



# **Biotest AG**

## **Company Presentation**

June 2014

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## 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
- All comparative figures relate to the corresponding last year s period, unless stated otherwise.

## **Biotest – Our mission**

### **Innovation**

- New drugs, new indications
- Further development of authorised drugs

### **Quality**

- Safety
- Tolerability
- User friendliness

### **Responsibility**

- Patient benefit
- Due diligence
- Long-term view

## Highlights first quarter 2014



Biotest headquarters in Dreieich

- Sales of € 122.2 million, an increase of 2.9% vs Q1 2013
- Position in the US market strengthened, internationalisation driven forward
- Capacity expansion project "Biotest next level" is progressing well
- Positive development of R&D projects

# Biotest Group

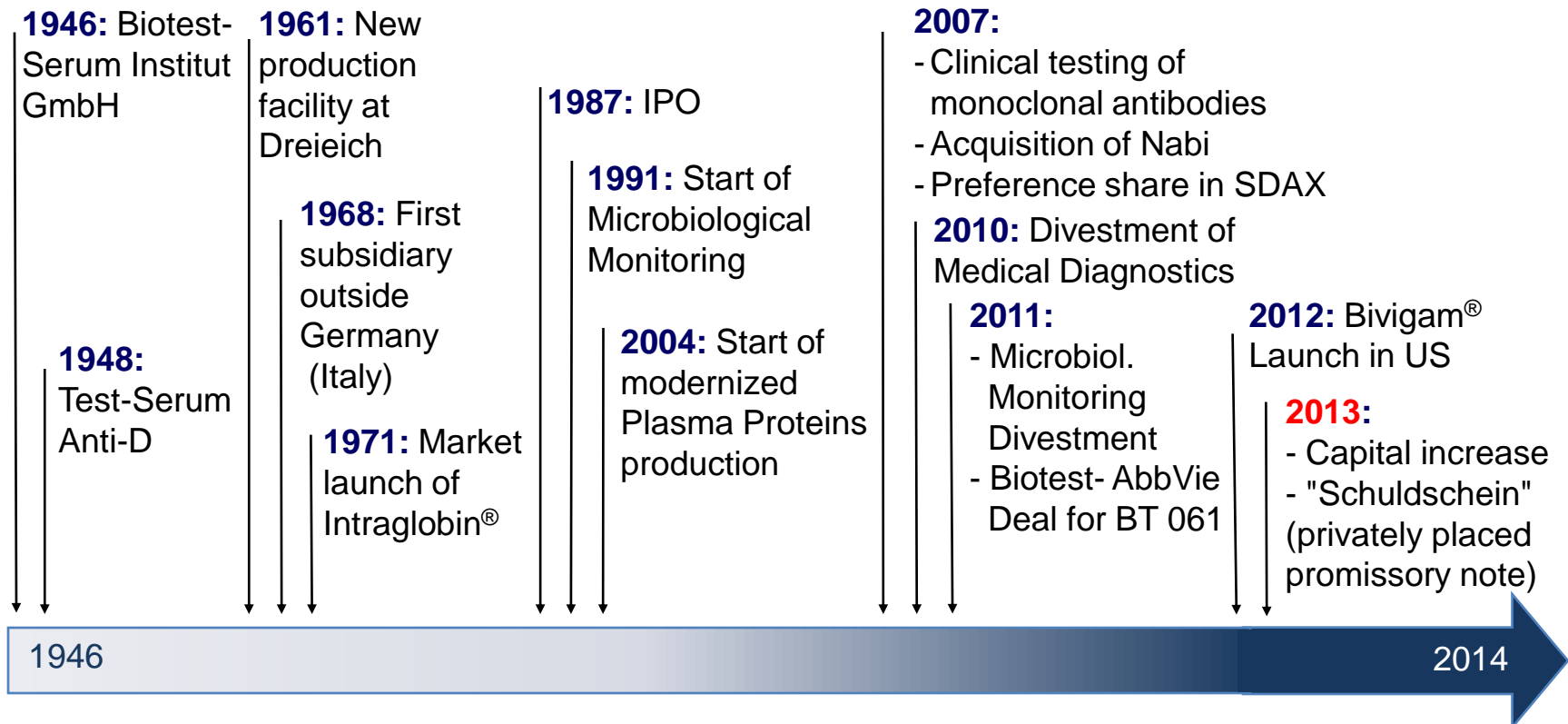
- Headquarter in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 11 countries worldwide
- Employees (FTE)\*: 2,090  
    Thereof 59% located outside Germany
- Founded in 1946, IPO in 1987, SDAX in 2007 (preference shares)
- Biotest shares:
  - 6,595,242 ordinary shares
  - 6,595,242 preference shares



Headquarter, Dreieich

\*: as of March 31, 2014

# Biotest: History and milestones achieved



## Focus of Biotest

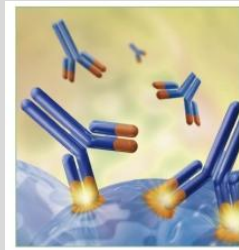
**Biotest** is a pharmaceutical company which develops, produces and sells **biological medicinal products**, that are either obtained directly from human plasma or manufactured using biotechnological methods.

### Haematology



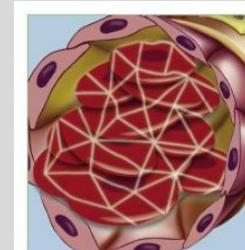
Diseases of the blood and blood-forming system

### Clinical Immunology



Disorders of the immune system

### Intensive Care Medicine

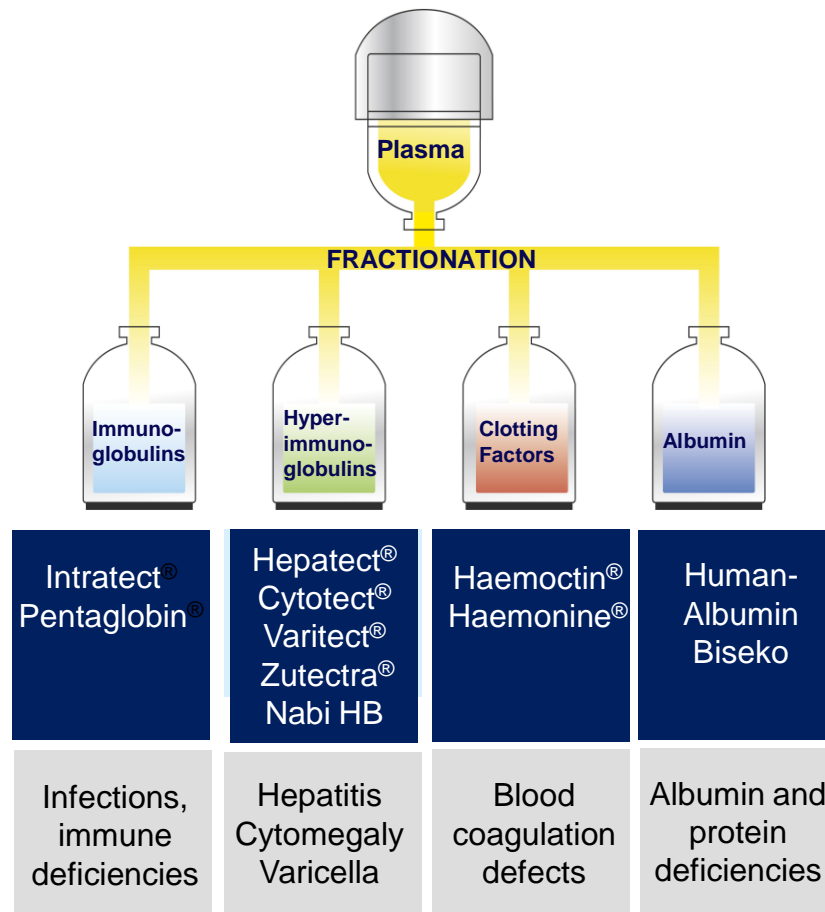


Acute, mostly life-threatening diseases



# Plasma Proteins business at a glance

## Biotest Plasma Protein products



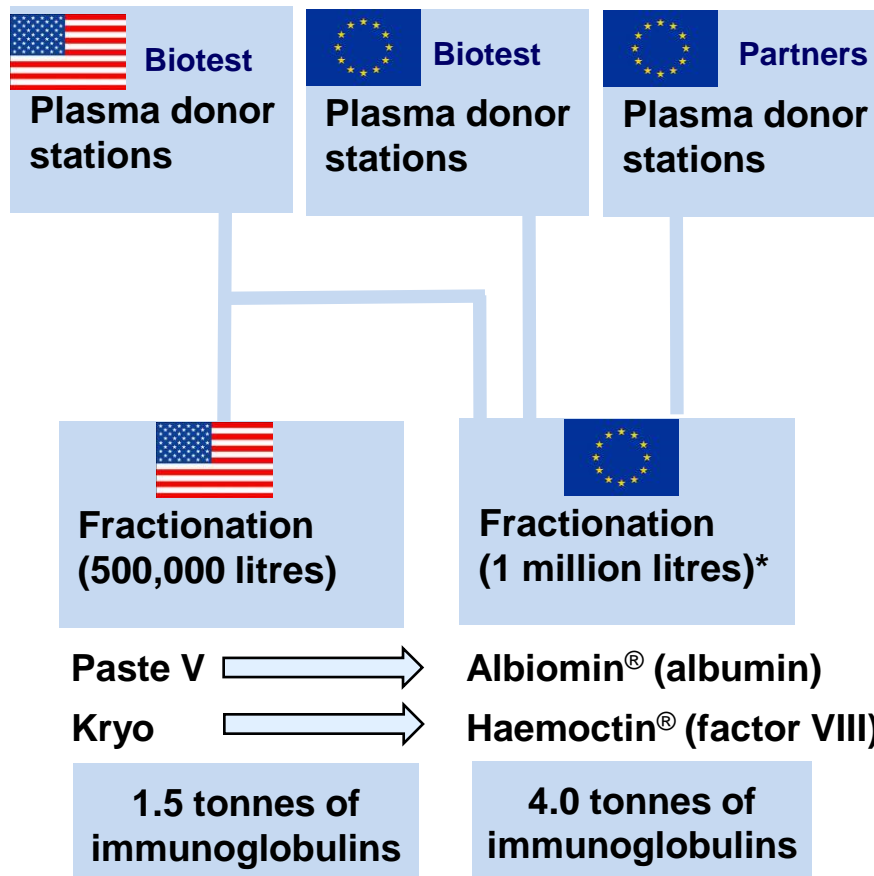
- Intratect® market share in (GER+ AUT+ CH) = ~ 13%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA
- Biotest covers full value creation chain: plasma sourcing, production, distribution

➔ vertical integration leads to rationalisation and higher productivity

■ = Biotest products    □ = lead indications



# Plasma Proteins – Efficient production network



- 26 plasma collection centres
- Level of self-sufficiency: 50% for standard plasma
- Exchange of intermediate products from US to Europe from 2013 onwards
- Network increases EBIT margin

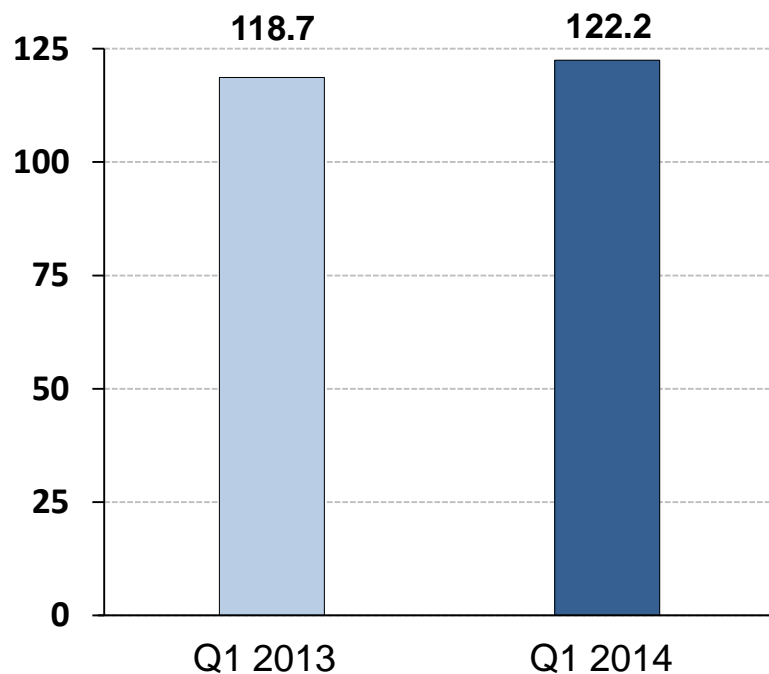
\* Production in Dreieich and capacities at partners



## Financials Q1 2014

## Sales in the first quarter 2014

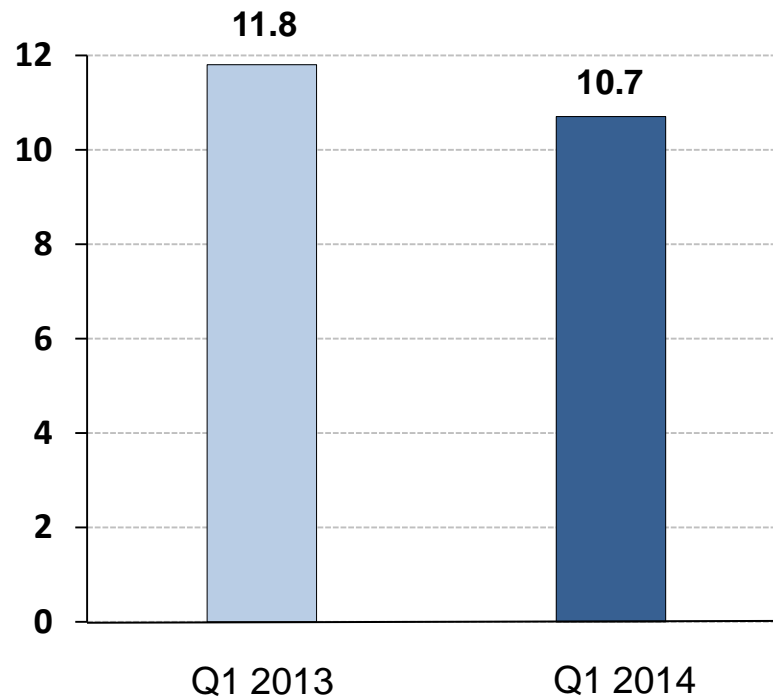
**Sales (€ million)**



- Sales increase in Germany 1.8%
- Sales increase in Europe w/o Germany 11.5%
- Sales in other countries stable

## Earnings in the first quarter 2014

### EBIT (€ million)

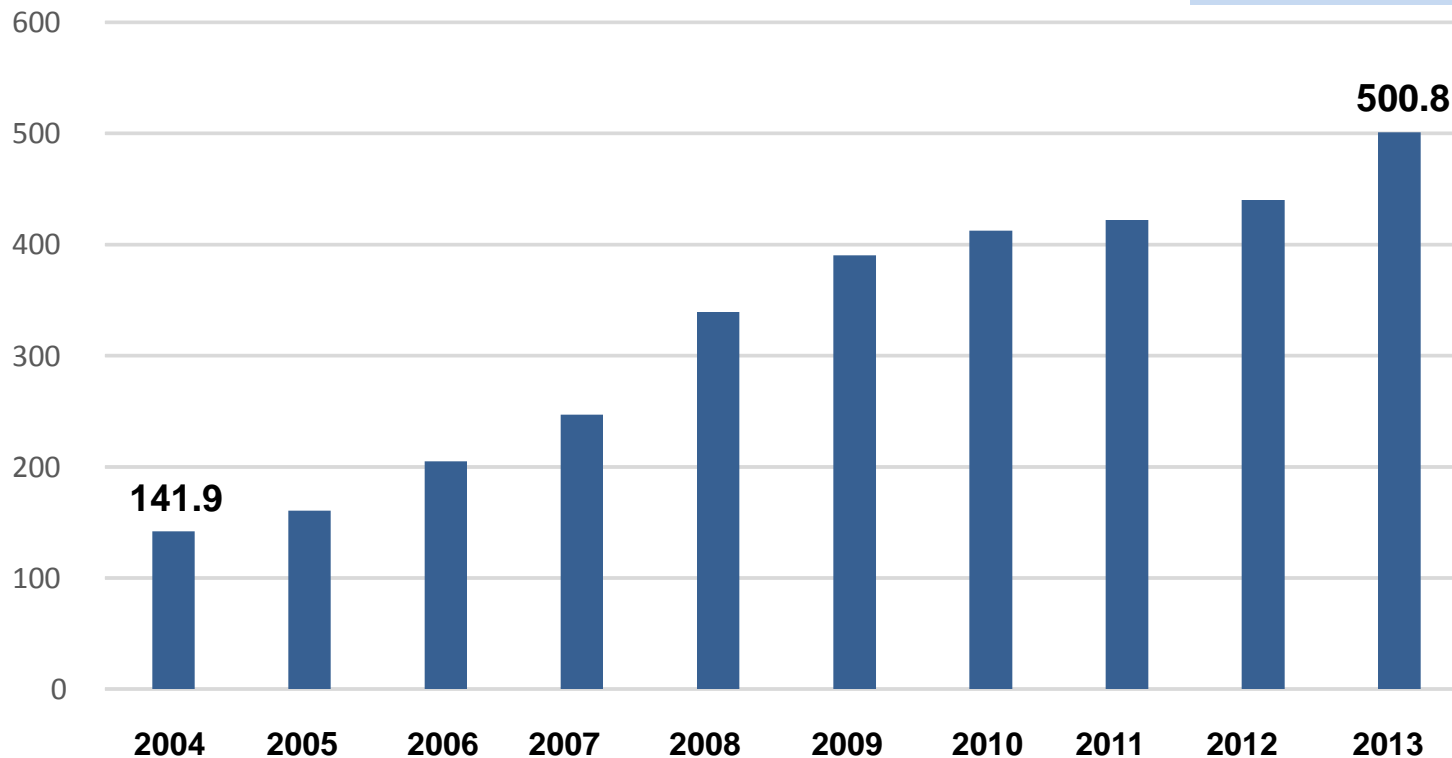


- Lower Bivigam<sup>®</sup> sales after recall
- Higher project cost for "Biotest Next Level"
- Advanced clinical studies incurred higher funding

## Continue and accelerate growth

### Biotest Group: sales 2004–2013 (€ million)\*

Sales target for 2020:  
**~ € 1 billion**



\* On a comparable basis, excluding pharmaceutical activities



**Innovation**  
**Quality**  
**Responsibility**  
**Strategy**

## Position strengthened in the attractive US market



BPC headquarters in Boca Raton, Florida

- Successful start to the marketing of Bivigam<sup>®</sup> in 2013
- Sales forecasts for Bivigam<sup>®</sup>
  - about US\$ 60 million for 2014
  - about US\$ 100 million p.a. from 2015 onwards
- Number of plasma collection centres in the US will increase to 18 by the end of 2014
- Promising development projects



## Production network offers great advantages



**1** Plasma collection in US collection centres, initial processing in Boca Raton

**2** Processing into finished products, filling/packaging at Dreieich

**3** Global marketing, including in the EU, China or South America

## Entering additional growth markets



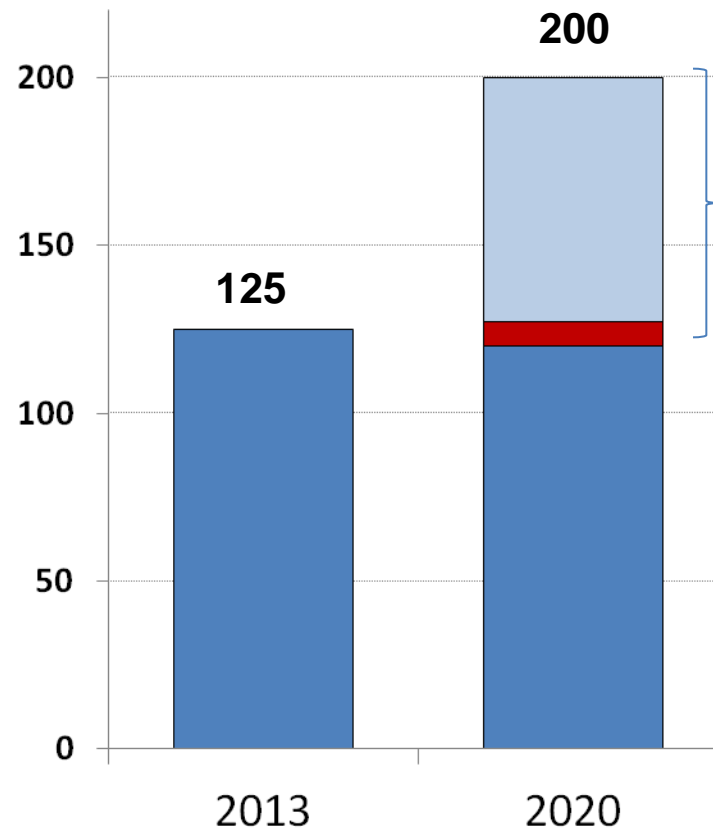
- **China:** third largest pharmaceutical market in the world, two-digit growth rates
- Marketing authorisation for Albiomin<sup>®</sup> 20% expected by Biotest for the fourth quarter 2014



- **Brazil:** fifth largest country (by population) in the world
- Rapidly growing market for plasma proteins
- Marketing authorisation for Albiomin<sup>®</sup> 20% received in November 2013, further plasma proteins in the marketing authorisation procedure

# Global market for immunoglobulins continues to grow

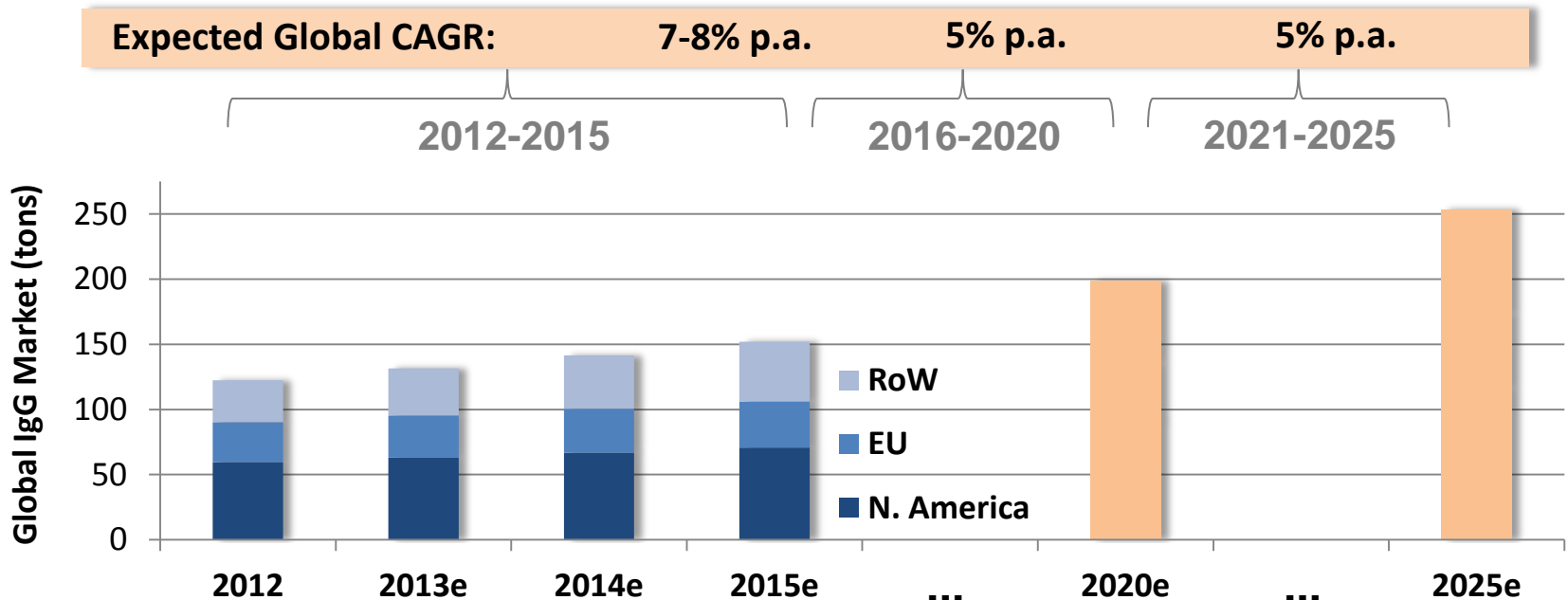
## Global market volume for IVIG (tonnes)



**Further additional demand of IVIG up to 2020: 75 tonnes**

**Capacity increase at Biotest up to 2018: 7.5 tonnes i.e. 10% of total additional demand**

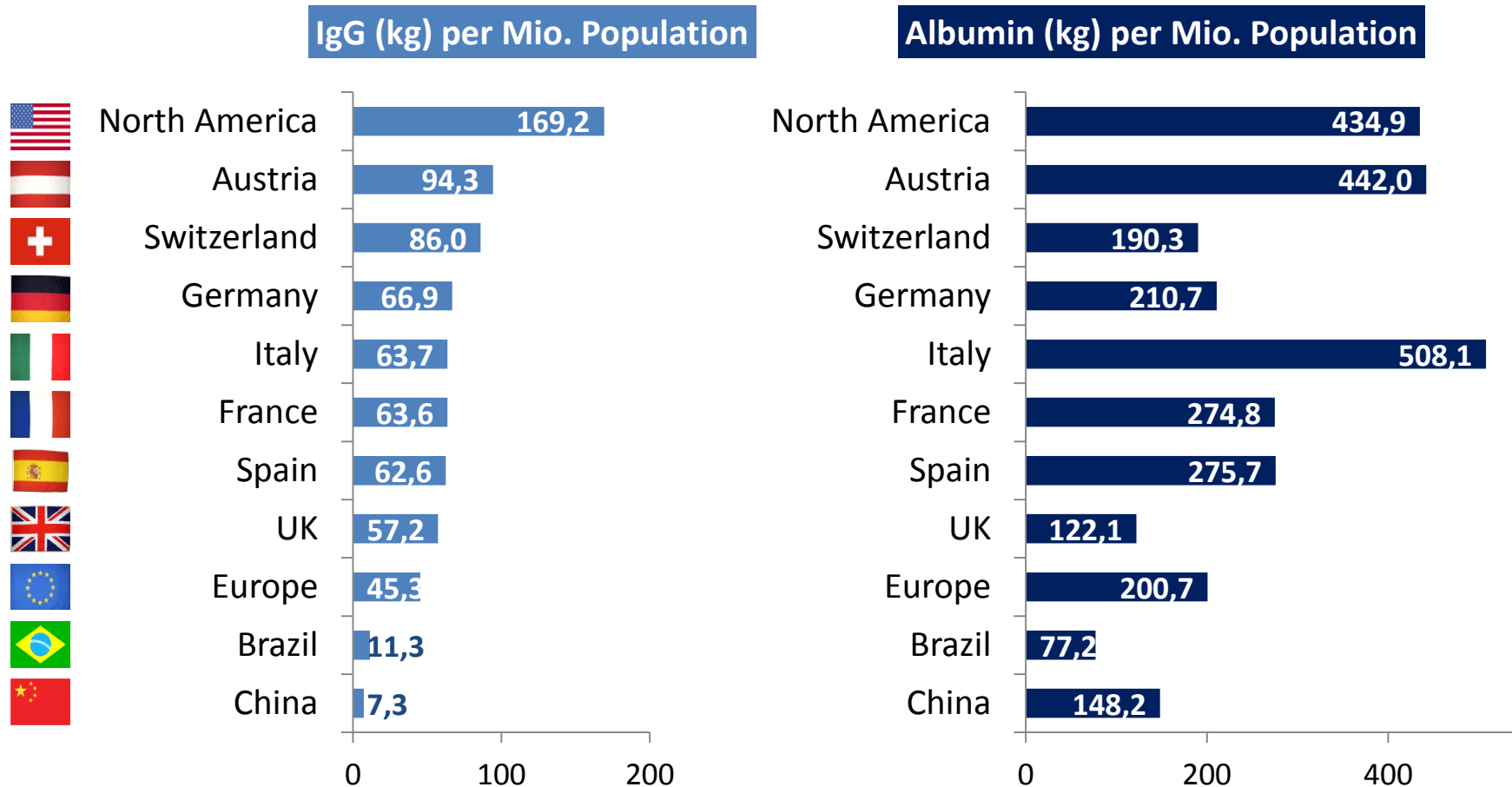
## Global market trend Immunoglobulin (SC/IVIG)



- In the midterm, up to 2015 the following regional growth rates are expected:  
EU: 4-5%, USA: 4-6%, **RoW: 12-13% CAGR**
- The global Immunoglobulin market is expected to grow with an average growth rate of ~5-6% p.a. in the period between 2012 and 2025.

Sources: Biotest Market Research based on MRB (2013) etc.

# Per capita usage Immunoglobulins and Albumin 2012



Sources: Biotest Market Research based on MRB (2010-2013), PPTA (2012), IMS (2012)

## Biotest Next Level: Investments in growth

Increase in global capacity to:

### Plasma fractionation:

**3.1 million litres per year**

current: 1.5 million litres per year

### Immunoglobulins:

**13 tonnes per year**

current: 5.5 tonnes per year

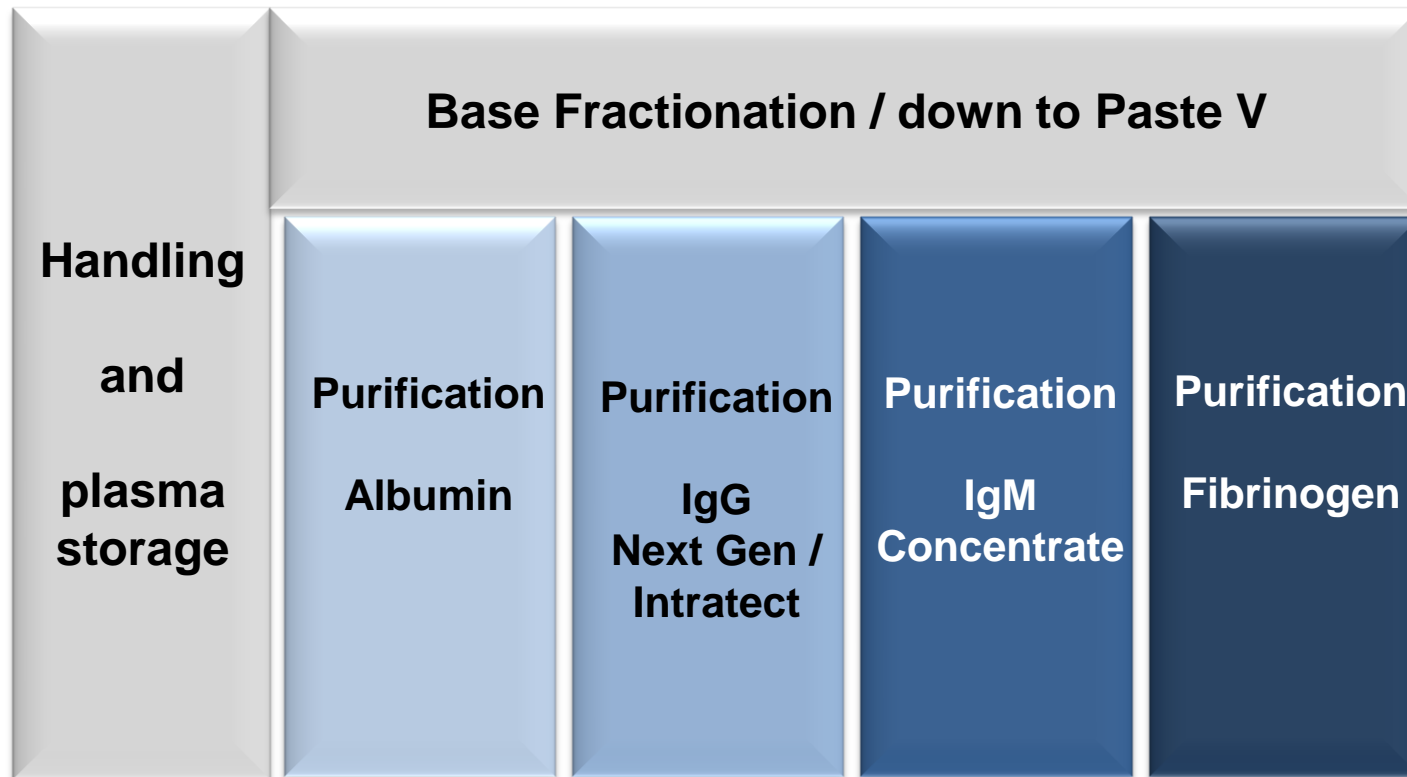
### Albumin:

**72 tonnes per year**

current: 42 tonnes per year

- Programme for increasing capacity at Dreieich
- Construction of new production facilities at the Dreieich location
- Period: 2013 to 2018
- Investment amount: > € 200 million
- More than 300 additional jobs

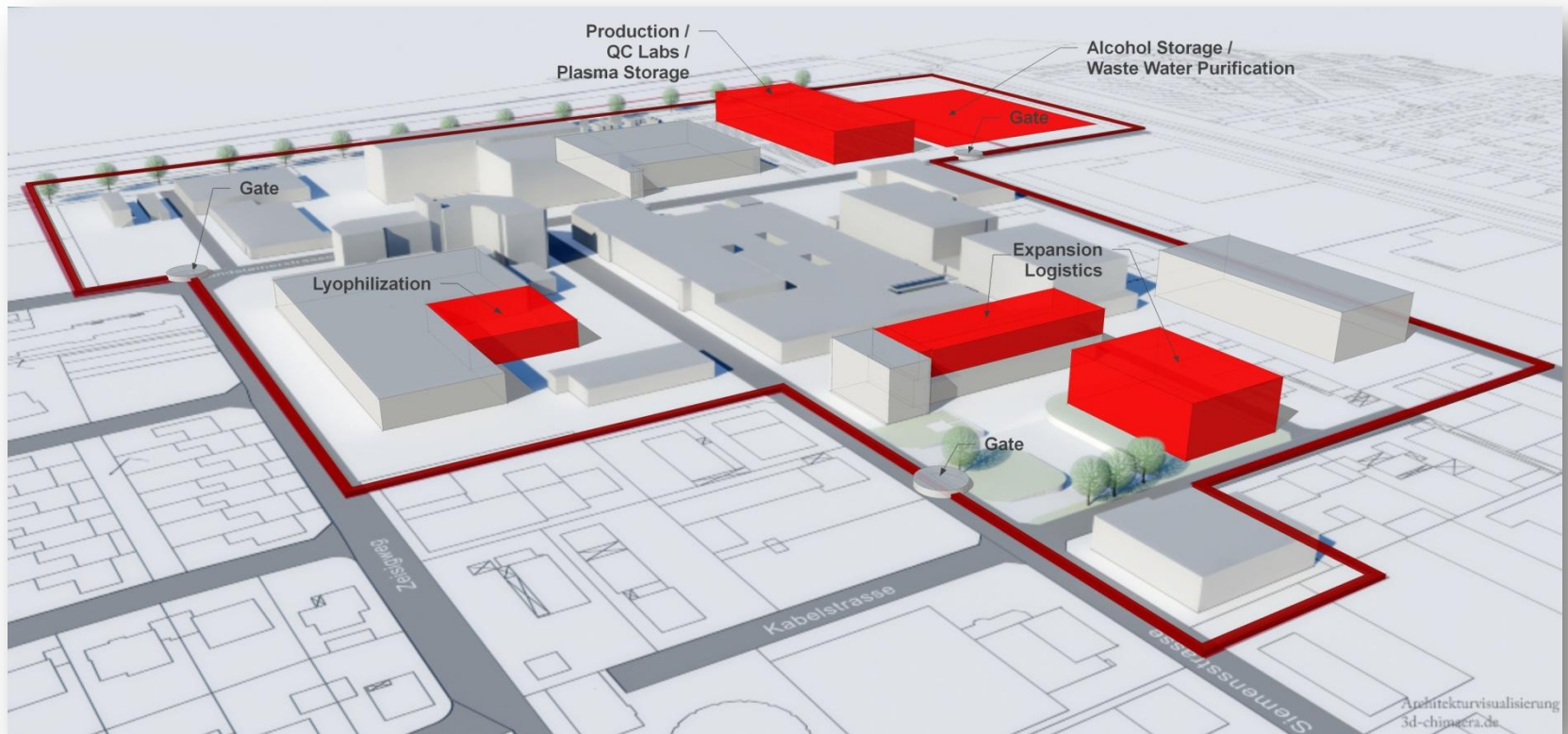
## A modular approach for a production building



**Building(s) and equipment will be implemented stepwise in connection with the progress of the development products.**



# Location of capacity expansion Dreieich



## First projects initiated or already completed



Completed multi-storey car park

### Already completed:

- Expansion of filling and packaging facilities
- First expansion of albumin production
- New multi-storey car park

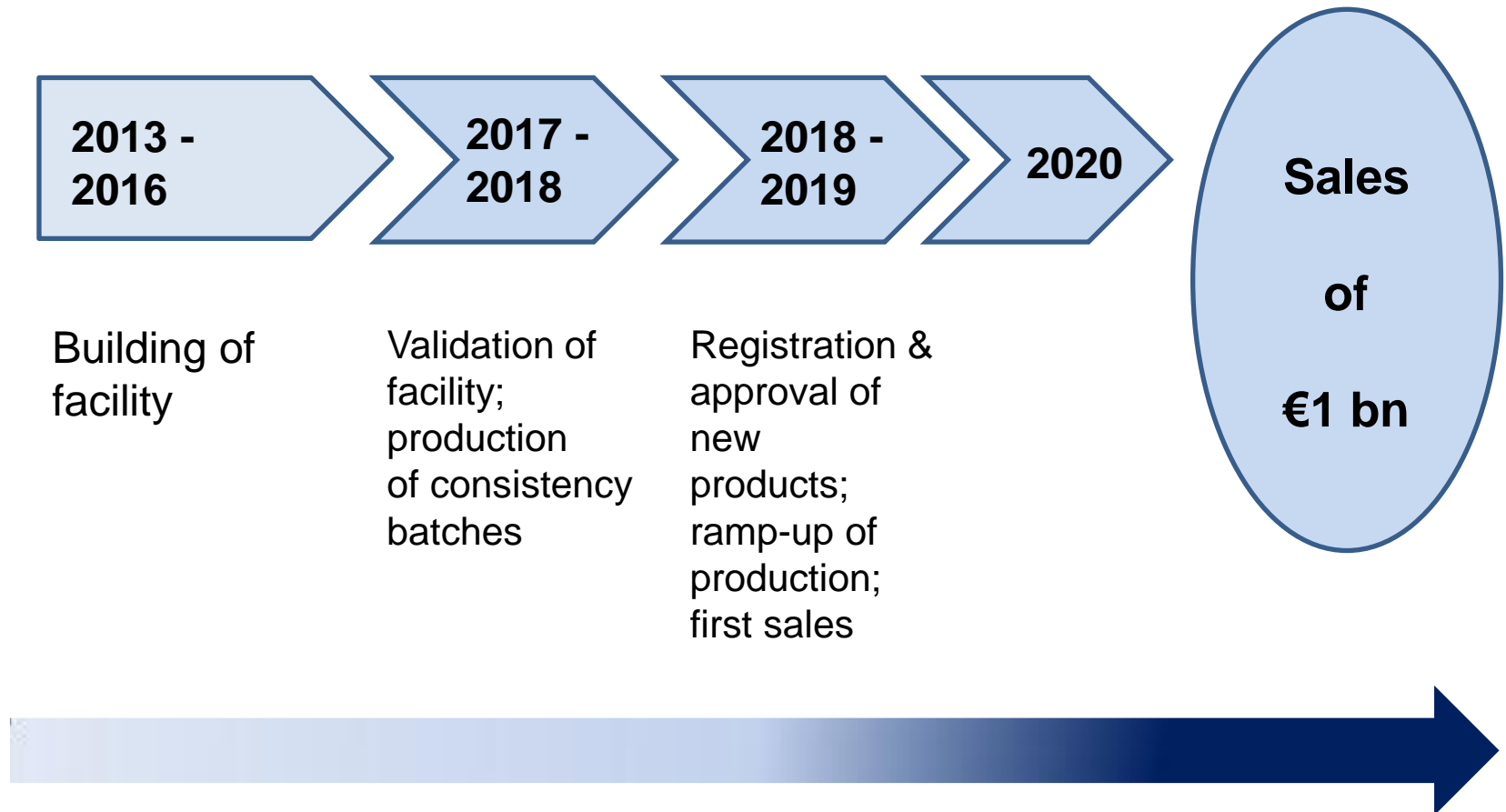
### Construction started:

- Plasma goods receipt area
- Virological test laboratory

### Next steps:

- Basic engineering completed in Summer 2014
- Ground broken for new production building by the end of 2014

# Timeline

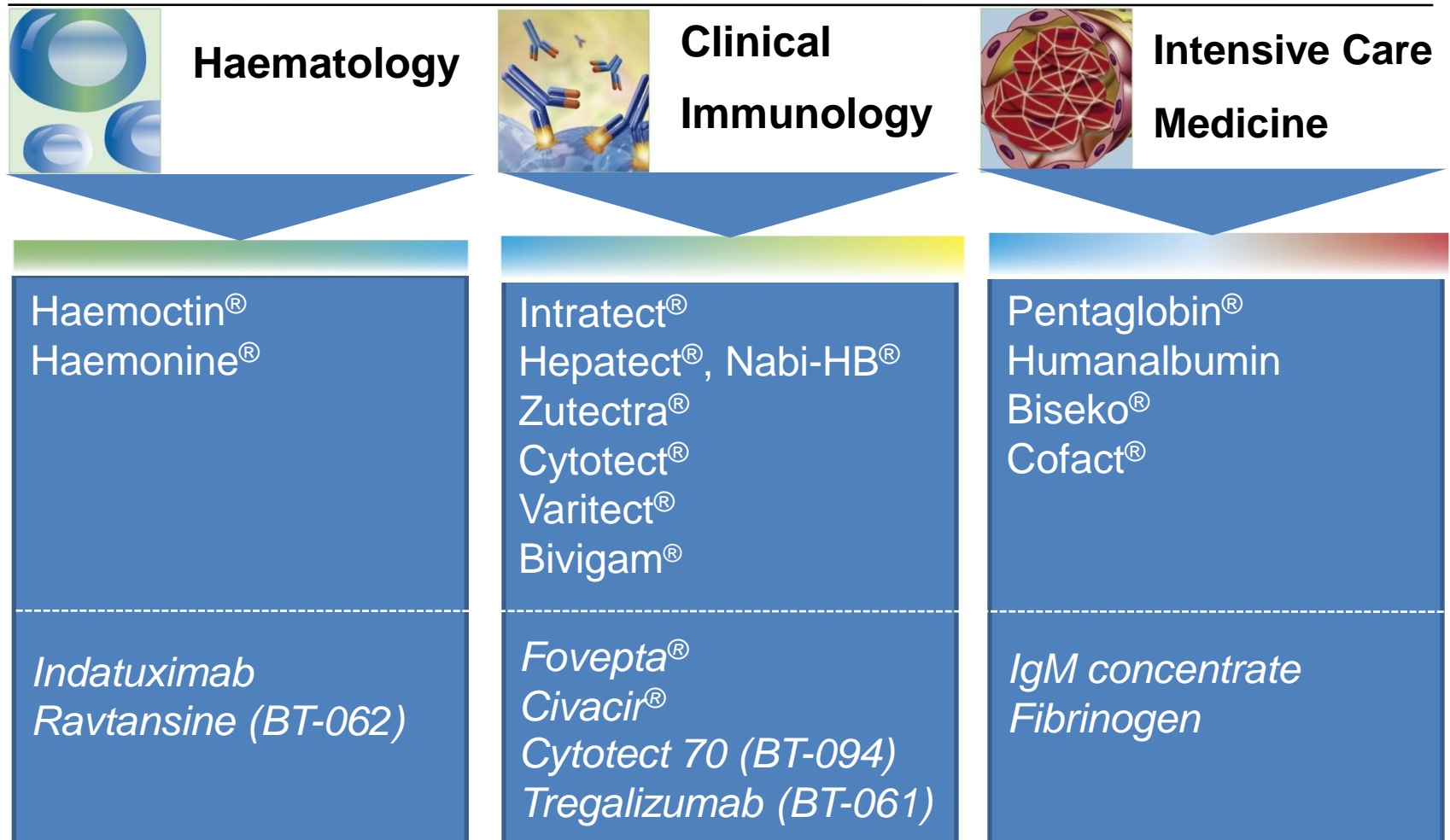




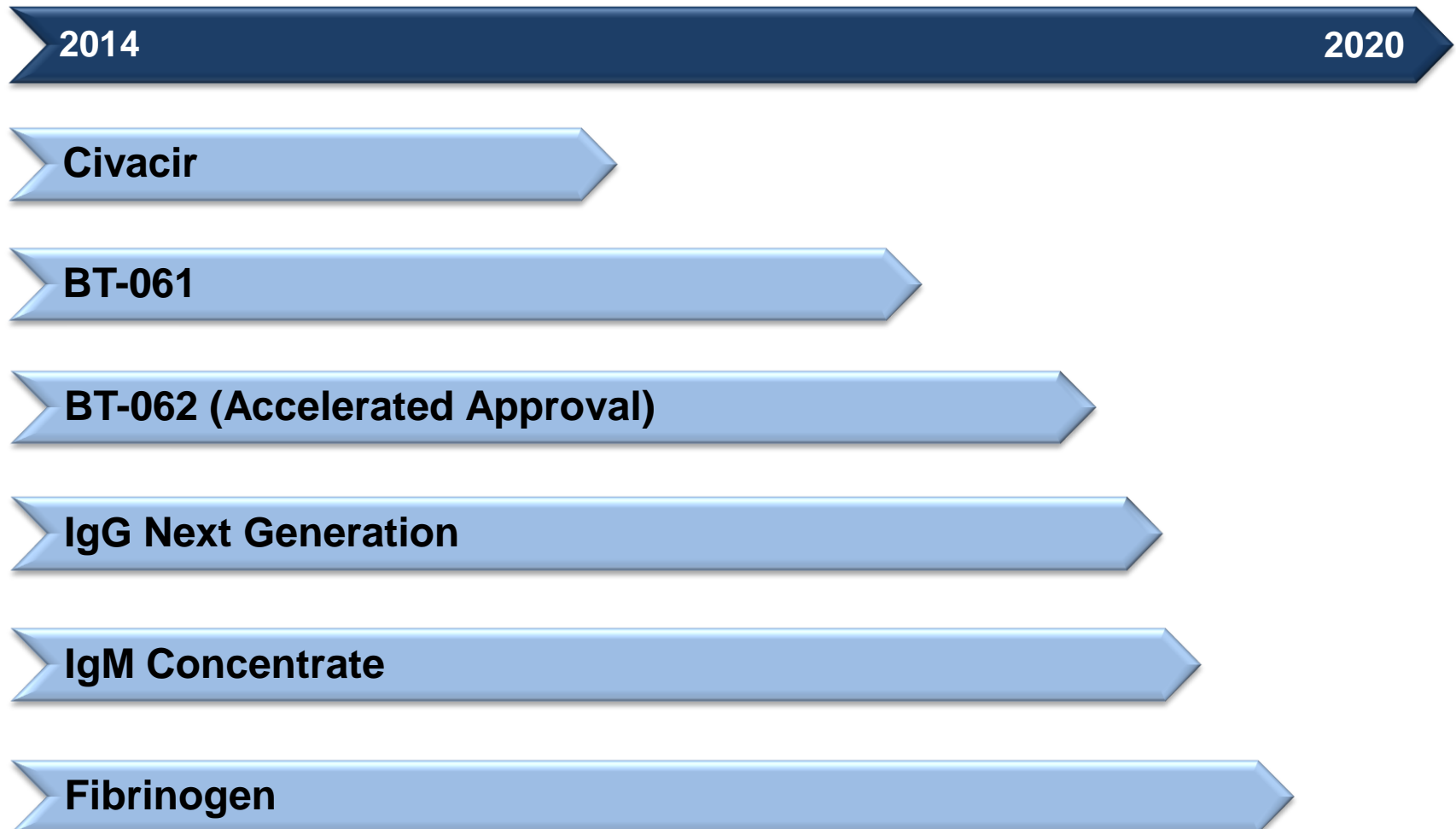
**Innovation**  
**Quality**  
**Responsibility**

**Research &  
development**

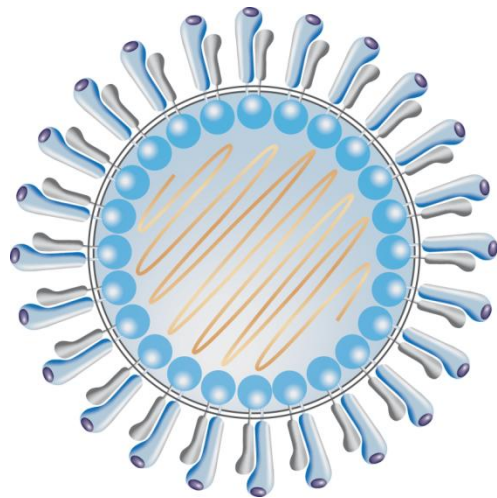
## Biotest products and pipeline



## New products at the horizon



## Clinical Immunology: Civacir®

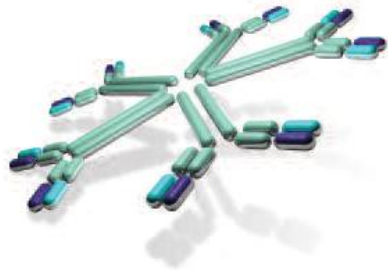


Model of hepatitis C virus

- Hepatitis C immunoglobulin for reinfection prophylaxis after liver transplantation
- Very high demand:
  - Currently no reliable prophylaxis for the critical period immediately after transplantation
  - New virostatic drugs are not an option
  - In the EU and USA alone, more than 5,000 liver transplants due to hepatitis C each year
  - Phase III study is underway; treatment of the first patients has already been completed

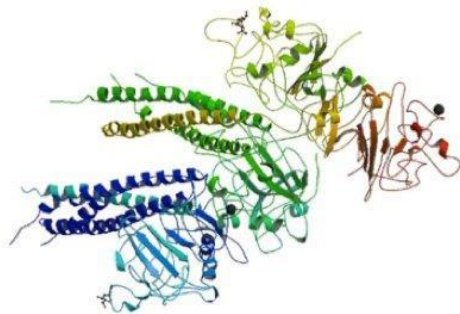


# Intensive Care Medicine: IgM concentrate and fibrinogen



## IgM concentrate

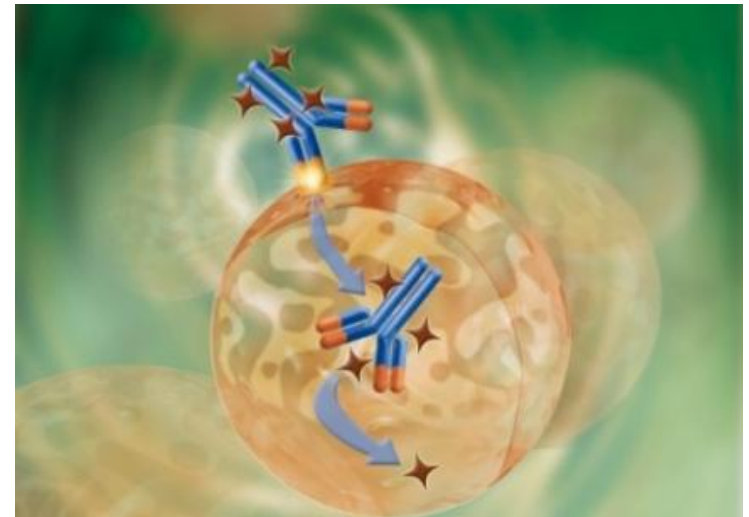
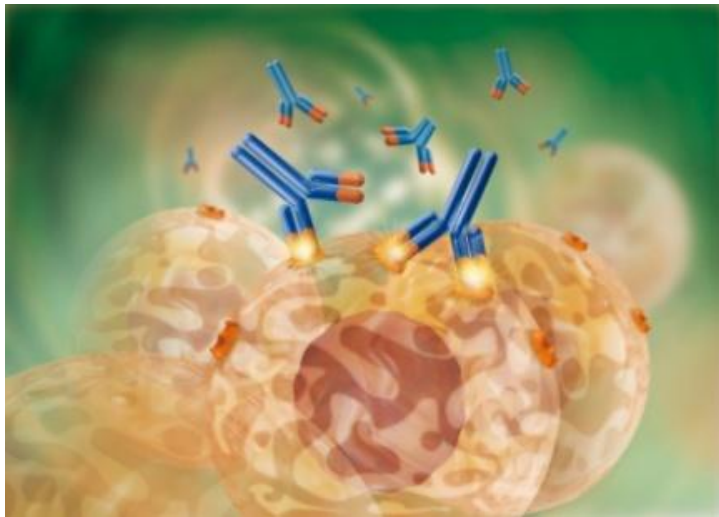
- IgM concentrate for the treatment of sepsis
- Unique mechanism of action
- Over 100 patients treated to date in phase II study



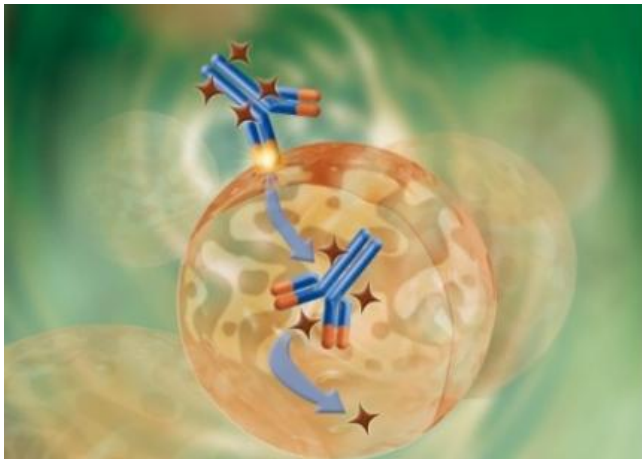
## Fibrinogen

- Fibrinogen for the treatment of severe acute bleeding due to fibrinogen deficiency
- Ready-to-use product is in development
- First patients treated in phase I/II study

# Monoclonal antibodies extend the range of products in the Clinical Immunology and Haematology areas



## Haematology: Indatuximab Ravtansine (BT-062)



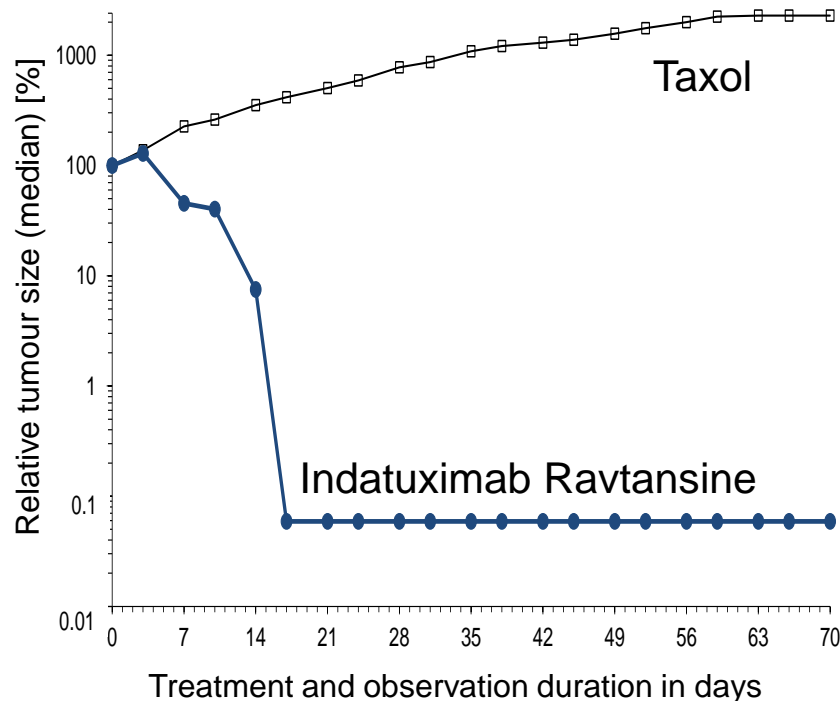
### Targeted mechanism of action:

- Antibody docks on cancer cell and toxin is then released:
- Targets cancer cells while healthy cells are very largely spared

- Clinical development in the lead indication multiple myeloma is continuing
- Very convincing data from current phase II study
- Partial to complete remission of the disease in about 75% of treated patients
- Presentation of the data at the prestigious ASH conference encountered a great response

# High efficacy in tumour treatment

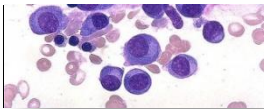

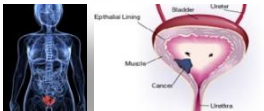
## Treatment of human breast cancer implanted in mice



- Very high efficacy with a tolerable dosage in the treatment of solid tumours that do not respond to standard therapy
- Tumours resolved completely within 14 days
- No recurrence (renewed growth) after the end of the treatment, no metastases
- Start of clinical development in breast and bladder cancer

# High need and large sales potential

## Indication focus of Indatuximab Ravtansine (BT-062)

	Patients*	Sales potential (peak net sales per year)
<b>Multiple myeloma (recurrent and treatment-resistant)</b> 	~ 80,000	~ € 950 million
<b>Triple-negative metastatic breast cancer</b> 	~ 50,000	~ € 300 million
<b>Metastatic bladder cancer</b> 	~ 90,000	~ € 750 million

\* Anticipated potential patients / Source: Decision Resources 2013 for seven important markets, Biotest estimates

## Clinical Immunology: Tregalizumab (BT-061)

**TREAT 2b**

T cell REgulating Arthritis Trial 2b  
(TREAT 2b)

- Developed in the lead indications of rheumatoid arthritis (RA) and psoriasis
- Treat 2b: phase IIb trial in RA started in autumn 2013
- Largest clinical trial in Biotest history:
  - Over 300 patients
  - Over 70 trial sites in 14 countries
  - Final results in the first six months of 2015
- Over half of the planned patients have already been included in the trial

# Contact and Financial Calendar 2014

## Investor Relations Biotest AG:

Dr. Monika Buttkereit  
Head of Investor Relations

Phone: +49 (0) 6103 - 801 -4406  
Fax: +49 (0) 6103 - 801 -347  
E-Mail: [investor\\_relations@biotest.de](mailto:investor_relations@biotest.de)

## Financial Calendar 2014

**12. Aug 2014**      **Q2 Report 2014**

**12. Nov 2014**      **Q3 Report 2014/  
Analyst Conference**