers for post hoc analyses were selected based on scientific / medical considerations

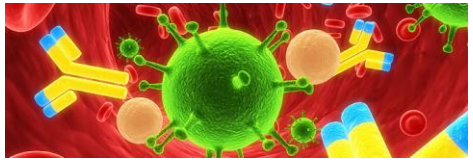
IgM Concentrate: CIGMA – summary incl. post hoc analyses

Stratification (baseline level)[1]



CRP = C-Reactive Protein.
(1) Descriptive p-values from a Fisher's Exact Test with a significance level of 0.05 have been calculated for subgroups.

IgM Concentrate



Attractive market potential

- **Severe community acquired pneumonia**
  - Value driver based on CIGMA study results
  - Market size in sCAP approx. 350,000 patients worldwide(1)
  - Sales potential approx. €300 million p.a.
  - Significant upside due to new pricing study based on excellent clinical data from Biotest-led study

Several upside indications

Current status

- Publication phase II results in preparation
- Phase III design in sCAP agreed with FDA and PEI

(1) Source: Biotest market research.

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	Phase III study acquired fibrinogen deficiency
Phase I: completed ✓ • Single dose of fibrinogen • PK parameters and surrogate efficacy (MCF) **Phase III: ongoing** • On-demand prophylaxis / treatment • Clinical efficacy / surrogate efficacy (MCF)	• Caused by major surgery associated with excessive blood loss ⇨ **Clinical study start 2017**

MCF = Maximum clot firmness.

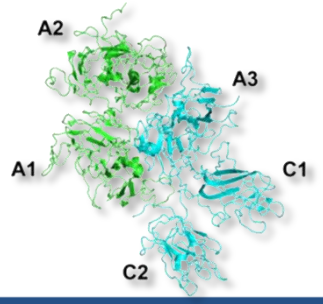
Haemophilia A therapeutic (HAT): Timeline

- Development of a recombinant Factor VIII closely related to the wild type Factor VIII with improved characteristics such as half life extension and lowered immunogenicity
- Preventing inhibitor development
- Extension of treatment intervals

Human cell line with high yield

Tolerance inducing modification

Reduced Immunogenicity



Next Gen FVIII therapeutic

Extended half-life

Albumin binding

RI-002

IVIG lead product

- Novel IVIG, manufactured from a unique plasma pool formed by blending high-titer Respiratory Syncytial Virus (RSV)
- Initial target indication Primary Immune Deficiency Disease (PIDD)

Respiratory Syncytial Virus (RSV)

- RSV Infection is a serious problem for Immune-Compromised patients
- Approximately 5-15% RSV infection rate in immune-compromised patient populations

Clinical trial data results

- Pivotal Phase III trial achieved primary endpoint (rate of serious bacterial infection (SBI) per patient / year < 1 SBI)
- RI-002 prevented serious bacterial infections such as bacterial pneumonia, osteomyelitis and bacterial sepsis demonstrating no SBI in 55 patient / years

Label expansion

- Potential future follow-on target populations for RSV specific indications: HSCT / BMT, solid organ transplant, chemotherapy and other immune-compromised patients

Source: ADMA company information.

Monoclonal antibodies

BT - 062

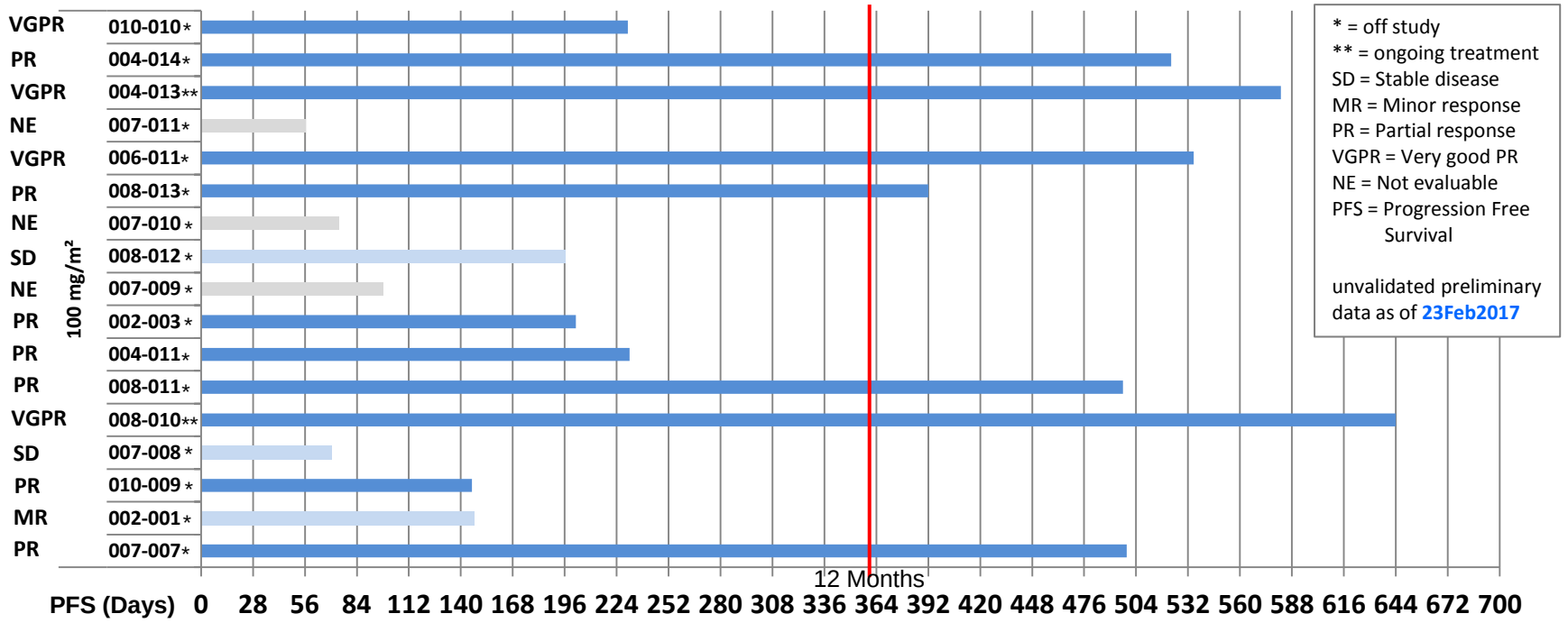
- Innovative therapy approach for the treatment of multiple myeloma (Antibody Drug Conjugate (ADC)) which targets cancer cells through combination of antibody and cytotoxic agent (combination of efficacy and tolerability)
- **Multiple myeloma study**
  - All patients recruited (17 in total of which 2 were replaced (not evaluable))
  - Treatment ongoing; 11 patients (73%) showed a response; 8 patients are on treatment for 18 months without progressive disease
  - Report on study data in Q1 2017
- **Solid tumours study (breast and bladder cancer)**
  - Phase I completed
  - Extension phase ongoing (6 patients)

BT - 063

- Humanised monoclonal antibody, which selectively neutralises human interleukin-10, thus representing a new approach to treat autoimmune diseases
- Currently undergoing proof of concept phase IIa study
  - Process duration: 3 months treatment + 4 months follow up
  - Last patient recruited in part I of the study
  - DSMB recommended to continue study (part II) / ongoing
- Study endpoints
  - Primary: Incidence of adverse events, changes of safety parameter
  - Secondary: Improvement of joints, improvement of skin, SLEDAI (disease score)

BT-062 phase I/IIa study no. 983 in Multiple Myeloma

Results of BT-062 with Pomalidomide / Dexamethasone



- A total of 17 patients were treated
- 3 patients were not evaluable for response (less than 2 complete treatment cycles)
- 11/14 = 79% showed an objective response (≥ PR) to treatment
- 7 patients without progressive disease for more than 12 months
- 2 patients are on treatment

Indatuximab Ravtansine (BT-062)

Solid Tumor Study no. 989 ongoing - current status

Study design:

Indications: Triple negative breast cancer and advanced bladder cancer

Objectives/ design: To evaluate pharmacokinetic, safety and anti-tumor activity of Indatuximab Ravtansine (BT-062) in selected solid tumor indications

- Phase I: Dose escalation to maximum tolerated dose (MTD)
- Phase IIa: Treatment of patients at selected dose level.

Current status:

- Maximum tolerated dose has been identified and 39 patients were enrolled and treated
- No additional patients required to evaluate safety and anti-tumor activity of BT-062. Relevant authorities had been notified that the recruitment of patients would not be continued

Next steps: As soon as the study is finalized and evaluated Biotest will report results

Interim analysis supports continuation of phase IIa trial in SLE* with BT-063

Clinical proof of concept study phase IIa study no. 990

Patients with moderate to severe SLE on stable medication with joint and cutaneous manifestations

Duration: 3 months treatment + 4 months follow up

Study endpoints:

- Primary: Incidence of adverse events, changes of safety parameter
- Secondary: Improvement of joints, improvement of skin, SLEDAI**

Status:

- The Data Safety Monitoring Board (DSMB) recommends the continuation of the study based on interim analysis from part I of the study.

*: SLE = Systemic Lupus Erythematosus
** SLEDAI: SLE Disease Activity Index

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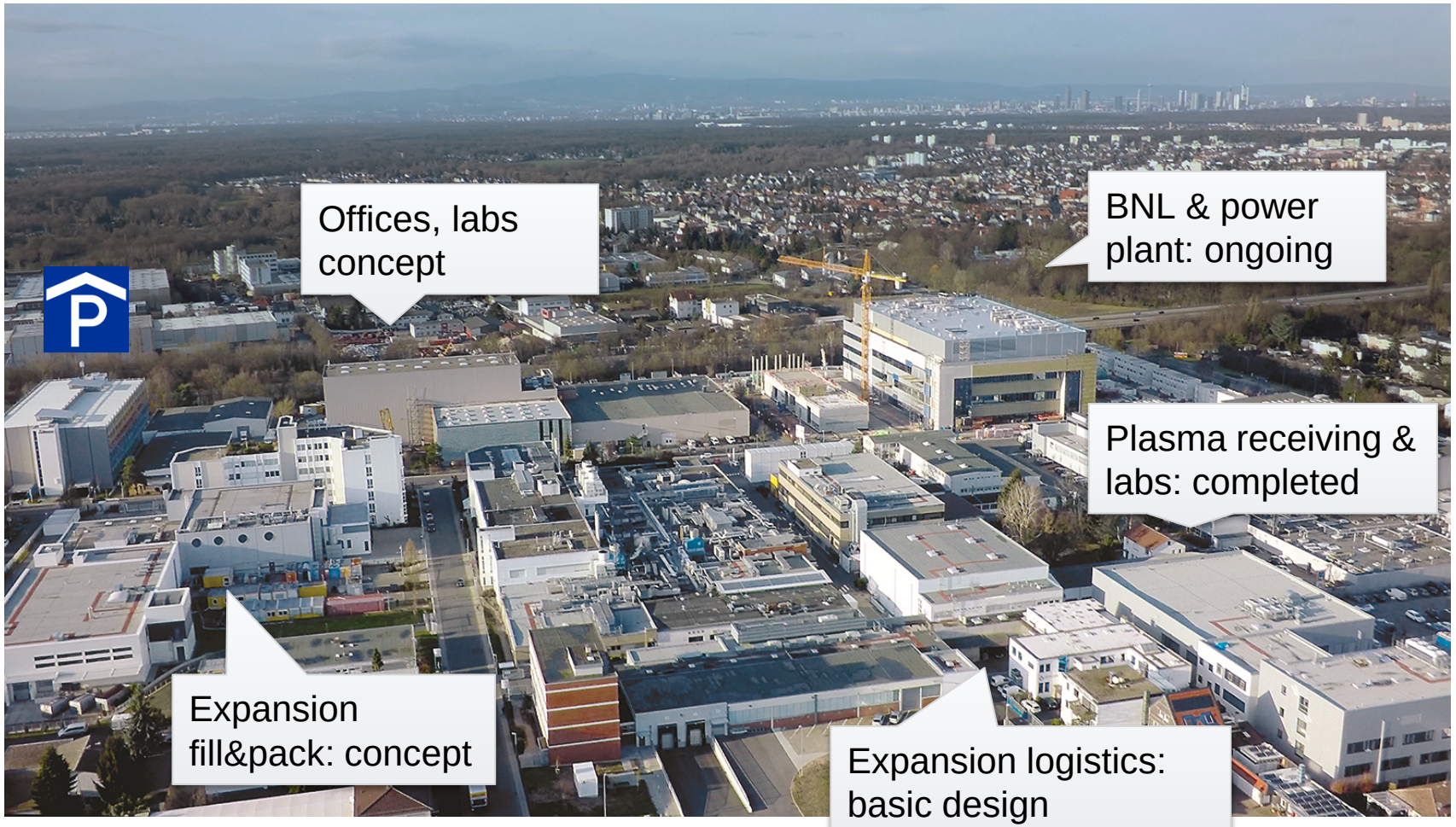
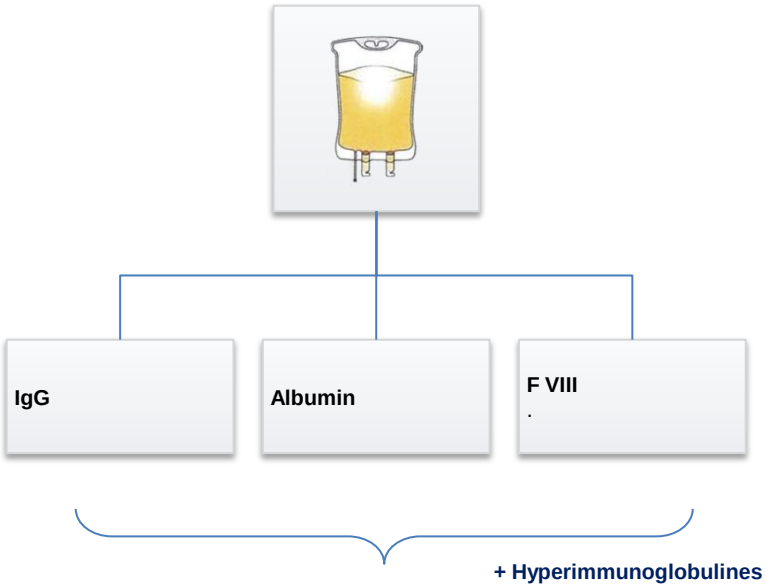
Biotest Next Level 2016



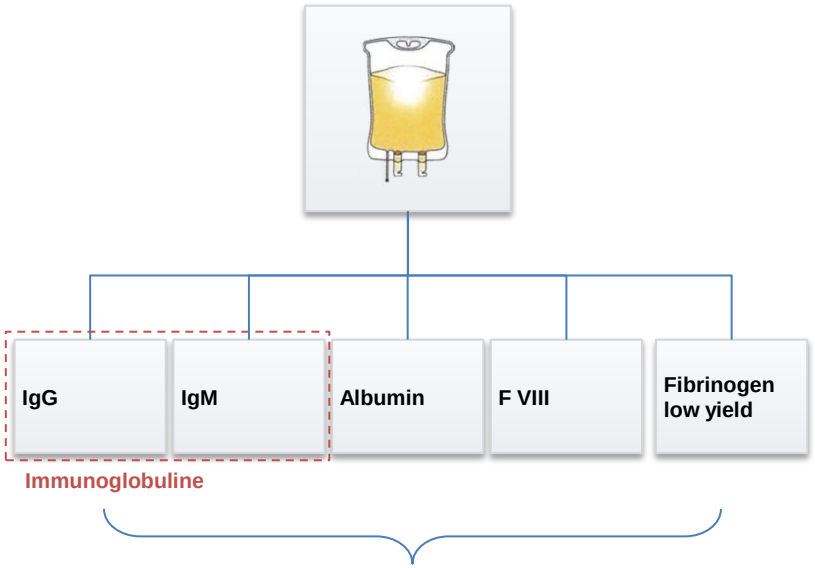
BNL enhancing utilization of plasma…

Today



Revenue ~€300 per litre

BNL fully ramped-up



~€550–€650 per litre

…will be long-term driver of profitability

Today (current factory)

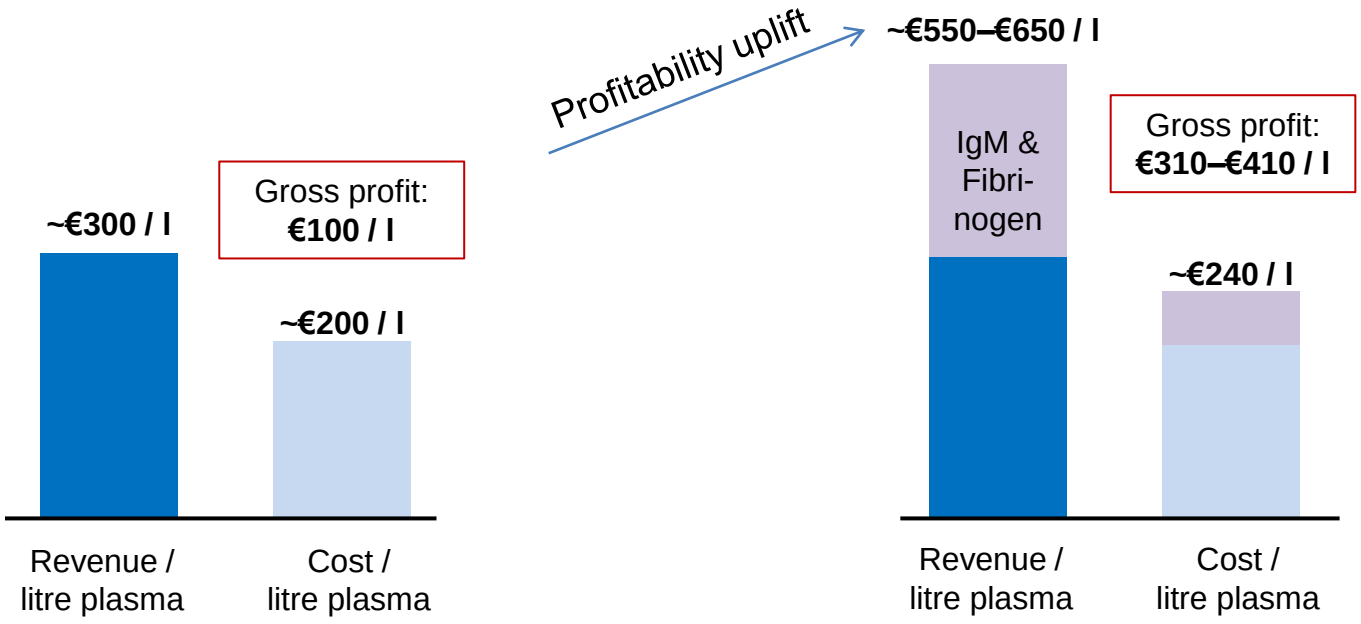
3 products out of **1** litre plasma

Capacity expansion: **~6t**

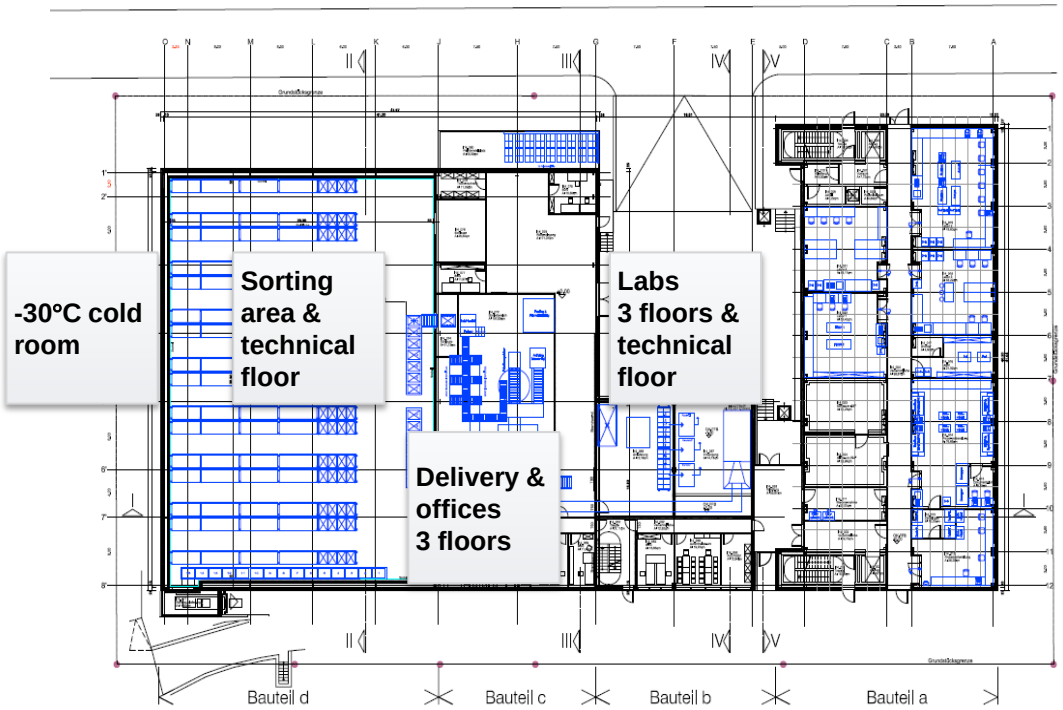
BNL ramped-up

5 products out of **1** litre plasma

~12.5t immunoglobulins



Biotest Next Level: New plasma receiving building and lab building already in operation



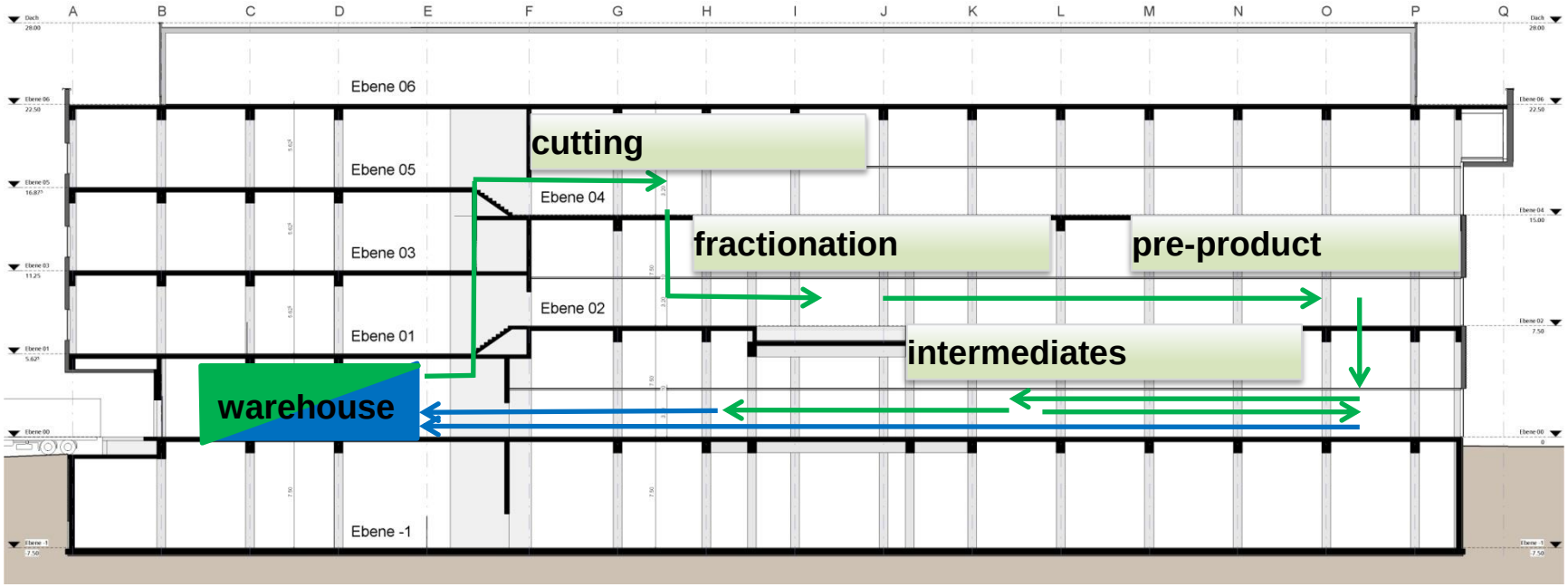
Lab building

- Virology
- Virus validation

Plasma receiving building

- Sorting area
- -30°C storage capacity

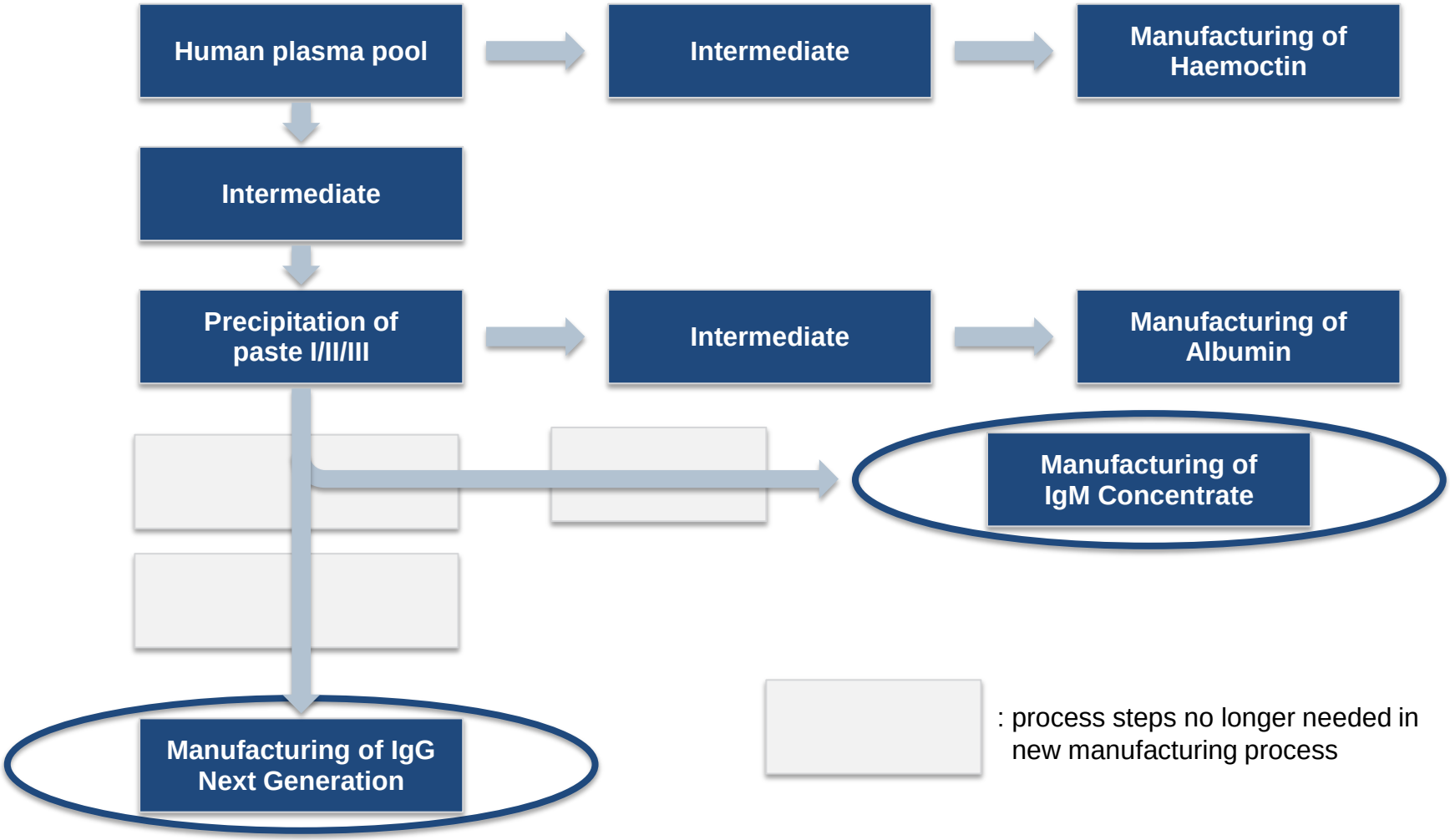
Biotest Next Level: State-of-the-art production process



Raw material – Plasma

Intermediates – Albumin, Fibrinogen, IgG / IgM, Cryo paste

New manufacturing scheme



Biotest Next Level

On track in terms of timeline and budget (February 2017)

Biotest Next Level - construction works on track

- Building shell is completed
- Interior fitting/ work (clean-rooms, laboratories, cold-rooms, doorways etc.) are about to be completed
- Technical installations (power, heating, air-conditioning, water/ waste water) as well as media supply (e.g. compressed air, pristine steam/ vapor, heating/ cooling medium) is currently being commissioned. In parallel the qualification of operations is ongoing
- Installation of process equipment is ongoing; first qualifications of process equipment has started

Biotest Next Level
Impressions from inside (1)

Biotest Next Level
Impressions from inside (2)

Financial Calendar 2017
Contact

Financial Calendar 2017

30 Mar 2017	FY Report 2016
10 May 2017	Annual Shareholder Meeting
10 May 2017	3M Report 2017
14 Aug 2017	6M Report 2017
14 Nov 2017	9M Report 2017

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