Biotest

From Nature for Life

VISION. FOCUS. TEAM SPIRIT.

Annual Shareholders' Meeting of Biotest AG

Frankfurt/Main, 12 May 2016

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 2015

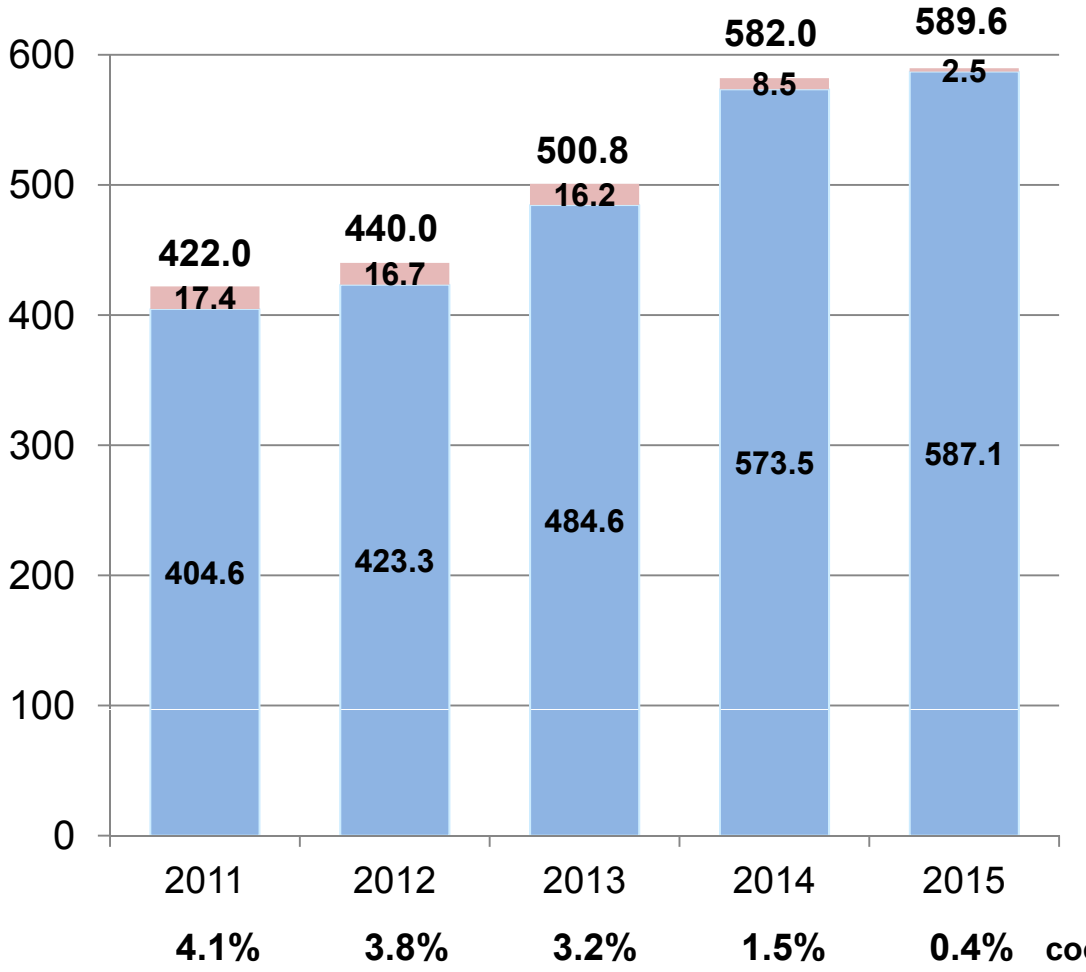
- Sales FY 2015: € 589.6 million, +1.3%
  EBIT FY 2015: € -71.8 million
- Re-focusing on core business
- Limitation of R&D investments in monoclonal antibody pipeline after not meeting the primary endpoint in BT-061 study
- Q4 2015 EBIT: € 10.2 million (above guidance*)
- Biotest Next Level is on track with respect to timeline and budget
- Positive results for IgM Concentrate, Pentaglobin® and marketing approval for Zutectra® early use
- Start of change process

*November 10, 2015

Financials - FY 2015

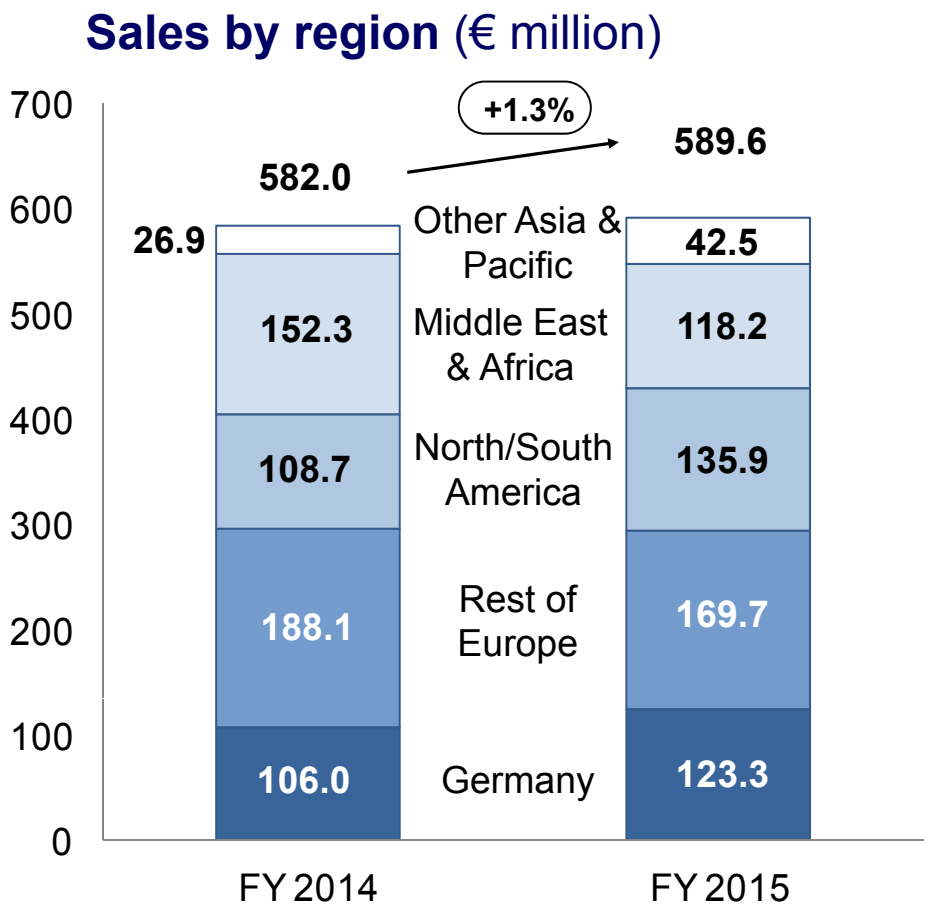
Sales development

Influence of cooperation agreement on sales and EBIT (€ million)



- Decreasing influence of cooperation agreement

Sales growth



- Solid growth in Germany
- Strong plasma sales in the US
- Good development in Asia

EBIT and adjusted EBIT

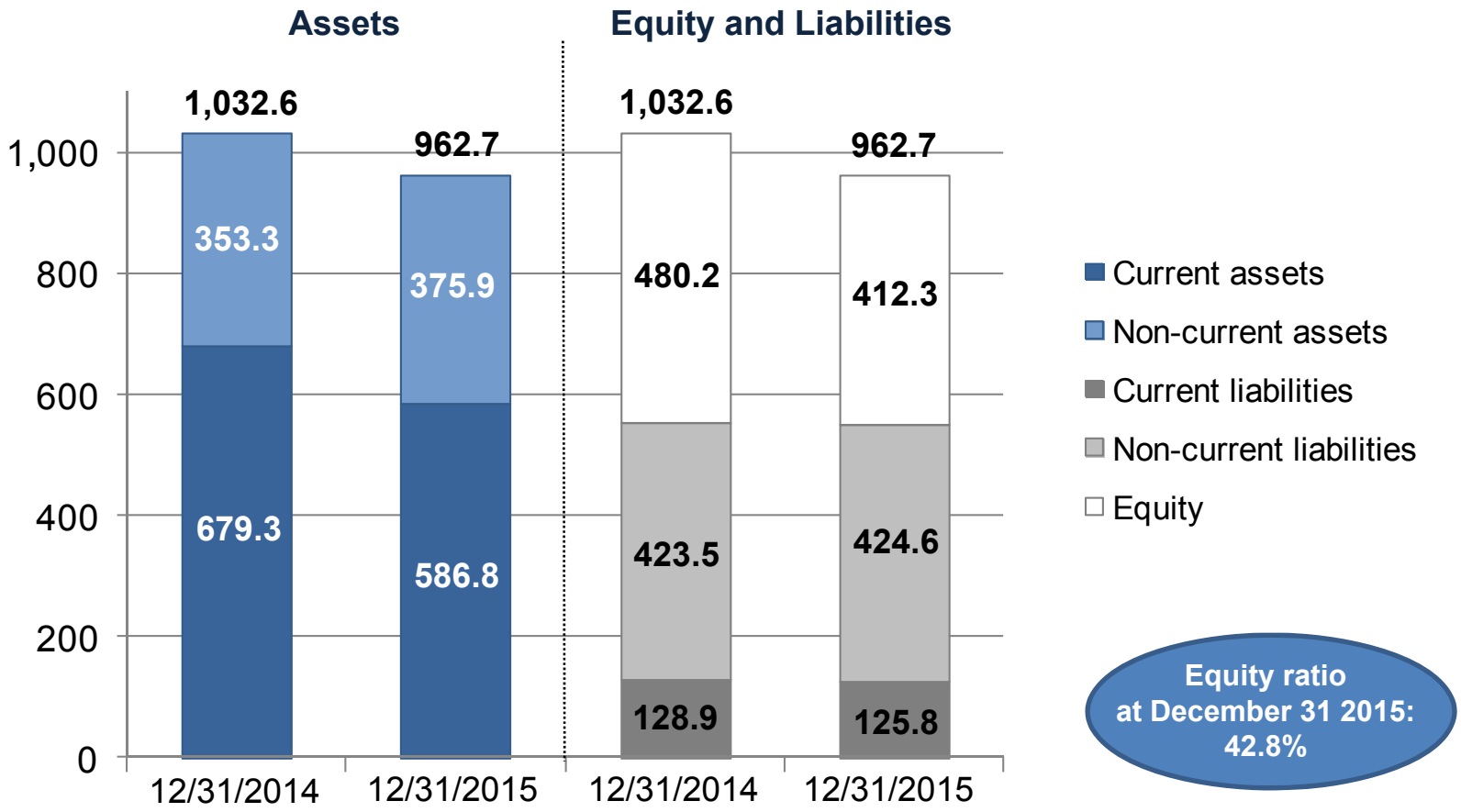
	2014	2015
EBIT (€ million)	**53.4**	**-71.8**
Impairment and one time effects*	-	77.2
Biotest Next Level costs**	15.4	23.3
Monoclonal antibodies	38.2	50.1
Idle capacity costs (Boca & Dreieich)	16.2	12.4
EBIT adjusted	**123.2**	**91.2**

* € 2.8 million are recognised in monoclonal antibodies

** R&D costs related to the BNL project are included in BNL costs

Balance sheet

Financial position of the Biotest Group (€ million)

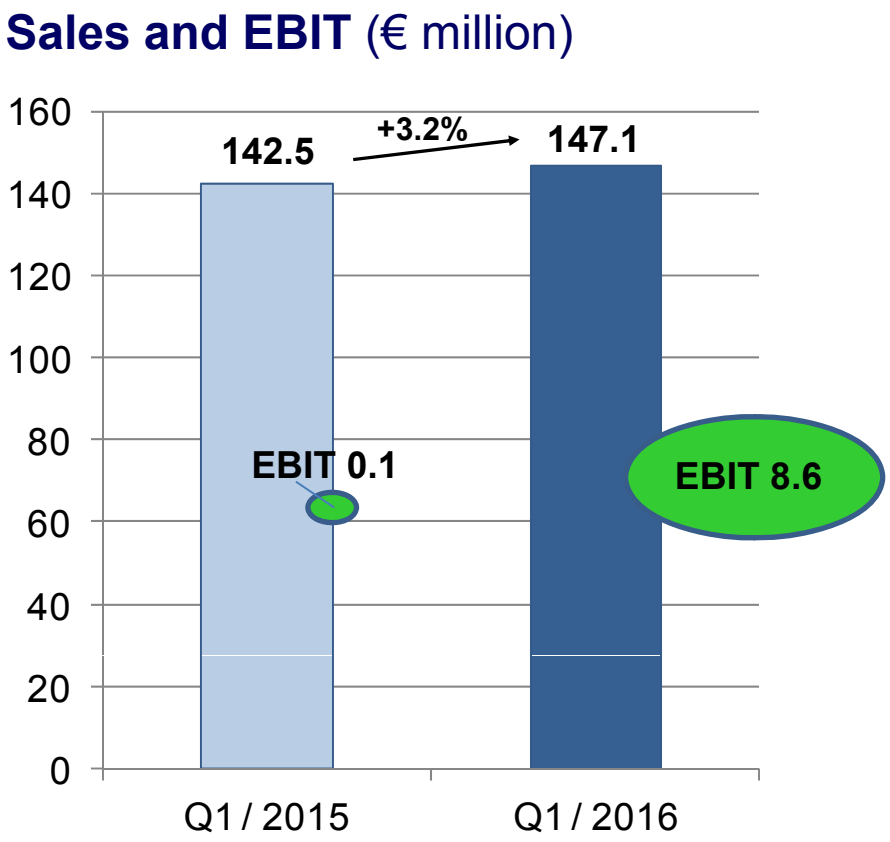


Cash flow from operating activities

January – December 2015 (in € million)

	2014	2015
Operating CF before changes in working capital	91.1	31.0
Cash flow from changes in working capital	-77.3	28.5
Interest and taxes paid	-25.2	-21.4
Cash flow from operating activities	**-11.4**	**38.1**

Sales and EBIT - Q1 2016

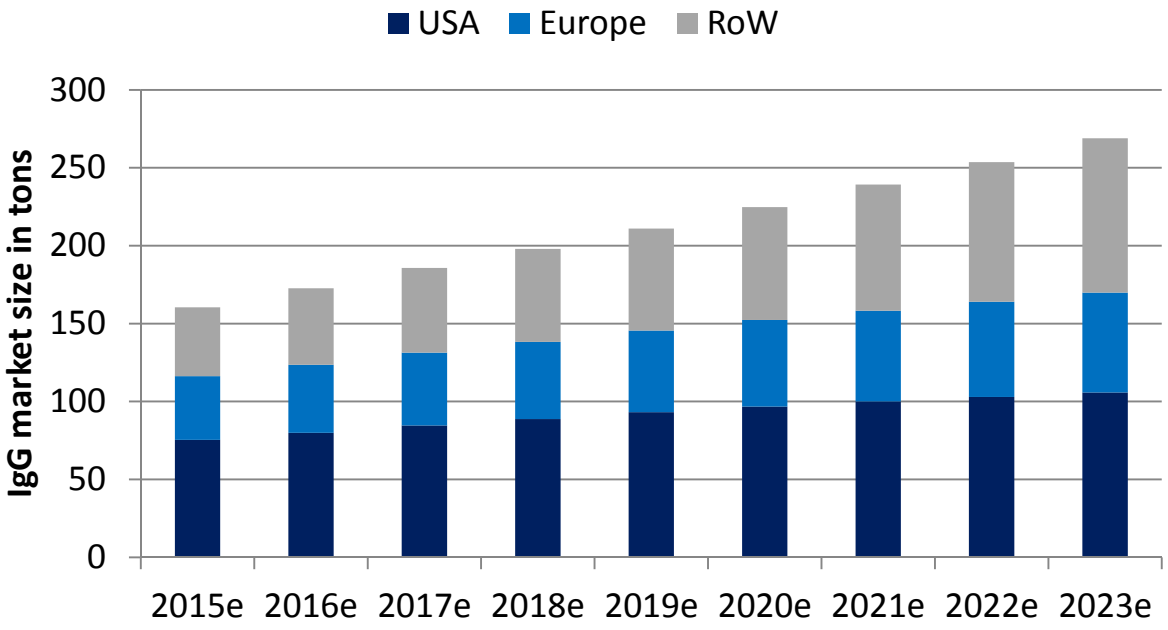


Strategic Targets of Biotest

Strategic targets of Biotest

- **Re-Focus on plasma business**
- **Strengthen US profitability**
- **Expansion project Biotest Next Level**
  - Broadening of product portfolio
  - Doubling of production capacity
- **Adjustment of R&D programme**
  - Focus on IgG Next Gen, IgM Concentrate, Fibrinogen and Haemophilia
  - Monoclonal antibodies: minimize expenses, continue activities solely up to next milestone to enable partnering
- **Continue of "partnering-strategy" in selected areas**

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

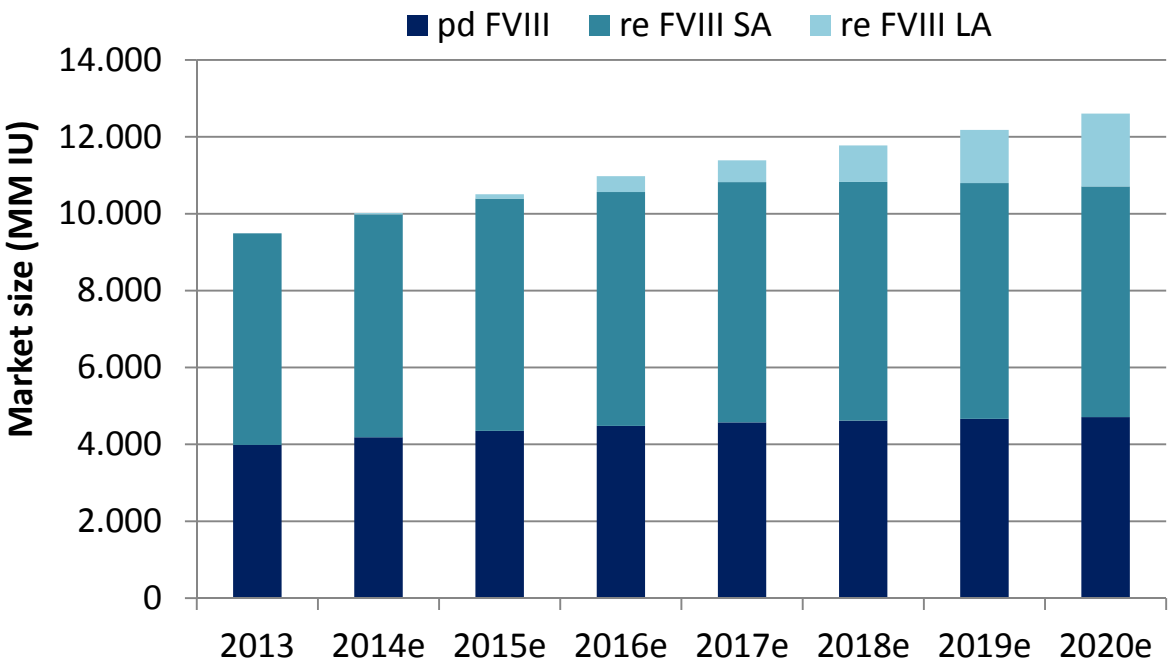


Exp. annual growth CAGR 2015e – 2023e	
RoW	10.5%
Europe	6%
North America	4.5%
World	6-7%

- The global IgG market is expected to grow to ~270 tons by 2023.
- Expected annual growth is highest in ROW countries.

Sources: Biotest Market Research based on MRB (2013), PPTA (2015), UBS (18 Feb 2015)

Global FVIII market forecast
Volume perspective



Exp. Annual Growth CAGR 2013–2020e	
Recombinant total	5%
Recombinant SA	1%
Plasmatic	2%
Total FVIII	**4%**

- The global FVIII volume is expected to grow by 4% p.a. in the period up to 2020.
- The plasmatic segment will grow by 2% p.a. in volume until 2020. In the recombinant segment, growth will predominantly come from the new long-acting preparations.

Source: Biotest Market Research

Note: SA = short-acting, LA = long-acting

Strengthen US profitability

Biotest Pharmaceuticals Corporation (BPC) and Kedrion Biopharma Inc., New Jersey signed in January 2016 a cooperation contract on marketing & sales of Bivigam®

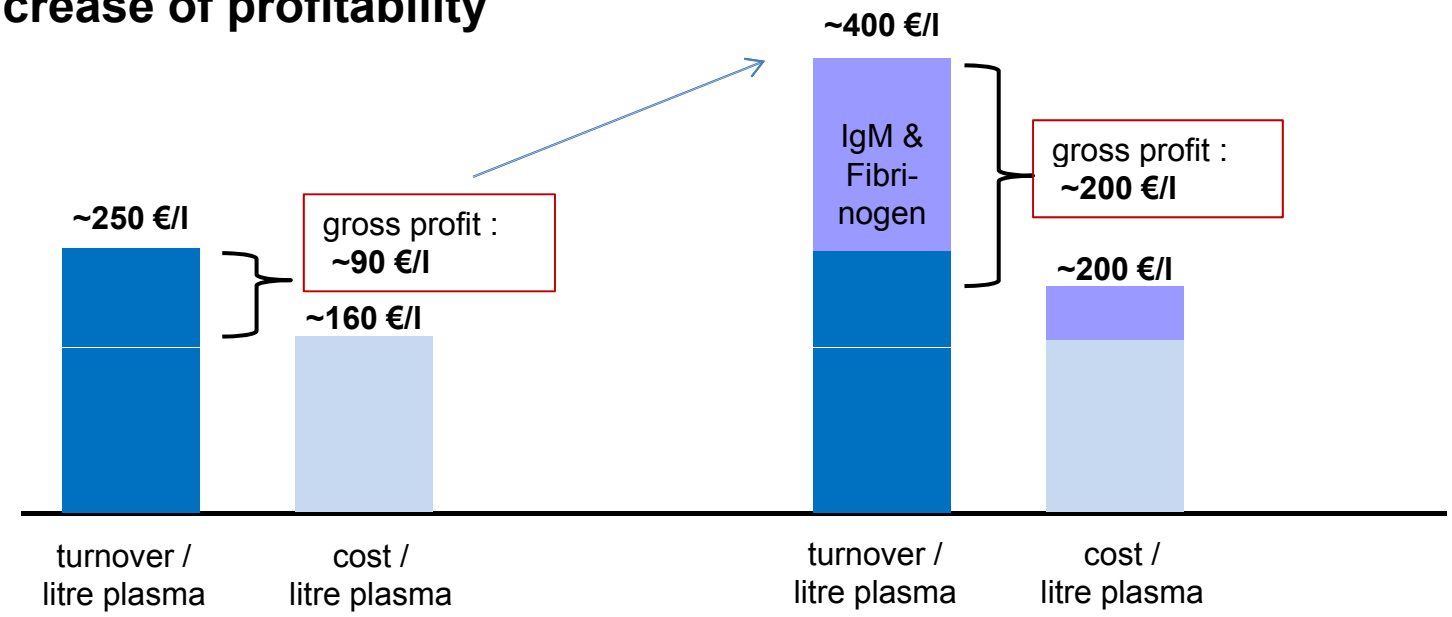
- Kedrion will take over exclusively the marketing & selling of Bivigam® in the US
  - The manufacturing capacity utilization will be significantly increased
  - **Increase of profitability, in 2016 by USD 4-5 million**


Biotest Next Level

Biotest Next Level

- **Product portfolio expansion**:
  3 products out of one litre plasma → **5** products out of one litre plasma
- **Improved, more efficient production process**
- **Capacity expansion:** **5.5t** → **13t** immunoglobulins

➢ **Increase of profitability**



Biotest Next Level

Lab building and plasma receiving building

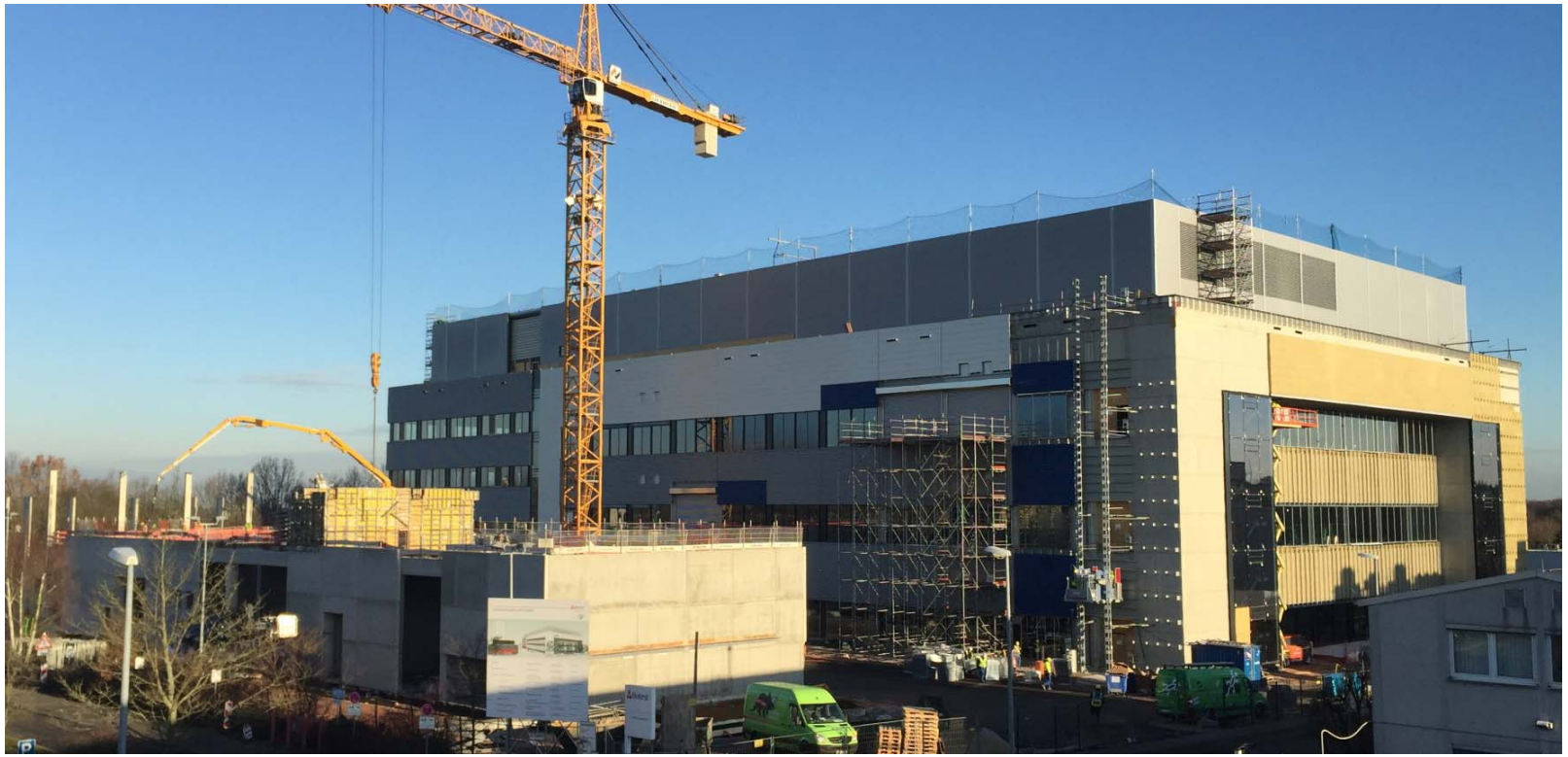
Lab building
- Virology
- Virus validation

Plasma receiving building
- Sorting area
- -30°C storage capacity

Biotest Next Level
As per April 2015

Biotest Next Level

On track in terms of timeline and budget (March 2016)



Development of Product Portfolio and R&D Programme

Biotest product and R&D portfolio

Lifecycle projects

- Zutectra Early Treatment ☑
- Cytotect
- Haemoctin 2000

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

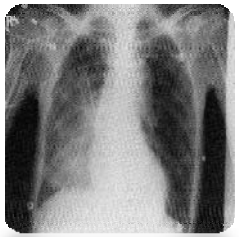
- Global commercialisation planned
- New efficient production process with high Ig yield established
- "Master product" for the Biotest Next Level production plant

Clinical development

- Phase III clinical development (EU/US) planned to start in H2 2016 in two indications
- An additional phase III study in a neurological indication is currently under evaluation - finalization of study design is planned for Q3 2016

IgM Concentrate
Severe Community Acquired Pneumonia (sCAP)

- Community acquired pneumonia (CAP) is a leading cause of illness and death worldwide[1]
- Mortality rates have not changed significantly over the past several decades despite the availability of improved broad-spectrum antibiotics



Chest radiograph

CIGMA study

Objectives

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

Primary Endpoint / Key Secondary Endpoints

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

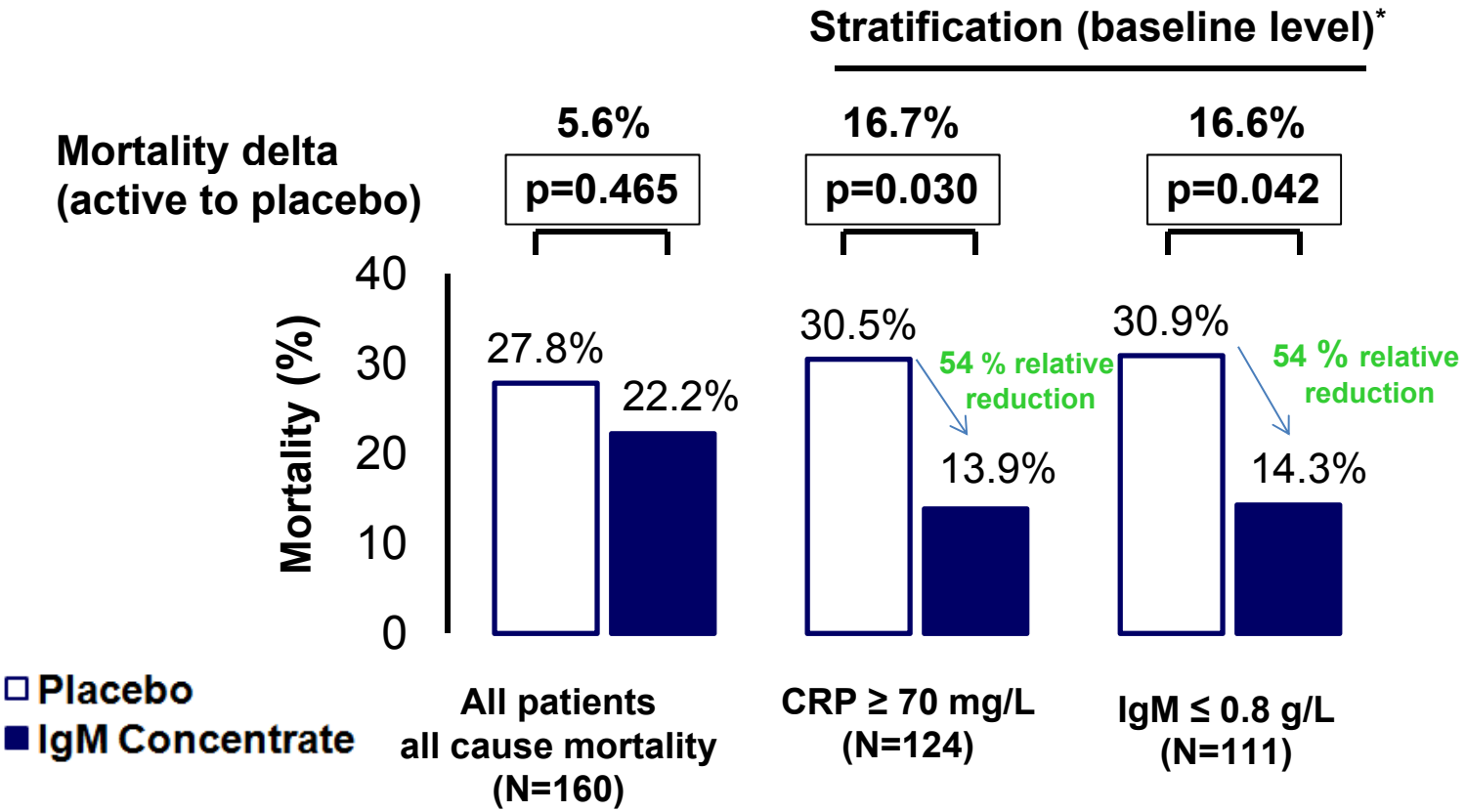
Key inclusion criteria

- Pneumonia has been acquired outside the hospital or diagnosed within 72 hours after hospital admission
- Patient receiving adequate antibiotic treatment for pneumonia

1: Wunderink 2014, N Engl J Med 370;6

IgM Concentrate

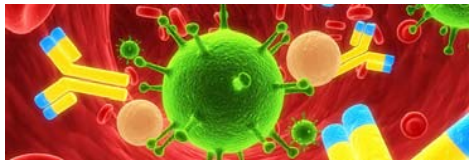
CIGMA – summary incl. post hoc analyses



CRP = C-Reactive Protein

* 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**
  - Market size in sCAP approx. 350,000 patients worldwide*
  - Sales potential approx. € 500 million p.a.

Potential upside indication

- **Common Variable Immunodeficiency Disease (CVID)**
  - e.g. IgM deficiency

* Source: Biotest market research

Pentaglobin®
Encouraging results in lung transplantation

- In lung transplantation donor specific antibodies (DSAs) are risk factors for mortality and acute and chronic graft rejection

- Patients treated with Pentaglobin (a IgM/ IgA enriched immunoglobulin) with early DSAs development after lung transplantation had a significantly **higher survival rate** than patients treated with therapeutic plasma exchange (standard therapy)

- Published data by the Hannover Medical School*
  - **> 70% reduction of relative mortality rate after one year**

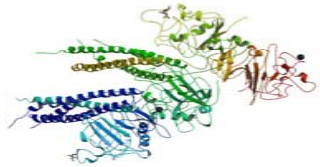
> **Mortality risk caused by DSA after lung transplantation was significantly reduced with Pentaglobin® (First generation IgM/ IgA enriched immunoglobulin)**

*: Ius.F et al. Transplantation, 2015 Dec 28

Fibrinogen

Development for congenital and acquired fibrinogen deficiencies

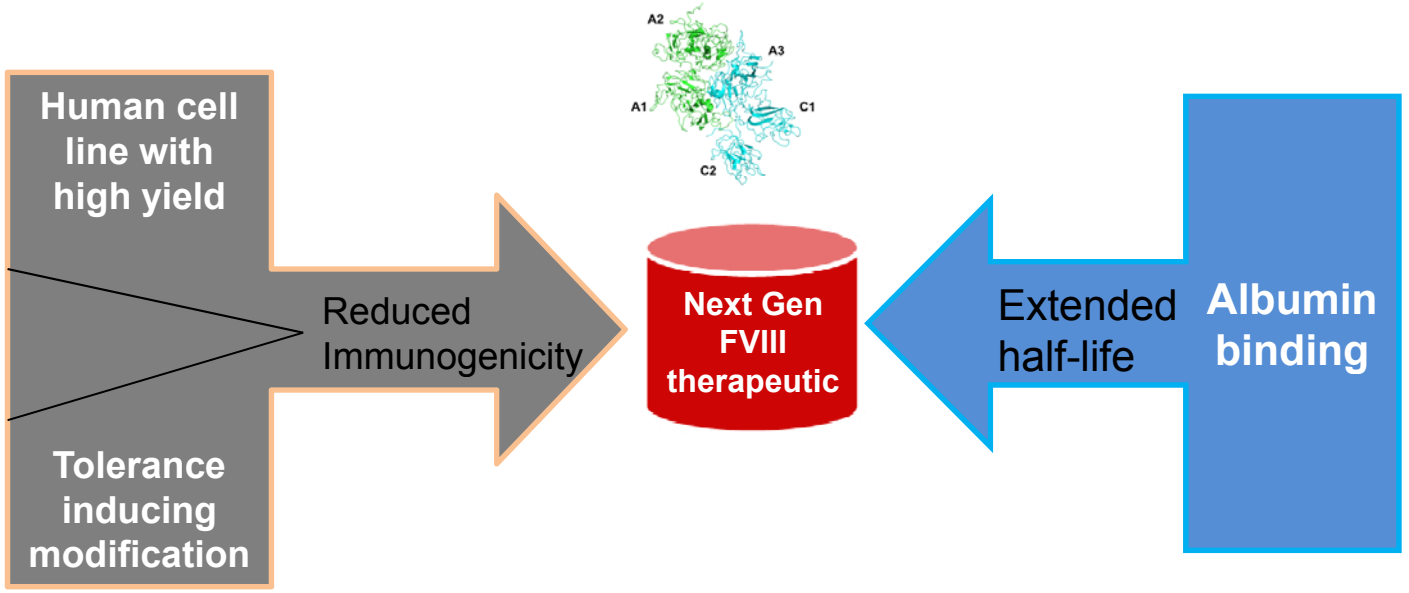
- Fibrinogen plays an essential role in blood clotting
- In the case of congenital fibrinogen deficiency patients can not produce sufficient or any fibrinogen
- In acquired fibrinogen deficiency, patients lose fibrinogen because of heavy bleeding, for example due to severe injuries and surgery



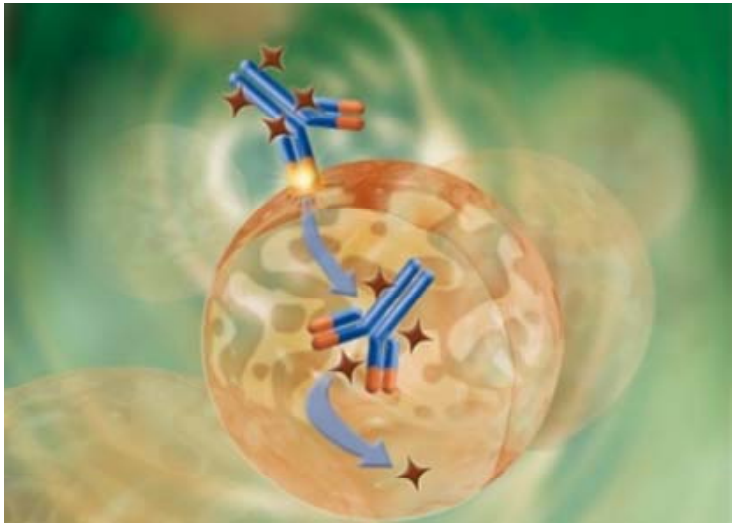
Phase I/III Study Congenital fibrinogen deficiency	Phase III Study Acquired fibrinogen deficiency
✓**Phase I: completed** **Phase III: ongoing** On-demand prophylaxis/treatment	caused by major surgery associated with excessive blood loss ⇨ **planning phase**

Next generation Haemophilia A therapeutic

- 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



BT-062 Indatuximab Ravtansine
Overview



- Combination of antibody and cytotoxic agent targets cancer cells
- Multiple myeloma: all patients recruited, treatment ongoing; report on study data expected in Q4 2016*
- Solid tumours: breast and bladder cancer; phase I completed, recruitment in extension phase ongoing

- 11/15 = 73% showed a response (≥ PR) to treatment
- 8 patients are on treatment without progressive disease for more than 8 months

•Pomalidomide/Dexamethasone Amendment

BT-063 in Systemic Lupus Erythematosus (SLE)

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:

- Last patient recruited in part I of the study
- Results of interim analysis from part I of the study expected for Q3 2016

* ClinicalTrials.gov Identifier-No.: NCT02554019; ** SLEDAI: SLE Disease Activity Index

BT-063
Role of Interleukin-10 (IL-10) in Immuno-Oncology

Background

- IL-10 levels are often elevated in serum and tumor microenvironment of cancer patients[1]
- Increased IL-10 serum levels correlate with poor survival[2]
- Elevated IL-10 serum levels are expected to inhibit the effects of new immuno-therapies like checkpoint inhibitors (PD-1, PD-L1), TLR agonists, cancer vaccines

Combining immune-stimulatory treatments with anti-IL-10 therapy (BT-063) has the potential to strongly increase the therapeutic success in cancer patients

- Sound scientific rationale
- Evidence from preclinical models
- High interest in anti-IL-10 treatment by academia and industry

1: Sato T. et al., Immunol Res (2011); Fayad L. et al., Blood (2001); 2: Zhao S. et al., PLOS One (2015)

Outlook & Summary

Guidance 2016

Outlook 2016

- **Increase of profitability (EBIT) >10% in comparison to November 2015**
- **Low single digit sales growth expected in 2016**
- **Profitable business with attractive R&D pipeline**

EBIT guidance 2016 in a range of € 33-35 million

Contact
Financial Calendar 2016

Financial Calendar 2016

11 Aug 2016	6M Report 2016
10 Nov 2016	9M Report 2016

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