Biotest

From Nature for Life

Biotest AG

Press and Analyst Conference FY 2015

Frankfurt am Main, 23 March 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
- Impairment of US business in Q3 2015
- Q4 2015 EBIT: € 10.2 million (above guidance)
- Re-focusing of core business
- Depriorisation of monoclonal antibodies after not meeting the primary endpoint in BT-061 study
- Biotest Next Level is on track with respect to timeline and budget
- Positive results :
  - IgM Concentrate shows encouraging results in life-threatening pneumonia
  - Pentaglobin® – very good results in treatment of donor specific antibodies after lung transplantation
  - Zutectra®: marketing approval for early use in EU


Biotest Next Level

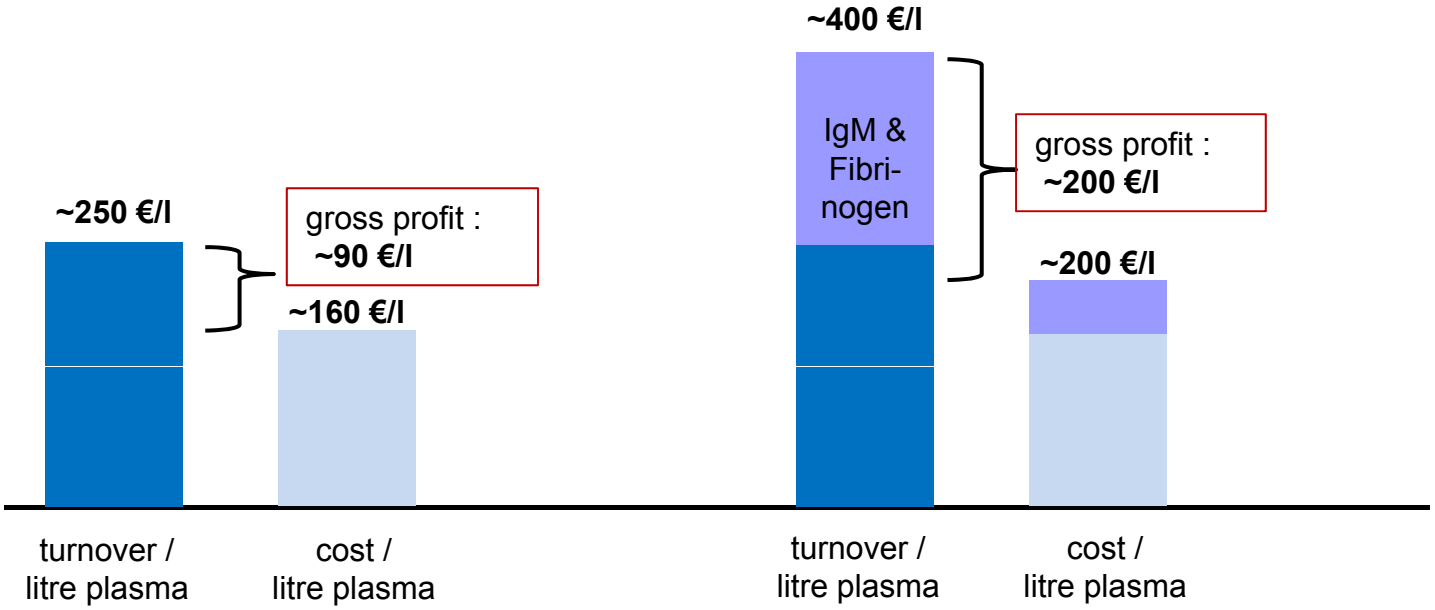
Biotest Next Level
Objectives

- **Broadening of product portfolio**
- **Facility expansion**
- **Increased profitability**

Biotest Next Level

- **Product portfolio expansion**:
  3 products out of one litre plasma → **5** products out of one litre plasma
- **Capacity expansion:** **5.5t** → **13t** immunoglobulins

➢ **Increase of profitability**



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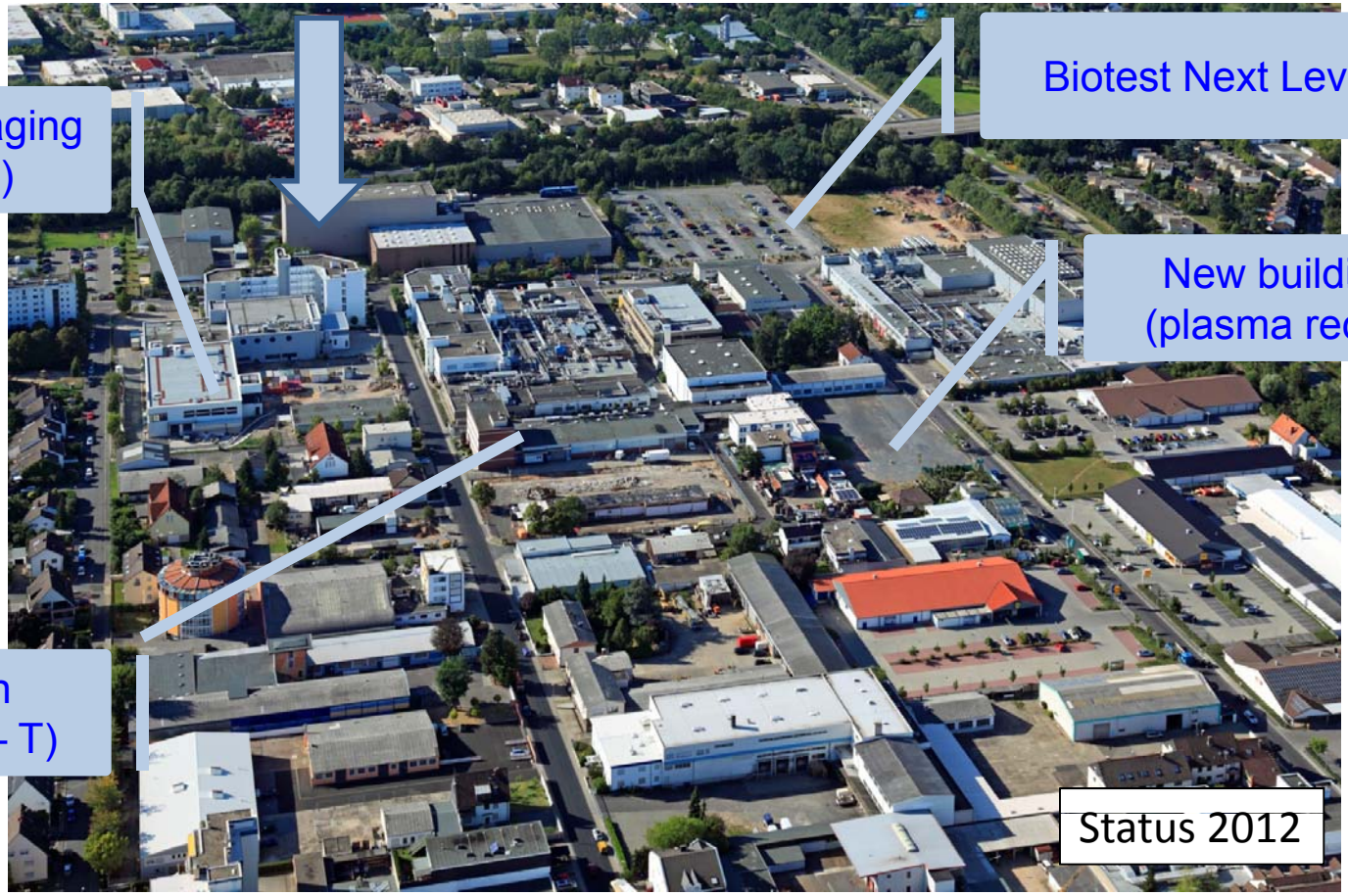
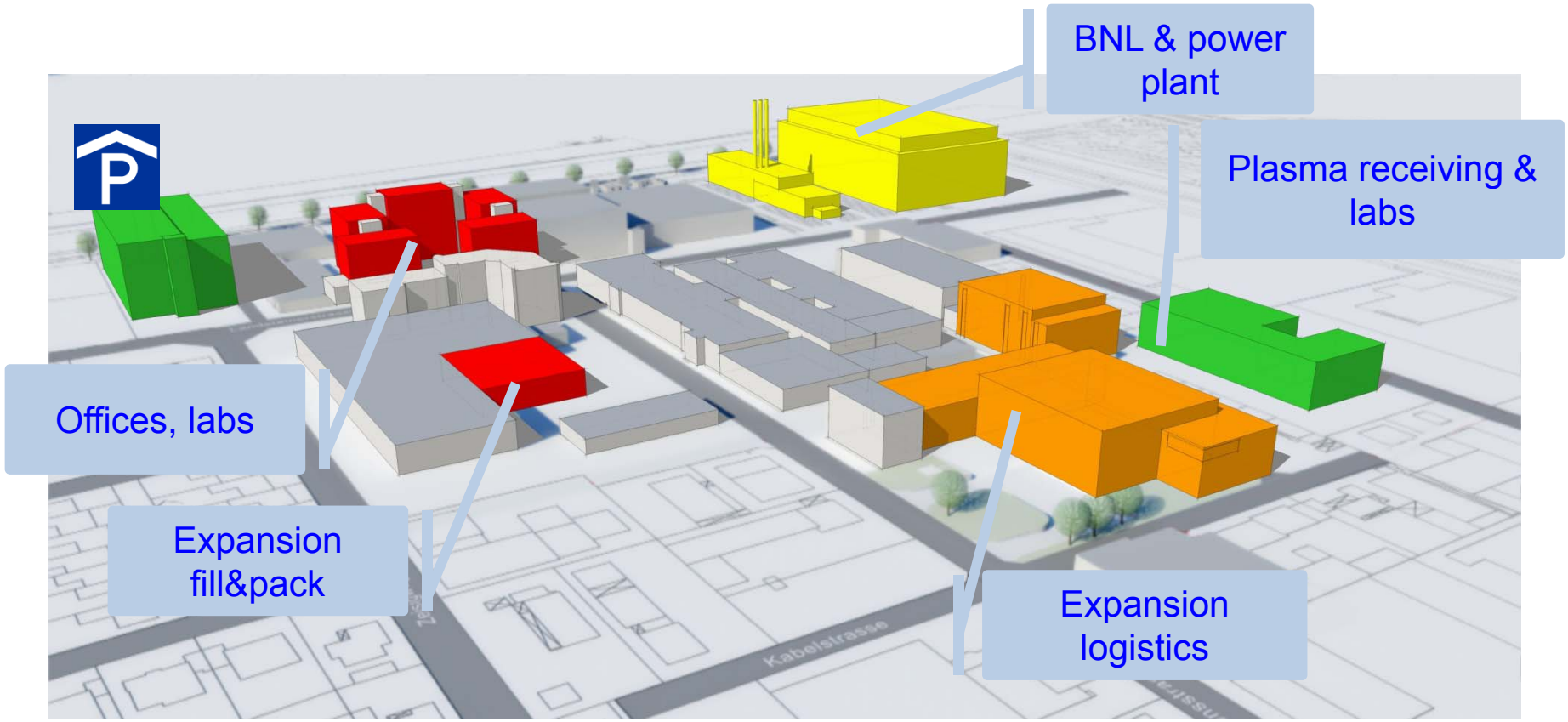
Biotest Next Level
Dreieich-Site 2012 => 2020



Biotest Next Level

Dreieich-Site today => 2020



completed | ongoing | basic design | concept

Biotest NEXT LEVEL

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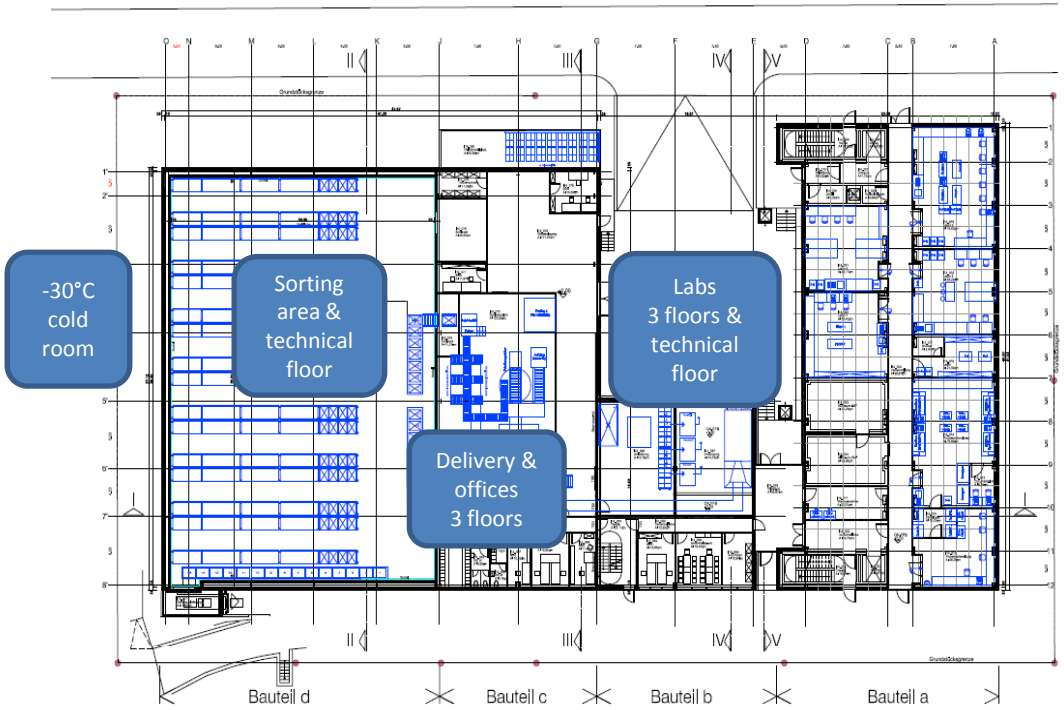
Biotest Next Level

Lab building and plasma receiving building



Lab building
- Virology
- Virus validation

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

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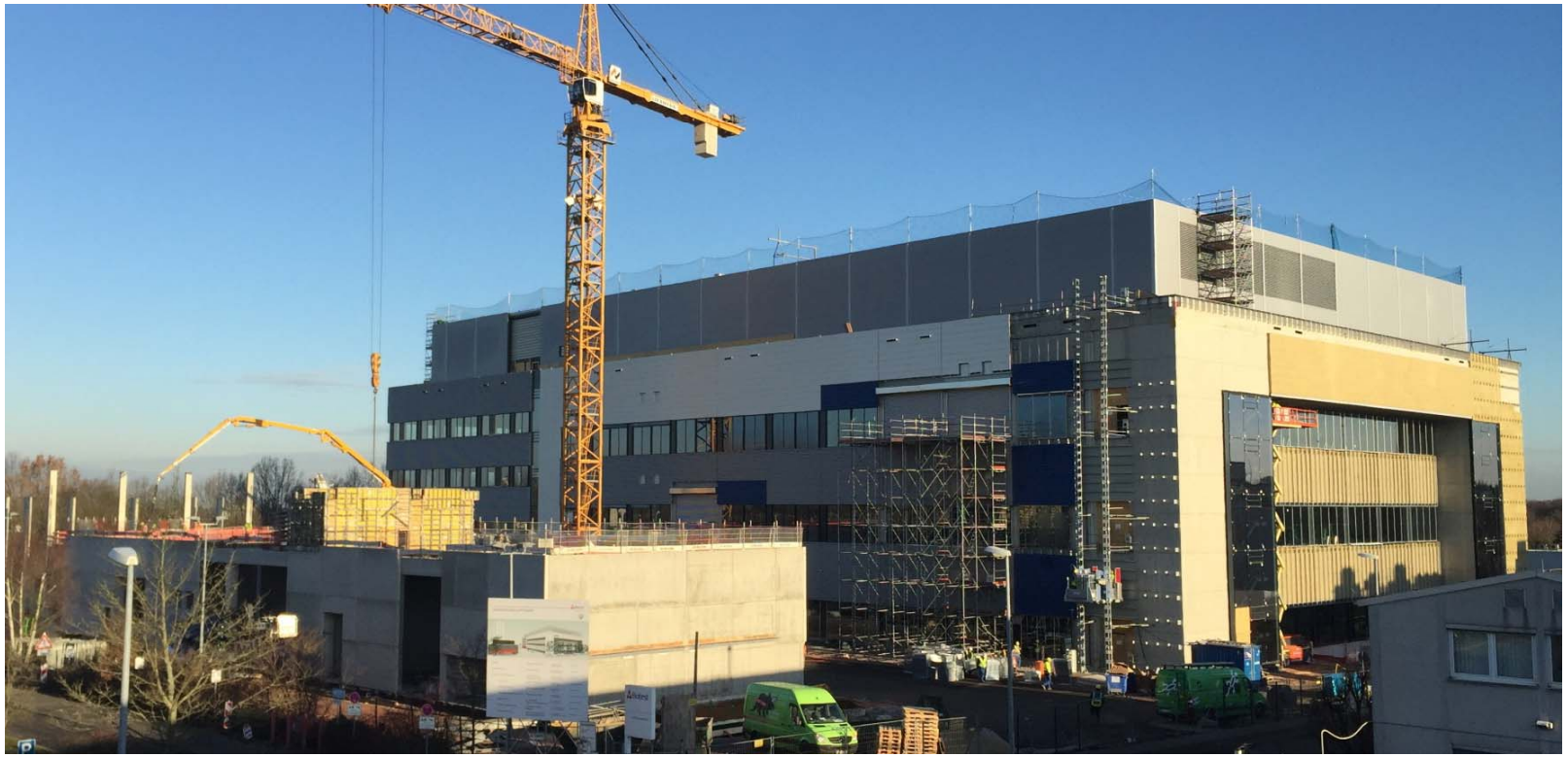
Biotest Next Level
As per April 2015

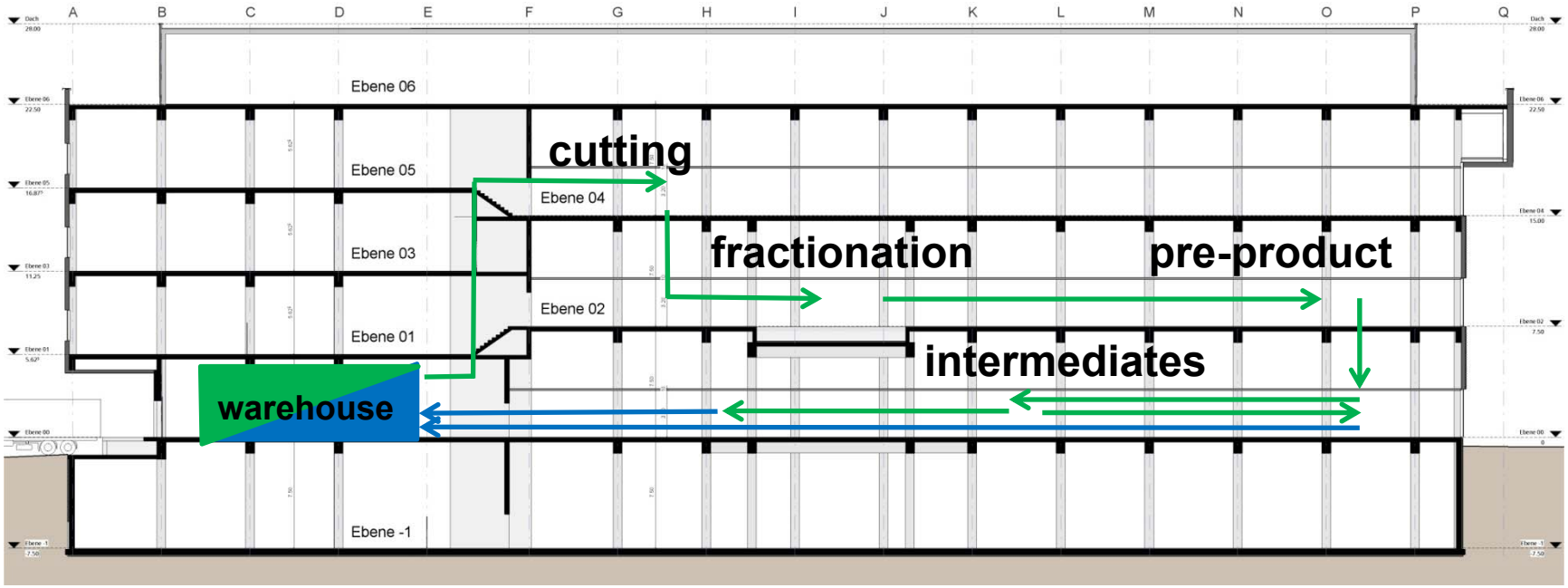
Biotest Next Level

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



Biotest Next Level

Production building - product flow



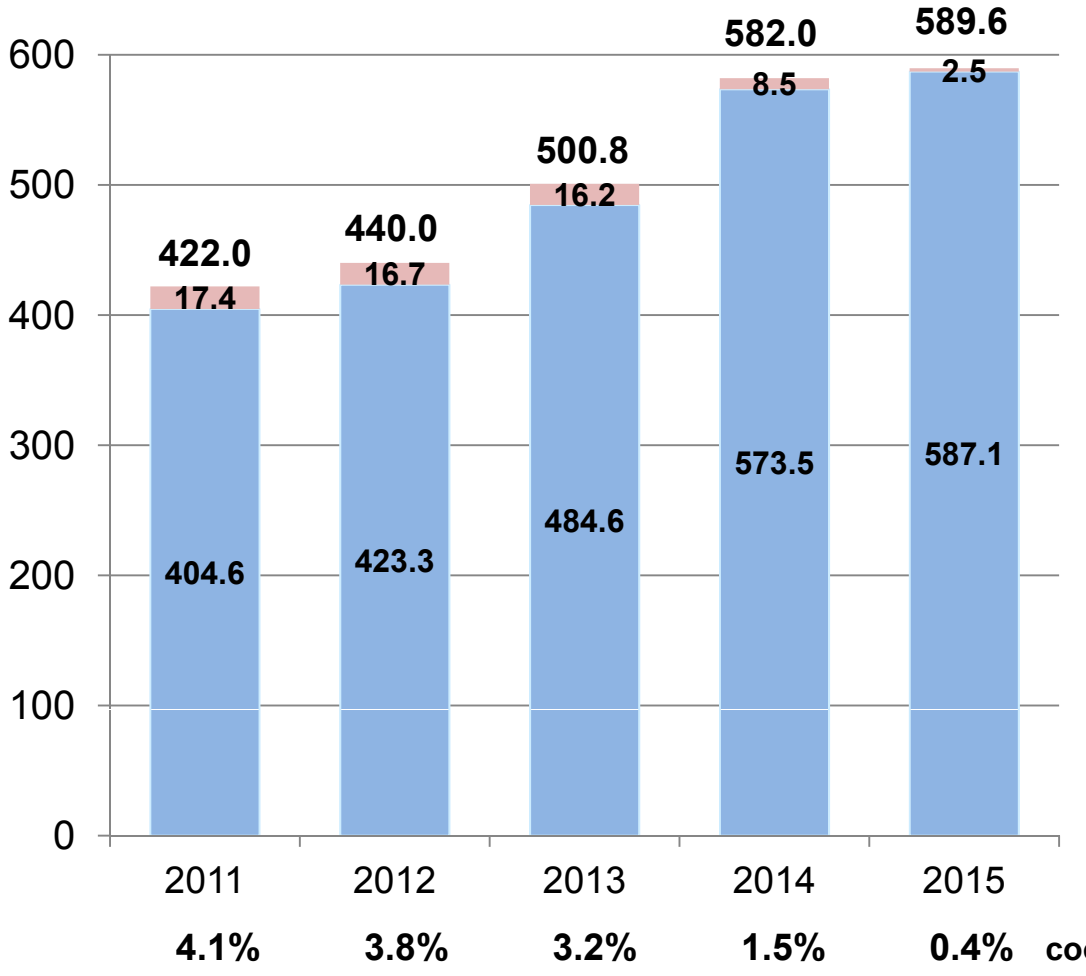
Raw material – Plasma, F VIII eluate for Fibrinogen

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

Financials - FY 2015

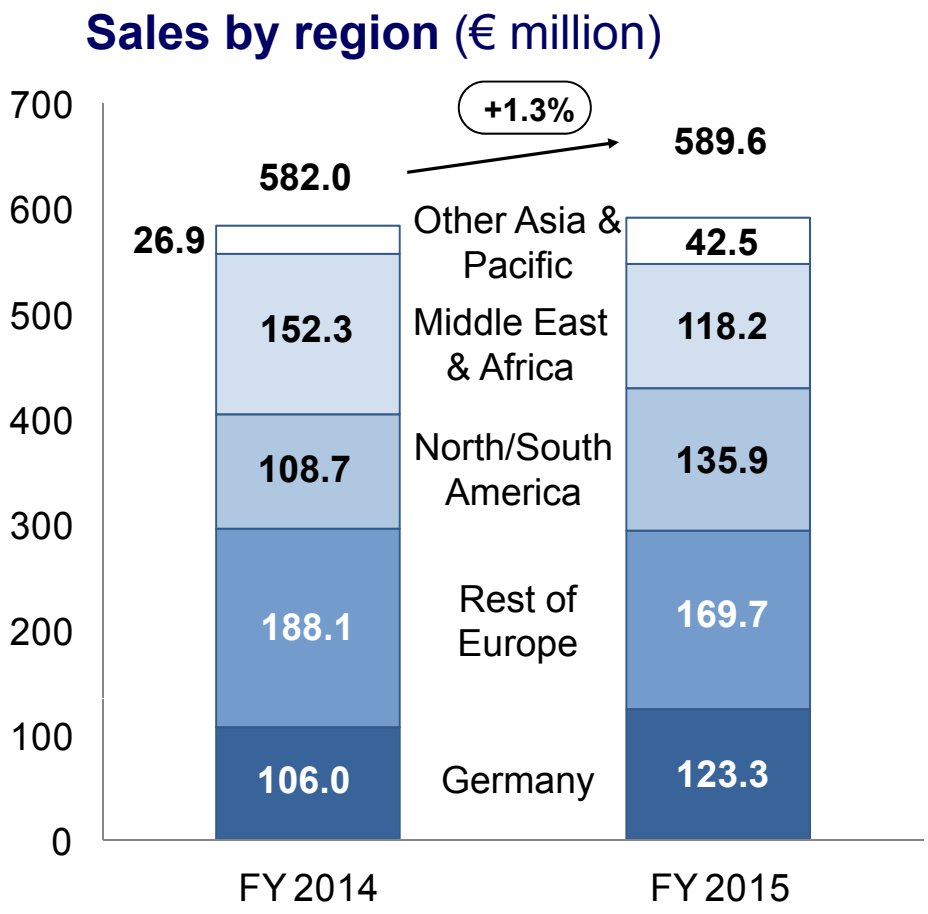
Sales development

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



- Decreasing influence of cooperation agreement

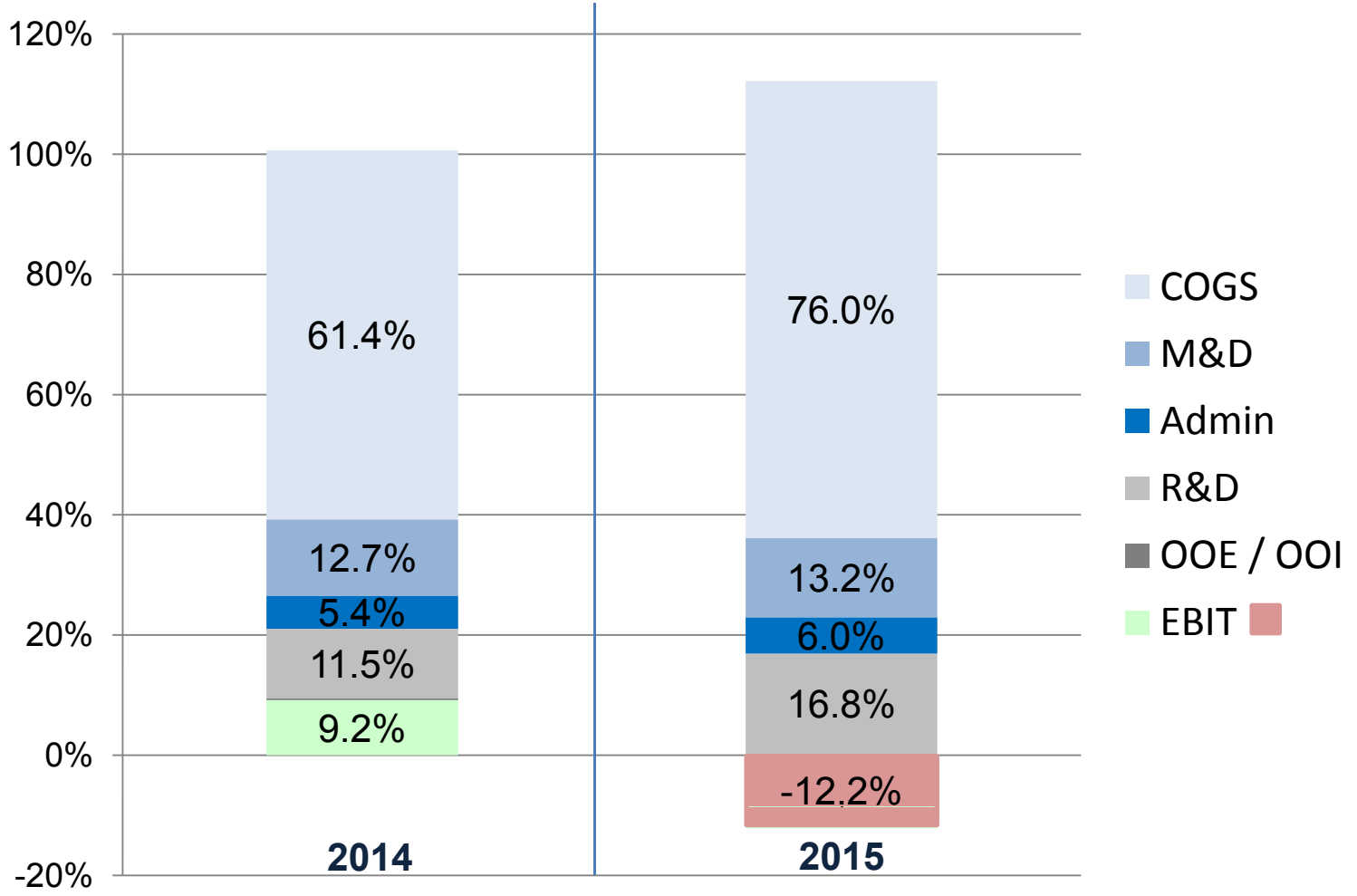
Sales growth



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

Statement of income

Profit & Loss positions in % of sales



EBIT and adjusted EBIT

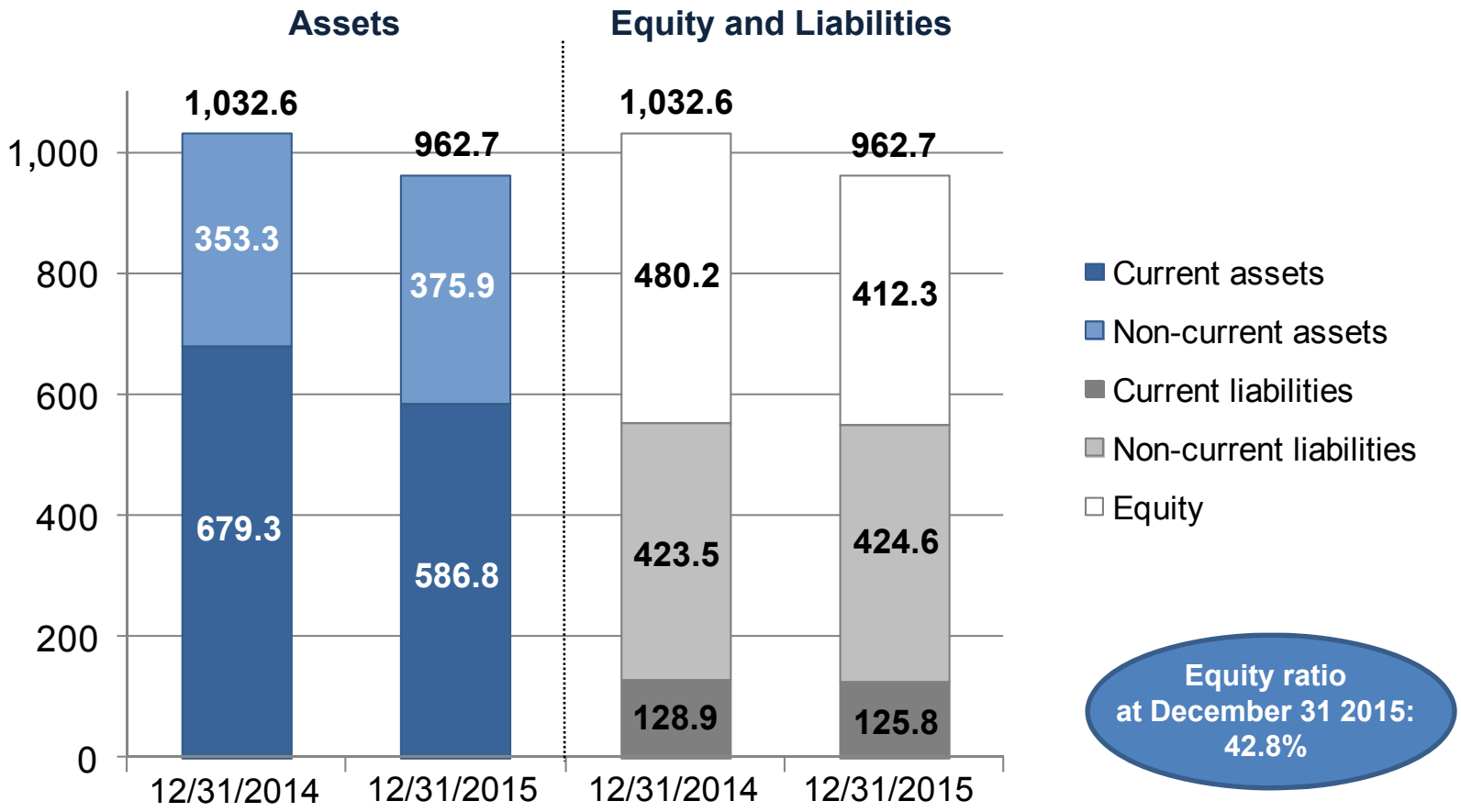
	2014	2015
EBIT (€ million)	**53.4**	**-71.8**
Impairment and one time effects*	-	77.2
Biotest Next Level costs**	15.4	23.3
Monoclonal antibodies	38.2	50.1
Idle capacity costs (Boca & Dreieich)	16.2	12.4
EBIT adjusted	**123.2**	**91.2**

* € 2.8 million are recognised in monoclonal antibodies

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

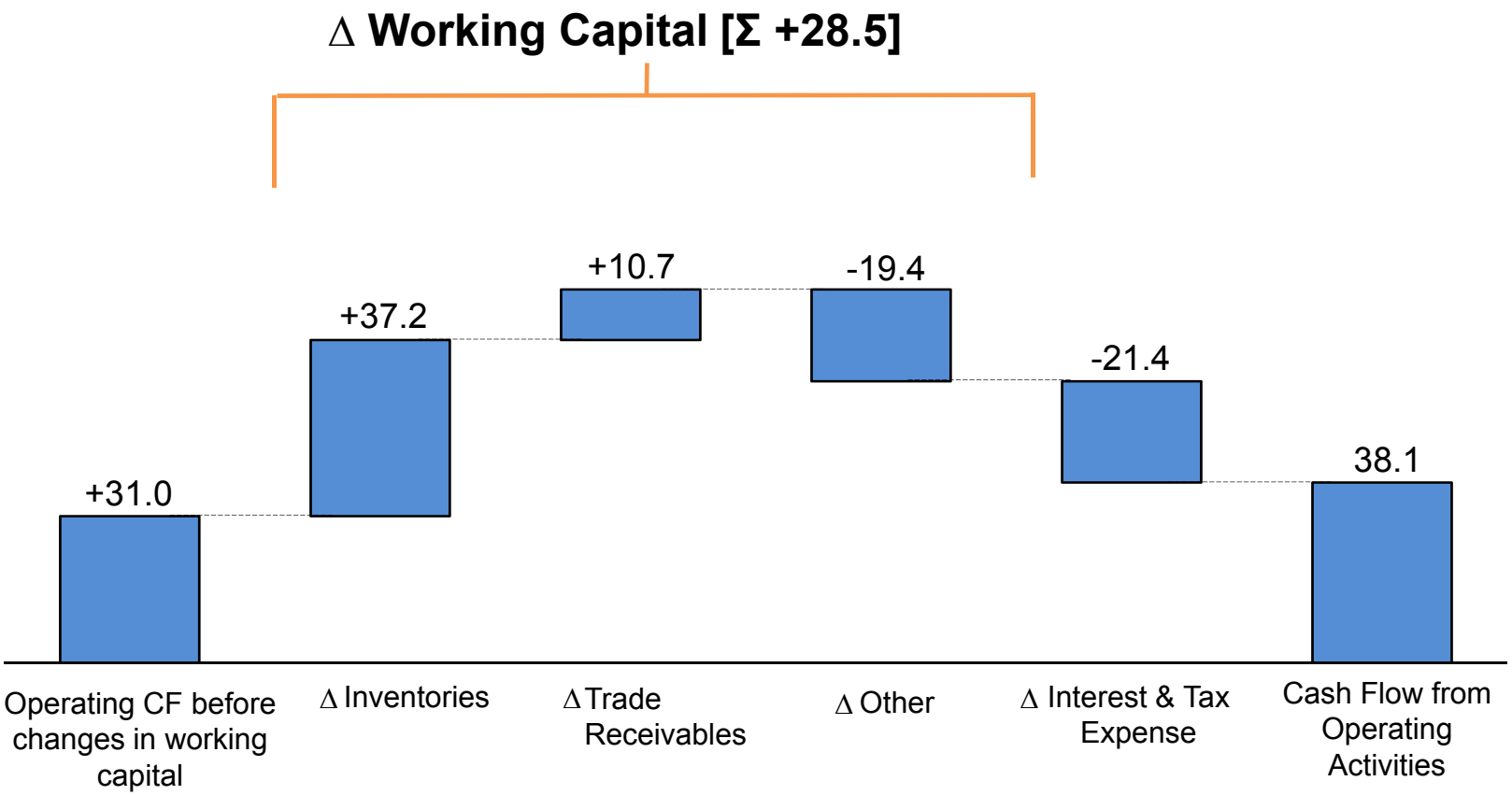
Balance sheet

Financial position of the Biotest Group (€ million)



Cash flow from operating activities

January – December 2015 (in € million)



Guidance 2016

as shown in November 2015

Sales: In the financial year 2016 sales will grow in a low single-digit percentage range

EBIT: We expect an EBIT in the range of € 30 million

Profitability 2016 will be influenced by :

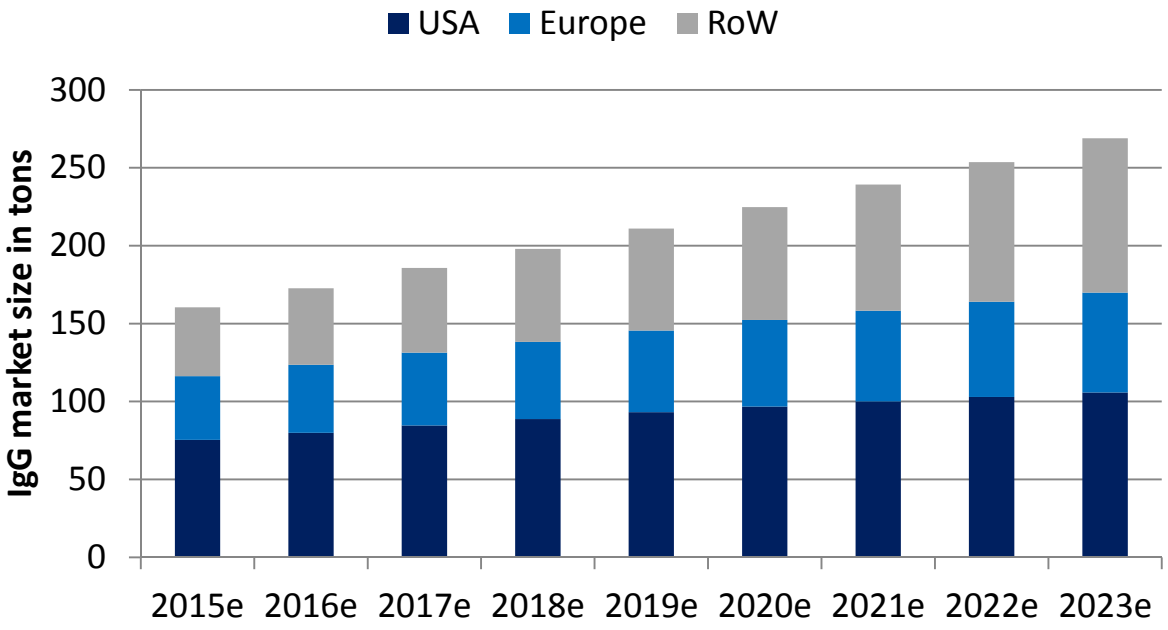
- Additional requirements in quality and safety ~ € 3-5 million
- Biotest Next Level costs ~ € 10-15 million
- R&D monoclonal antibodies ~ € 12 million
- Unabsorbed costs for idle capacity ~ € 8-10 million

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
  - Monoclonal antibodies: minimize expenses, continue activities solely up to next milestone to enable partnering
- **Continue of "partnering-strategy" in selected areas**
- **Increase of profitability**

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

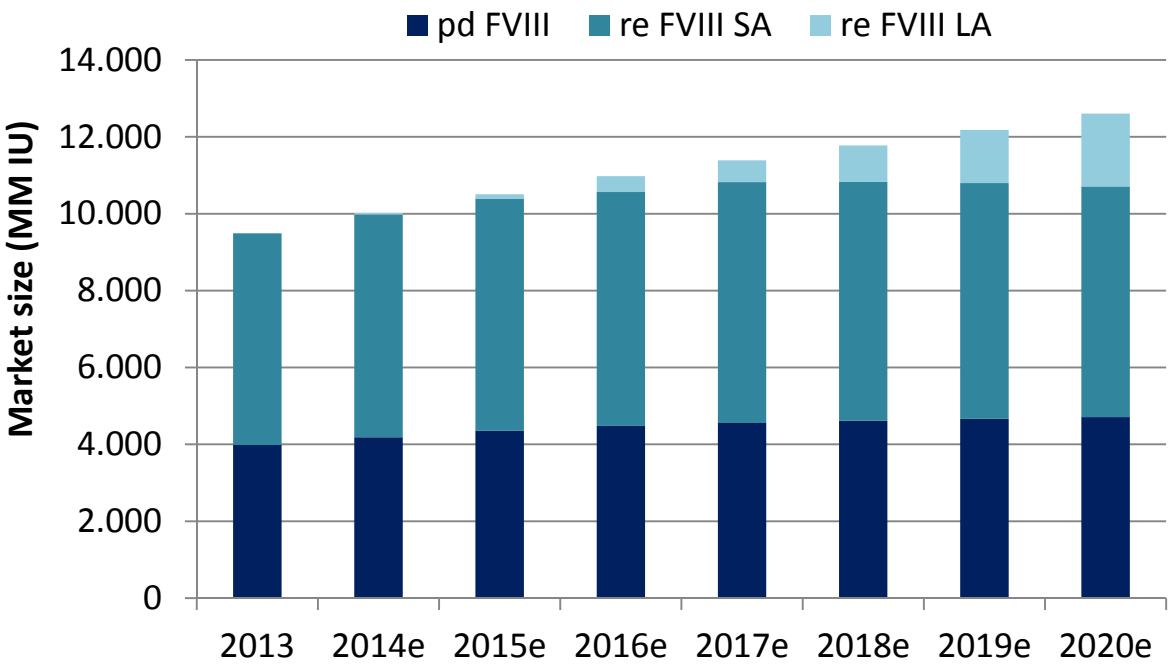


Exp. annual growth CAGR 2015e – 2023e	
RoW	10.5%
Europe	6%
North America	4.5%
World	6-7%

- 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 2013–20e	
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 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**

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

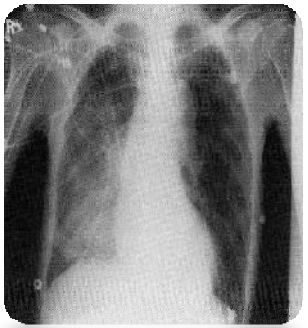
- Development of successor of Intratect® and Bivigam® helps patients with immune system dysfunctions and some autoimmune disorders
- Global commercialisation planned
- New efficient production process with high Ig yield established
- "Master product" for the Biotest Next Level production plant

Clinical development

- Phase III clinical development (EU/US) 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]
- 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[3]

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 – 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 (VFD)s
- 28-day all cause mortality

Key inclusion criteria

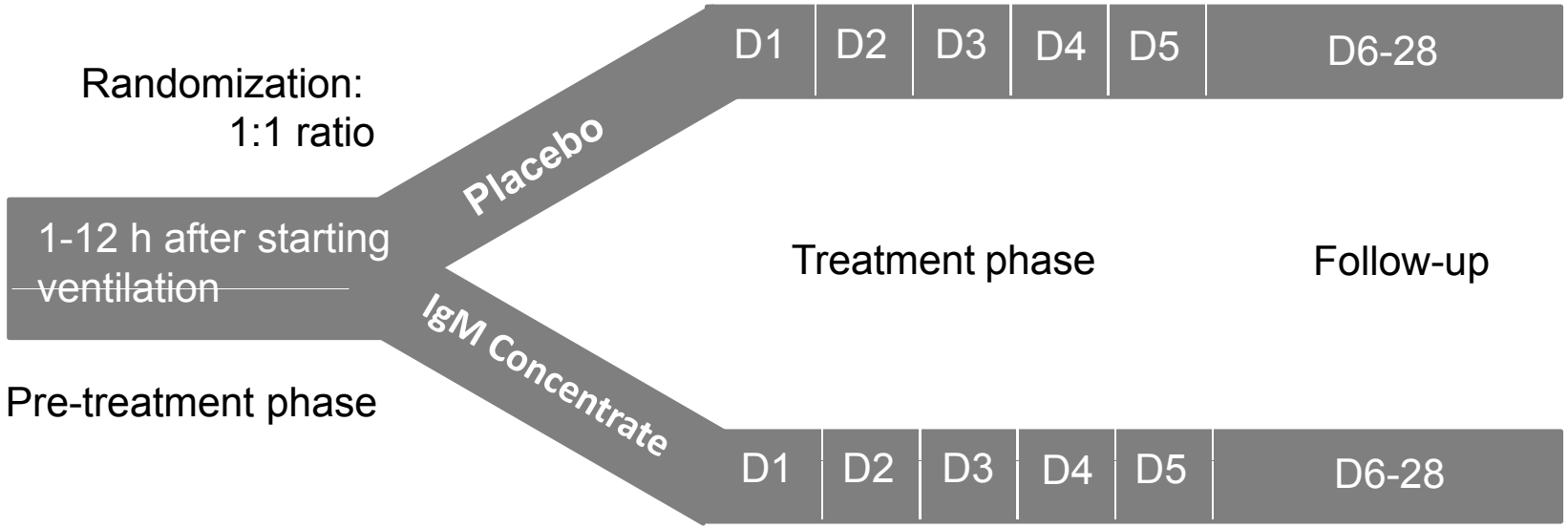
- Pneumonia has been acquired outside the hospital or diagnosed within 72 hours after hospital admission
- Patient receiving adequate antibiotic treatment for pneumonia
- Major sCAP criterion: need for invasive mechanical ventilation

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

VFD = Ventilator free days

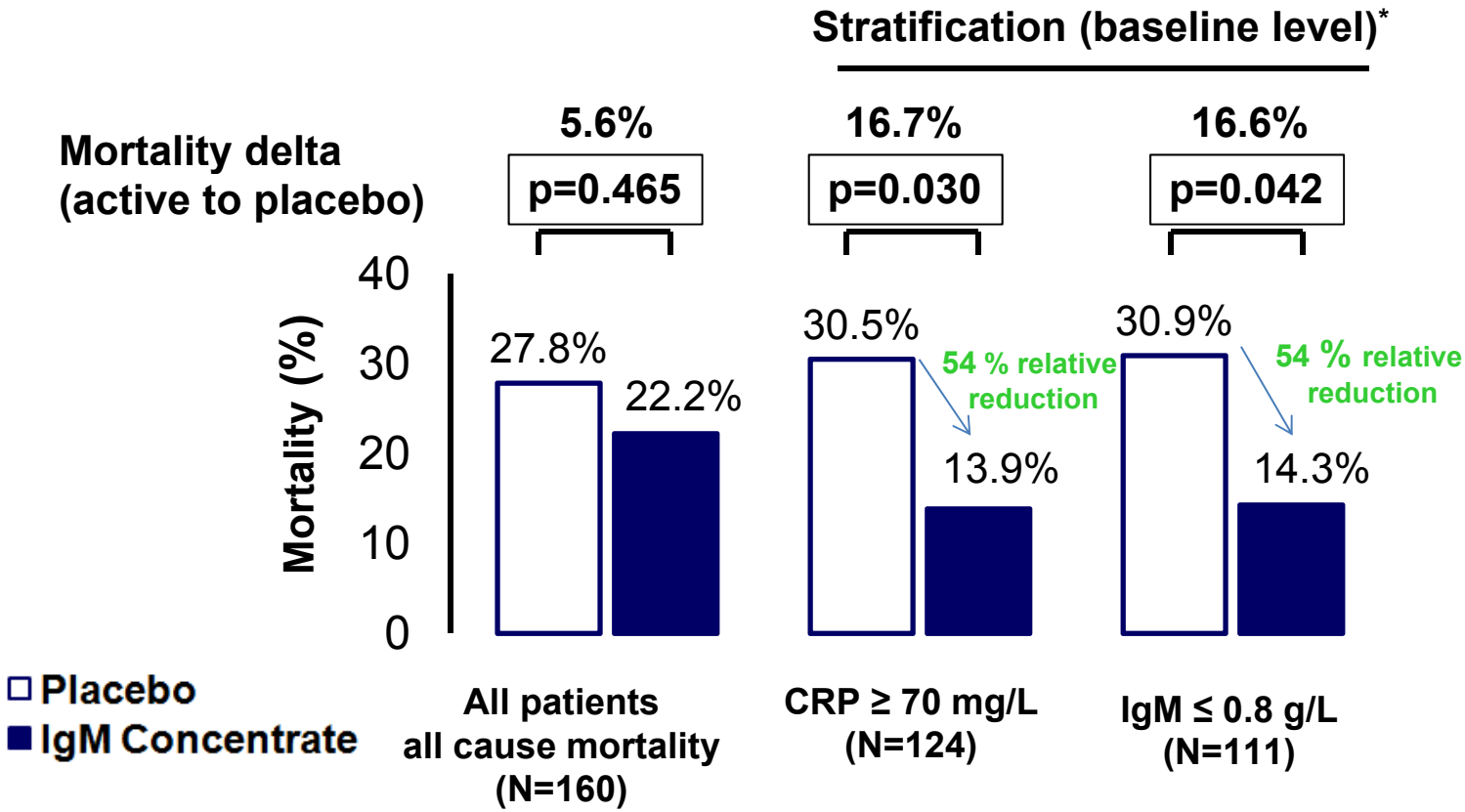
IgM Concentrate
CIGMA study design

- A randomized, double-blind, placebo-controlled, multicenter, parallel group, adaptive group-sequential phase II study
- 160 patients randomized in Germany, Spain and UK
- 5 daily infusions of IgM Concentrate (42 mg IgM /kg body weight) or placebo
- Start of IgM Concentrate or placebo within 1-12 h after start of ventilation



IgM Concentrate

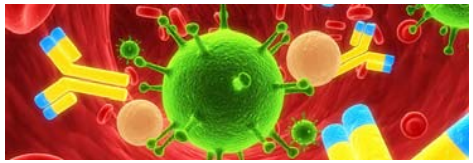
CIGMA – summary incl. post hoc analyses



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**
  - Value driver based on CIGMA study results
  - Market size in sCAP approx. 350,000 patients worldwide*
  - Sales potential approx. € 500 million p.a.

Potential upside indication (early to market 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)

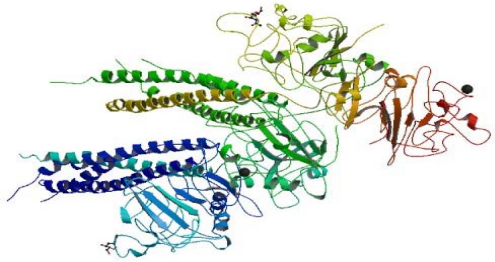
- Published data by the Hannover Medical School*
  - **> 70% reduction of relative mortality rate after one year**

> **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

- Fibrinogen plays an essential role in blood clotting
- A sufficient plasma fibrinogen level is critical for effective haemostasis
- 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
- In both cases, fibrinogen is needed to stop bleeding



Fibrinogen

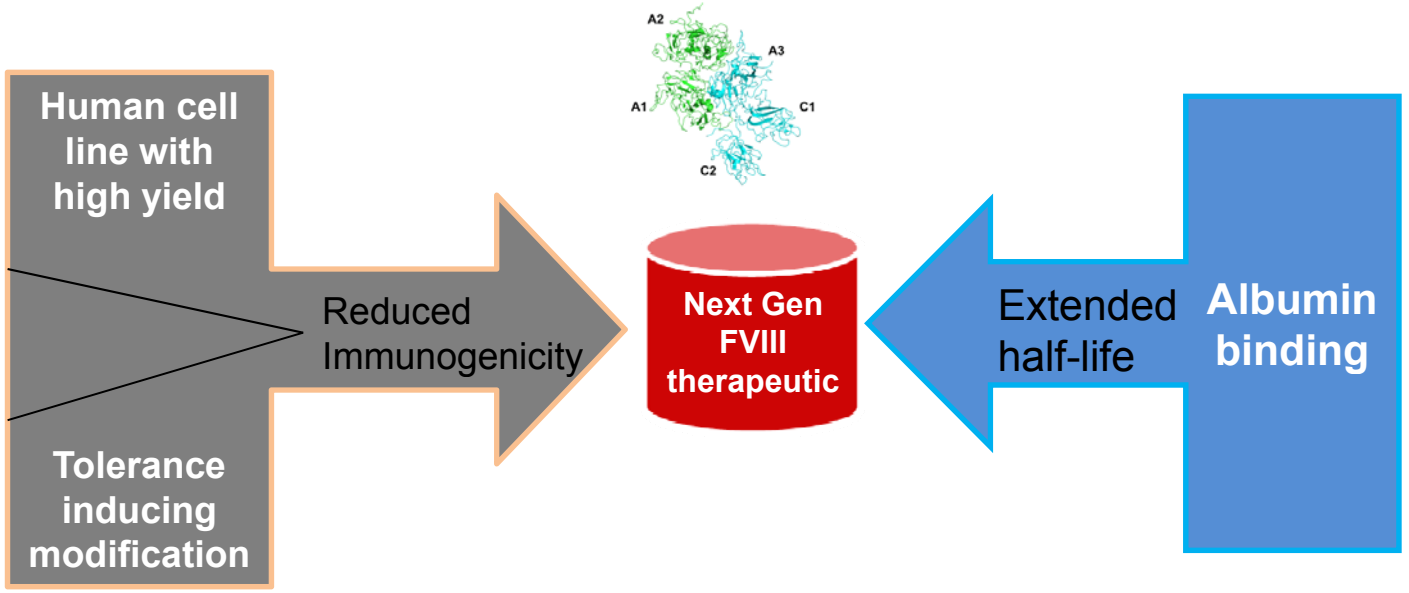
Development for congenital and acquired fibrinogen deficiencies

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 ⇨ **planning phase**

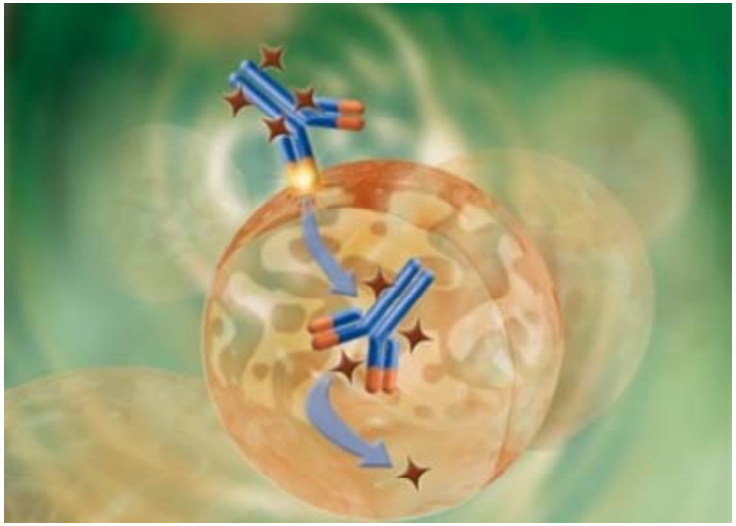
MCF = Maximum clot firmness

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

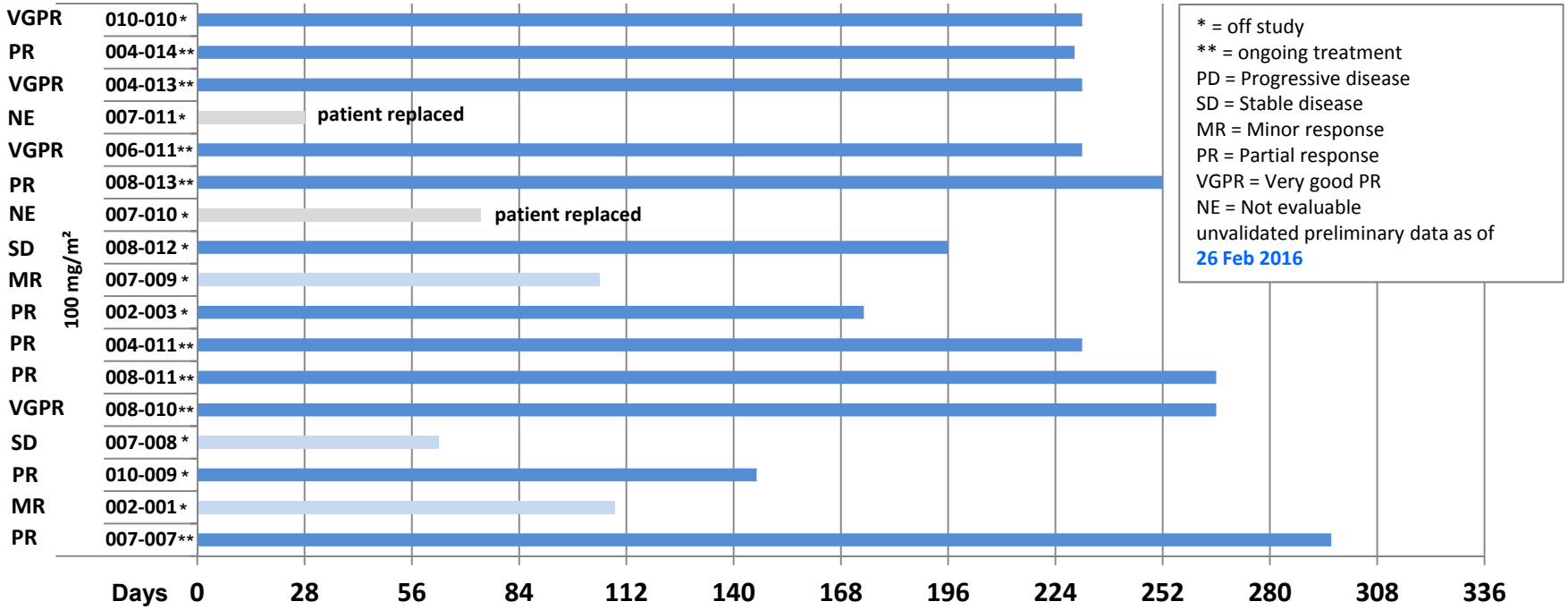


- Antibody Drug Conjugate (ADC), an innovative therapy approach for the treatment of multiple myeloma
- Combination of antibody and cytotoxic agent targets cancer cells
- Combination of efficacy and tolerability
- Multiple myeloma: all patients recruited, treatment ongoing; report on study data incl. PK* modeling expected in Q4 2016
- Solid tumours: breast and bladder cancer; phase I completed, recruitment in extension phase ongoing

* PK: Pharmacokinetics

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

Results of BT-062 with Pomalidomide / Dexamethasone



- A total of 17 patients were enrolled; 2 patients were replaced (not evaluable for efficacy)
- 11/15 = 73% showed a response (≥ PR) to treatment
- 8 patients are on treatment without progressive disease for more than 8 months

* Pomalidomide / Dexamethasone

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

Increase of EBIT guidance

Outlook 2016

- **Increase of EBIT guidance >10% due to good start in 2016**
- **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

12 May 2016	3M Report 2016
12 May 2016	Annual Shareholder Meeting
11 Aug 2016	6M Report 2016
10 Nov 2016	9M Report 2016

Investor Relations

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