

# **Biotest Group: Creating Value. Living Values**



Management Presentation

**Biotest AG**

August 2010

## 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 after the disposal of the transfusion and transplantation diagnostic activities to Bio-Rad Laboratories Inc. These activities are being reported as Discontinued Operations. With the exception of the statement of financial position, the previous year's figures have been adjusted accordingly.

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

## Biotest at a glance

Key Figures:	FY 2009	H1 2010
<b>Sales</b>	€ 438.6 m (+14.2%)	€ 227.1 m (+4.0%)
Thereof Plasma Proteins	€ 390.1 m (+14.9%)	€ 200.6 m (+3.2%)
<b>EBIT</b>	€ 61.6 m (+4.6%)	€ 23.7 m (-24.0%)

### Business sectors

Pharmaceuticals

Diagnostics

### Divisions

#### Plasma Proteins

- Immunoglobulins
- Hyper-immunoglobulins
- Clotting factors
- Albumin

#### Biotherapeutics

- Monoclonal antibodies

#### Microbiological Monitoring

- Hygiene monitoring

## Biotest Group

- Headquarters in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 14 countries worldwide
- Employees (FTE)\*: 1,828\*\*  
    Thereof 41% located outside Germany
- Founded in 1946, IPO in 1987, SDAX in 2007 (preference shares)
- Biotest shares:
  - 6,595,242 ordinary shares
  - 5,133,333 preference shares

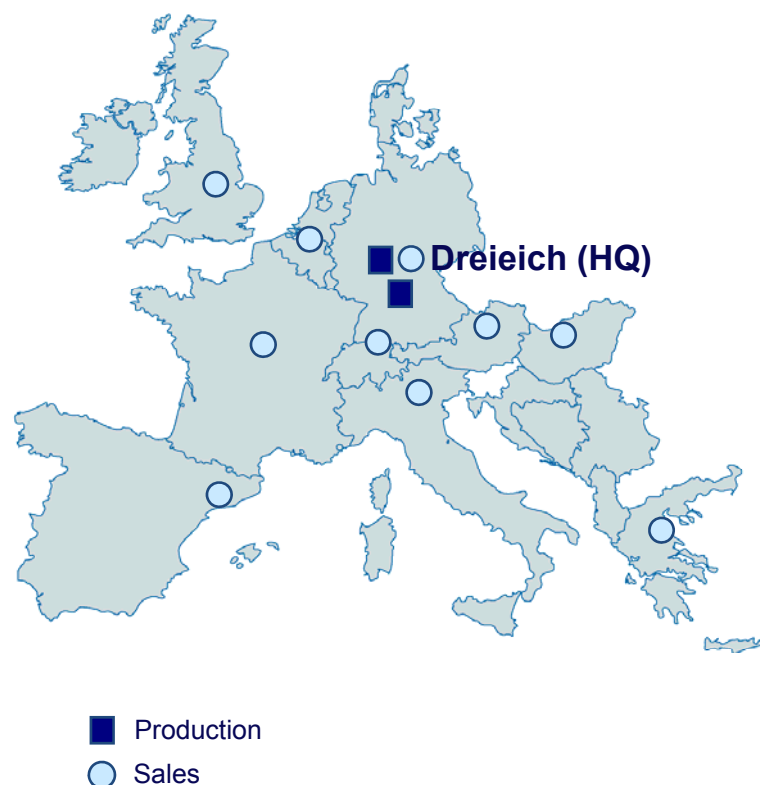


Headquarter, Dreieich

\*: as of 30 June 2010    \*\*: Continuing Operations

# Biotest Group overview

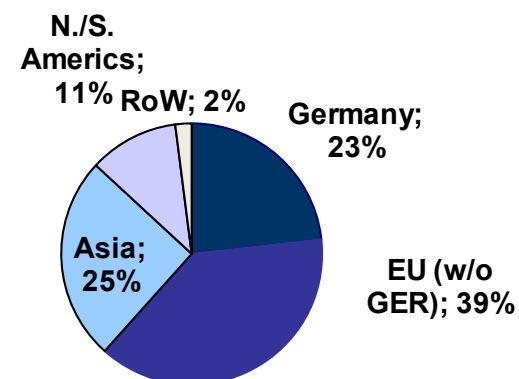
## European production and distribution sites



## Additional sites overseas:

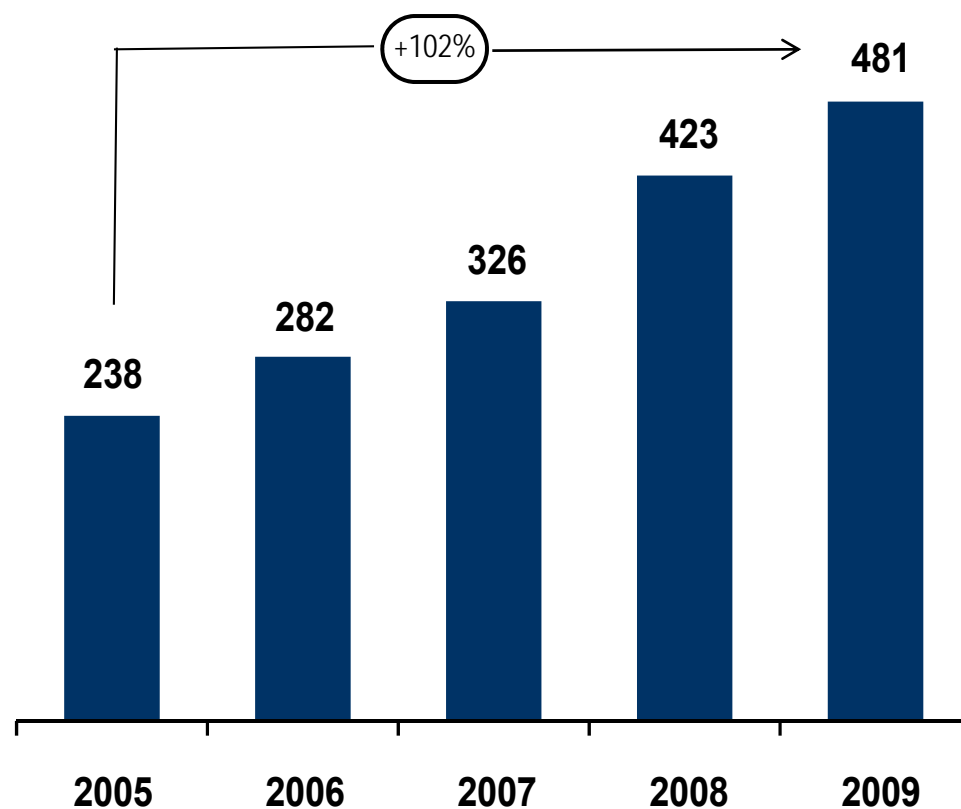
- USA: Florida (■ ○), Rockaway (○)
- Japan: Tokyo (○)
- Distribution also via 138 distributors in 76 countries

## Sales by region (H1 2010):



## About Biotest – strong track record

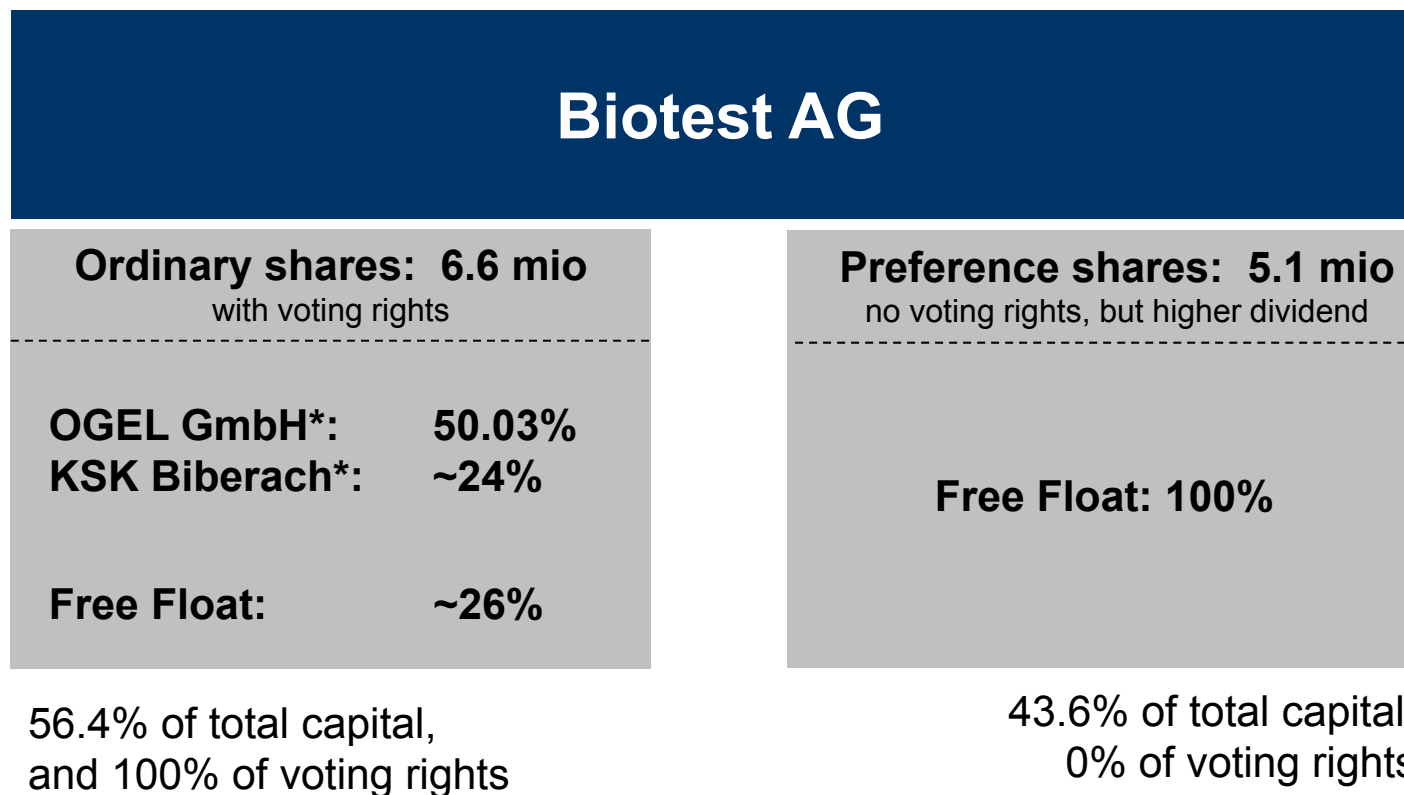
### Sales of Biotest Group (in € million)\*



- Strong revenue growth, particularly in Plasma Proteins business
- Plasma Proteins account for 81% of Group's sales in 2009
- EBIT increase by 131% from 2005 to 2009

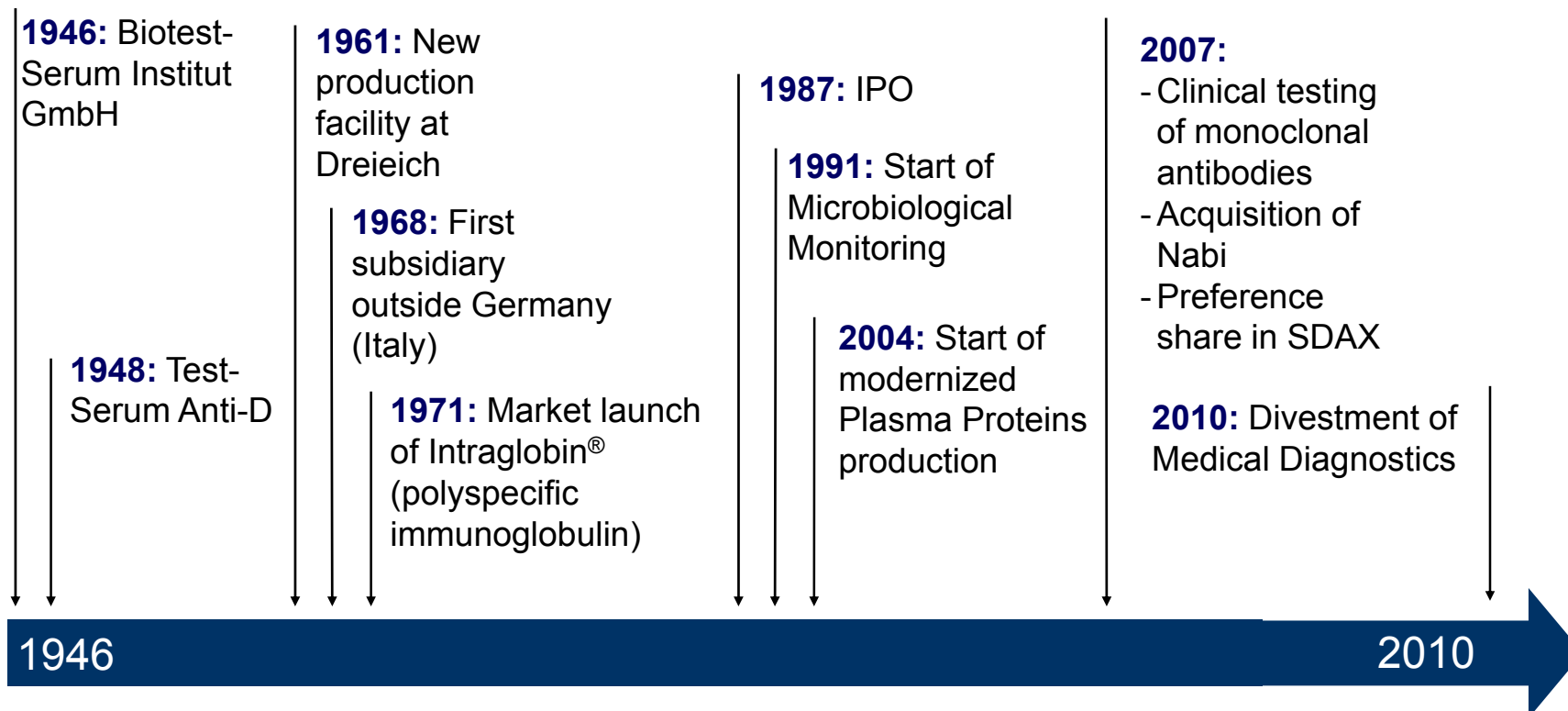
\*: Biotest Group incl. Discontinued Operations

## Shareholder structure



\* as of August 2010

## Biotest: History and milestones achieved







## **Financials H1 2010**

## H1 2010 – At a glance

- H1 Sales increase + 4.0% to € 227.1 million in difficult market environment
- Continued influences on EBIT:
  - further price decrease for plasma protein products
  - continued unabsorbed costs in US (finalisation production facility Boca Raton)
  - increased R&D expenses: € 4.1 million (+19%) incl. consistency batches at BPC and regulatory filing for BLA Bivigam™
- H1 EBIT € 23.7 million (-24%)
- Revised EBIT Outlook



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## Expectations FY 2010

- **Sales growth in lower single digit range**
- Further price pressures expected for Intratect and Haemoctin
- Negative impact by German Healthcare Reform
- Continued unabsorbed costs in US (production facility Boca Raton)
- Shifting of products in higher margin markets not successful
  - EBIT level of 2009 will not be reached



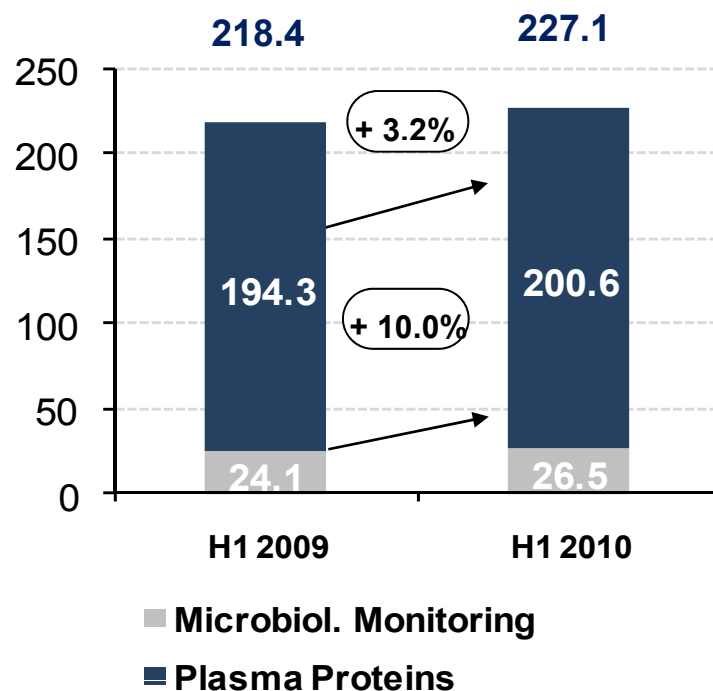
New EBIT guidance: € 45 million +/- 10%

EBIT Guidance incl. Discontinued Operations:

€ 45 million +/- 10% plus € 18 million

## Sales growth despite difficult environment

### Sales of Plasma Proteins & Microbiological Monitoring (€ m)



- Sales in the first half year of 2010 were up by 4.0% to 227.1 million vs. H1 2009
- The Microbiological Monitoring segment increased by a rate of 10.0 %, mainly through products manufactured by heipha
- The Group's Plasma Proteins business grew with 3.2%
- Robust performance in challenging business environment

## Sales Plasma Proteins

Sales Plasma Proteins H1 2009	€	194.3 m
Volume effect	€	20.9 m
Price effect	€	-14.6 m
<hr/>		
<b>Sales Plasma Proteins H1 2010</b>	<b>€</b>	<b>200.6 m</b>

## EBIT Plasma Proteins H1 2010 vs H1 2009

EBIT Plasma Proteins H1 2009	€	42.7 m
EBIT from increased volume	€	8.7 m
EBIT loss from reduced prices	€	- 14.6 m
Net changes of other costs/expenses	€	- 1.2 m
<b>EBIT Plasma Proteins H1 2010</b>	<b>€</b>	<b>35.6 m</b>

## H1 2010: EBIT Biotest Group (€ m)

	H1 2009	H1 2010	
Plasma Proteins	42.8	35.6	- 17 %
Biotherapeutics	- 8.8	- 10.4	- 18 %
Microbiology	2.5	3.3	+ 32 %
Corporate	- 5.3	- 4.8	+ 9 %
<b>Biotest Group</b>	<b>31.2</b>	<b>23.7</b>	<b>- 24 %</b>

## Loss in EBIT due to higher R + D Expenses (€ m) vs. 2009

	2010	Δ to 2009
EBIT H1 2010 (actual)	23.7	- 24 %
Δ R + D Plasma Proteins	2.1	
Δ R + D Microbiology	0.2	
Δ R + D Biotherapeutics	1.8	
<b>EBIT H1 2010 ( adjusted for increased R+D expenses)</b>	<b>27.8</b>	<b>-11%</b>



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## Reasons for increased R & D expenses

### Plasma Proteins:

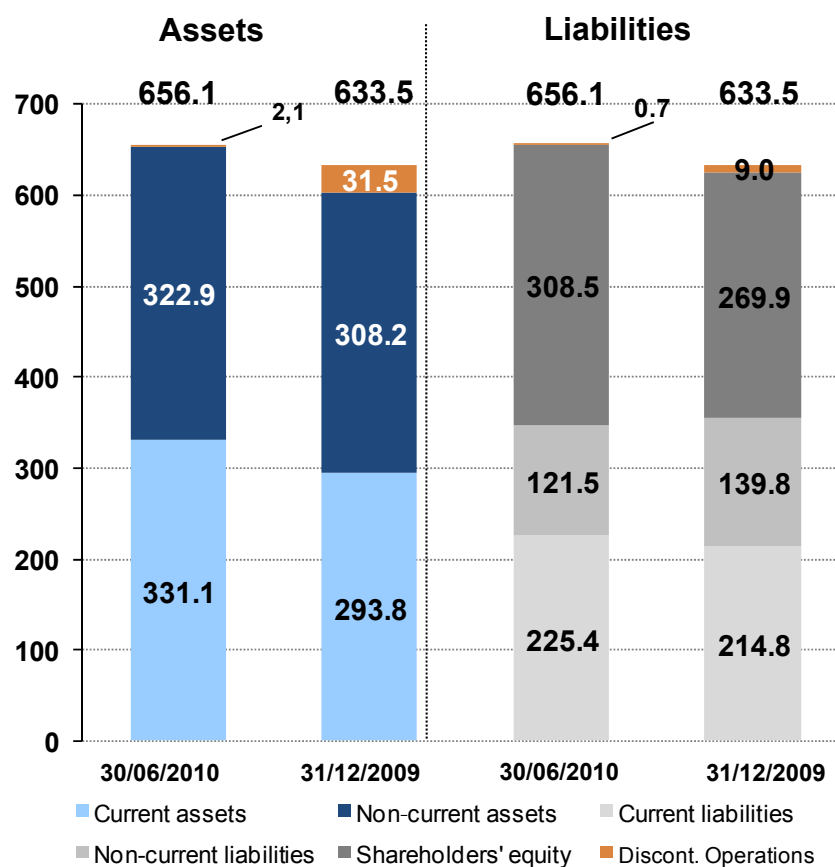
- BPC has produced IVIG consistency batches, regulatory expenses for preparation of BLA submission
- Dreieich: Intensified development of plasma protein projects e.g. IgM, Cytotect and others

### Biotherapeutics:

- 5 Clinical studies ongoing with BT-061, BT-062 and BT-063
- Production Technology transfer of BT-061 and BT-062 to Boca Raton

## Strong balance sheet

### Balance sheet of the Biotest Group (in € million)



### Assets

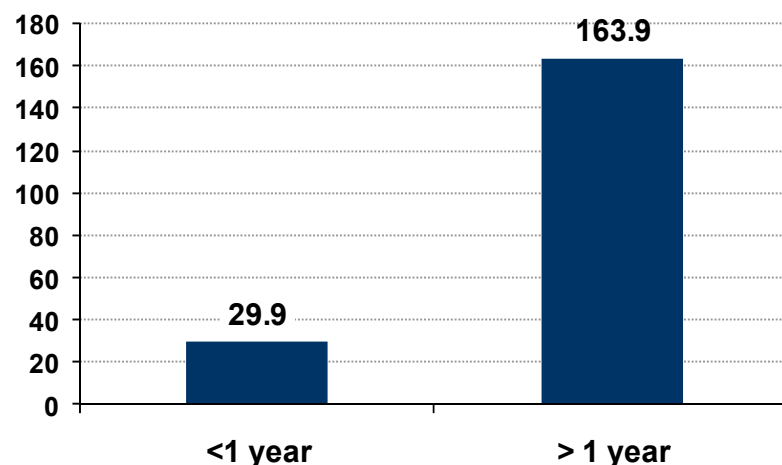
- Higher inventories driven by expected growth in 2010
- Higher Trade receivables due to higher sales volumes mainly in the plasma proteins segment

### Liabilities

- Increase in current financial liabilities, primarily corresponding to working capital development
- Equity ratio as of 30 June 2010: 47.0% ( 31 Dec. 2009: 42.6%)

## Long term secure debt financing

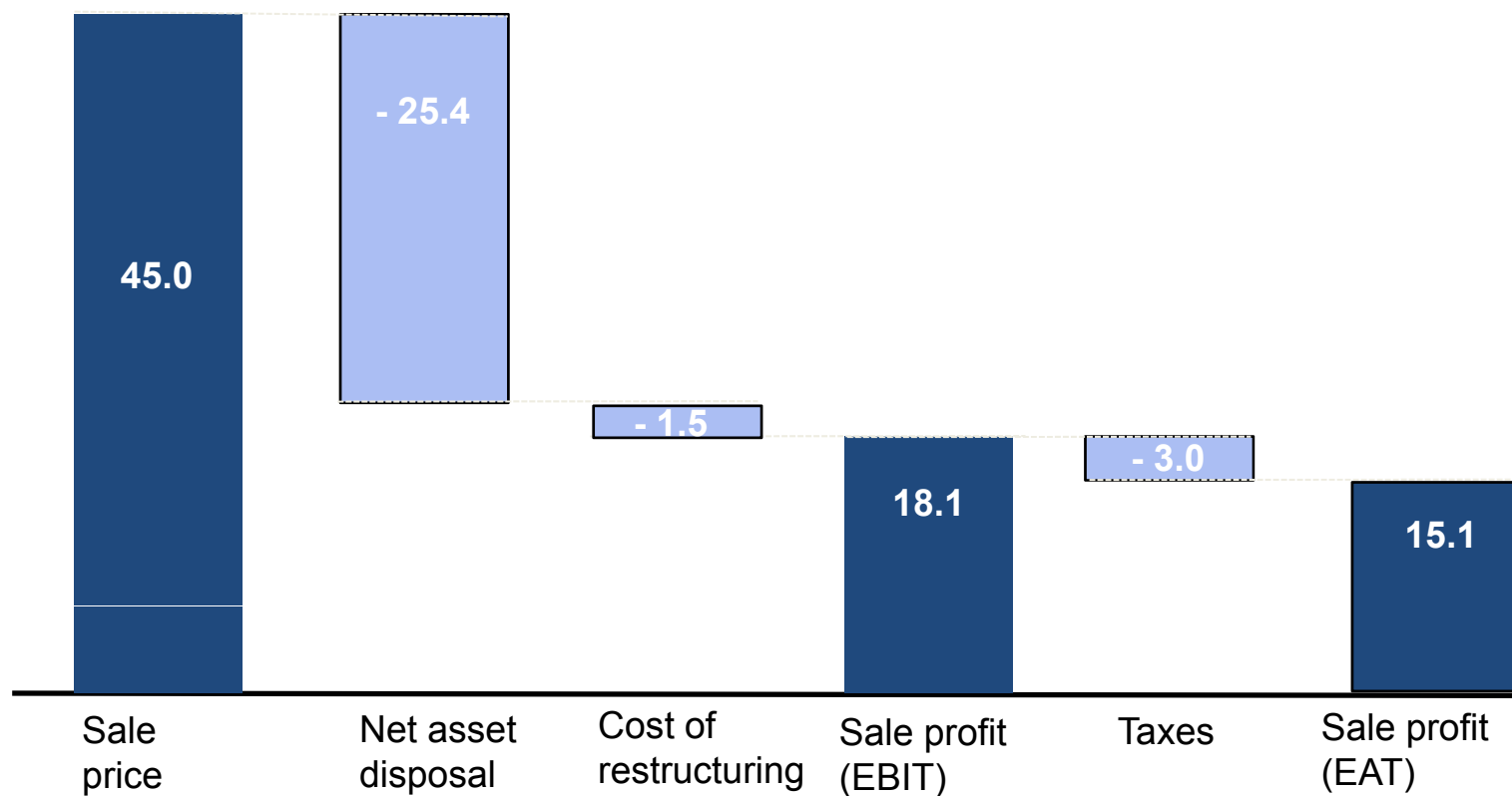
### Biotest Group: Maturity of financial liabilities (€ million)



- Total financial liabilities as of 30 June 2010: € 193.8 million (31 Dec. 2009: € 204.5 million)
- Successful renewal of working capital facility of € 40 million and new working capital line of € 10 million
- Further financing available – but at higher interest rates
- Purchase price of € 45 million was received on Jan. 6<sup>th</sup> 2010

## Probable sale profit of €15.1 million after taxes (EAT)

in € million





## **Outlook for 2010**

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## Outlook for 2010

### Reason for revised Guidance:

- Expected negative impact from anticipated German Healthcare Reform legislation of 5-6 million; driven by increases in mandatory rebates of additional 10% in public sector and out-patient hospital sector
- Transition in Global Plasma Protein market
  - continued price pressure in some markets, slower market growth in some territories

### Revised Guidance for 2010:

- Low single-digit percentage sales growth
- EBIT at € 45 million +/- 10% (incl. Discontinued Operations: € 45 million +/- 10% plus € 18 million)

Outlook statements are subject to:

Material price and volume movements on core plasma products, competitor activity, changes in healthcare regulation and reimbursement policies, pending payments of Greece hospitals and foreign exchange rate movements

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## Outlook Plasma Protein Industry

- Volumes of collected plasma decline again; Industry consolidation continues; overcapacities are being reduced
- The demand for final products continues
- Therefore the markets will begin to level out beginning from mid 2011 onwards; prices will stabilize and the business will continue to grow

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## Outlook Plasma Protein Market

### **Biotest's business environment fundamentally attractive:**

- Confidence in mid/- long-term growth of plasma proteins products
- Demand driven by:
  - Favorable demographics: age, weight, time on therapy
  - Better diagnosis and awareness driving increased use and higher dosing
  - Continued clinical evidence supporting new and emerging indications
  - Growth opportunities in industrialised countries and emerging markets
- Products often life-saving treatments – long-term demand independent of cyclical effects



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## Further Outlook Biotest Group

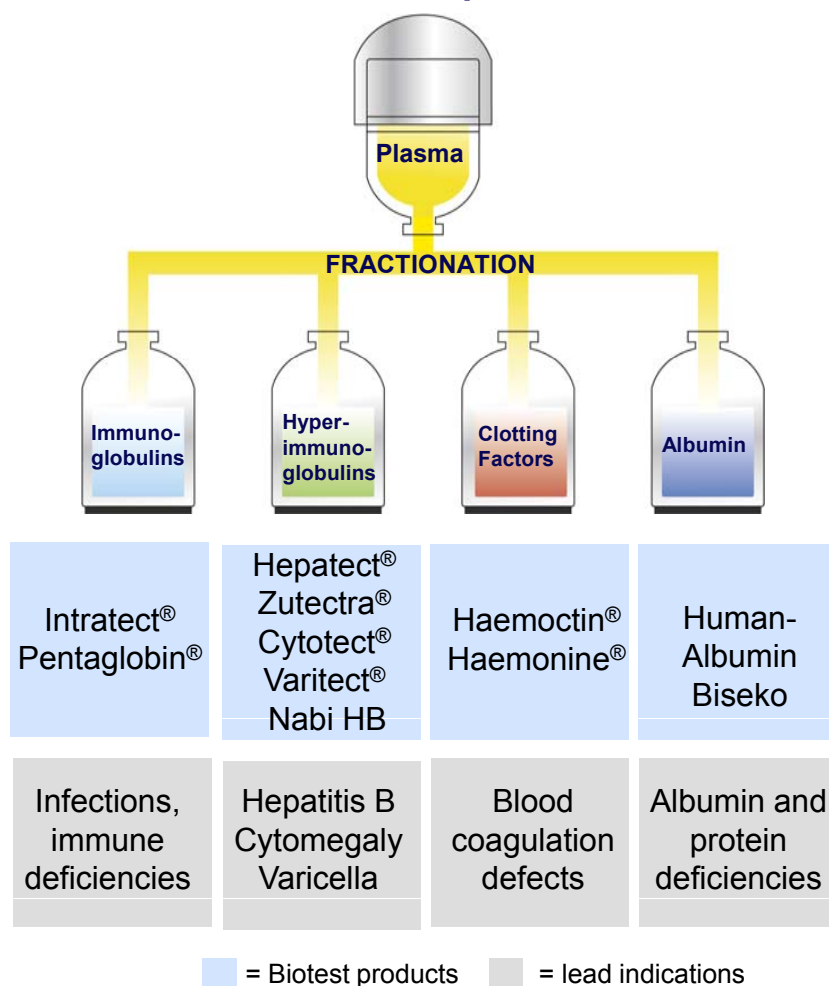
- Despite difficult business environment we continue to invest into R&D of Plasma Protein Projects and Biotherapeutics
- Full pipeline of Plasma Protein products and Biotherapeutics with a potential to reach the market within the next years
- BPC/ USA: access to the single biggest plasma protein market
  - Q3 2010 BLA submission of Bivigam™ on track
  - Launch of Bivigam™ (IVIG) expected to take place in H2 2011
  - Additional market potential of \$ 100 million



## Plasma Proteins

# Plasma Proteins business at a glance

## Biotest Plasma Protein products



- Global market share: 3%
- Market share in relevant markets (GER, AUT, CH, GRE, UK): 14%
- Intratect® market share in GER, AUT: > 13%, in UK, CH, I: > 10%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA
- Zutectra® launch in Feb. 2010
- Biotest covers full value creation chain: plasma sourcing, production, distribution  
 ➡ vertical integration leads to rationalisation and higher productivity

## Major progress in development of Plasma Proteins



**Zutectra<sup>®</sup>**

EU-wide approval  
(centralised procedure)



**Hepatect<sup>®</sup>CP**

Approvals in 13  
other European countries  
(mutual recognition procedure)



**Albiomin<sup>®</sup>**

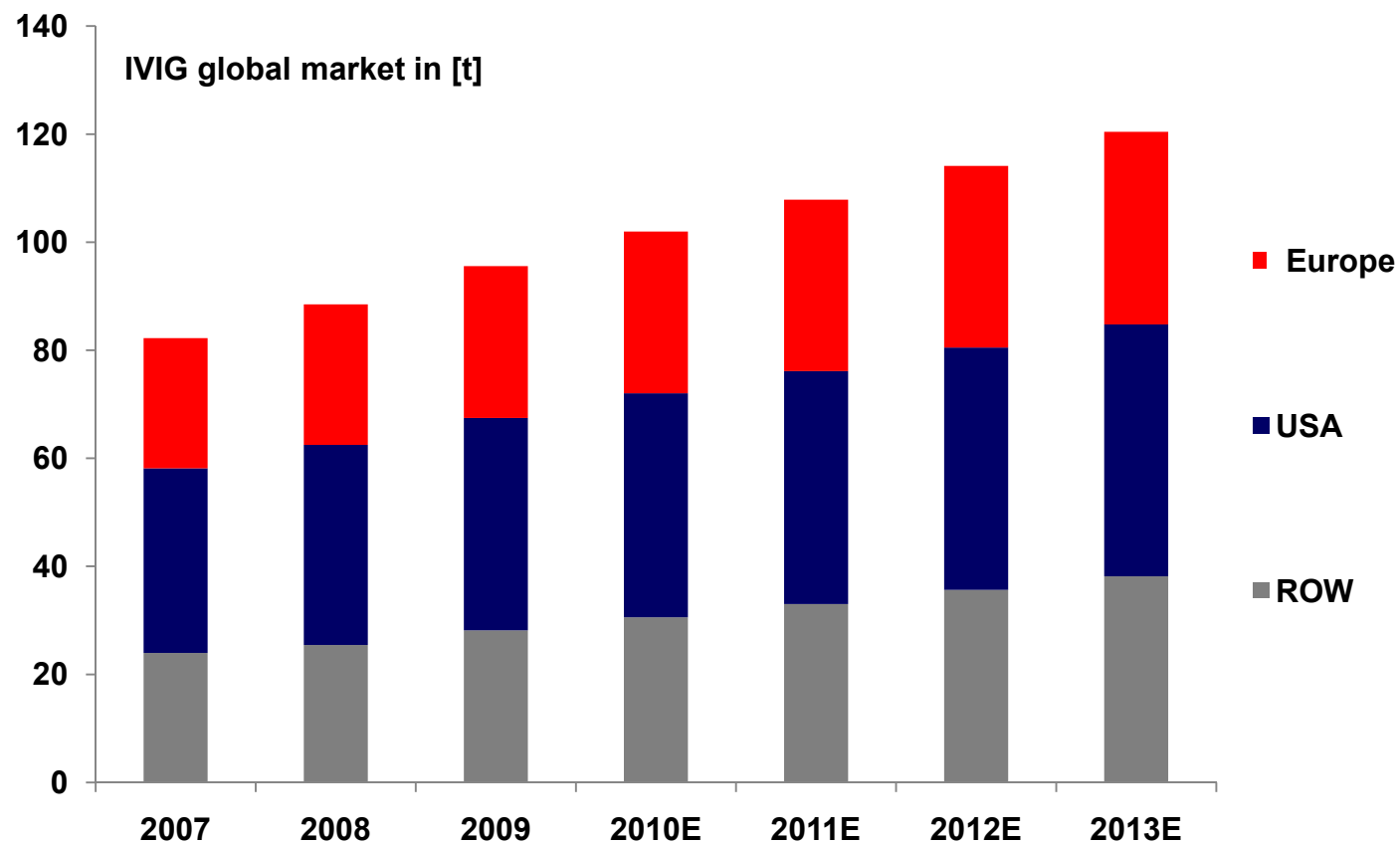
Approvals in Germany and 10  
other European countries



**Intratect<sup>®</sup>**

Use in fibromyalgia patients:  
trial completed –  
scientific publication finalised

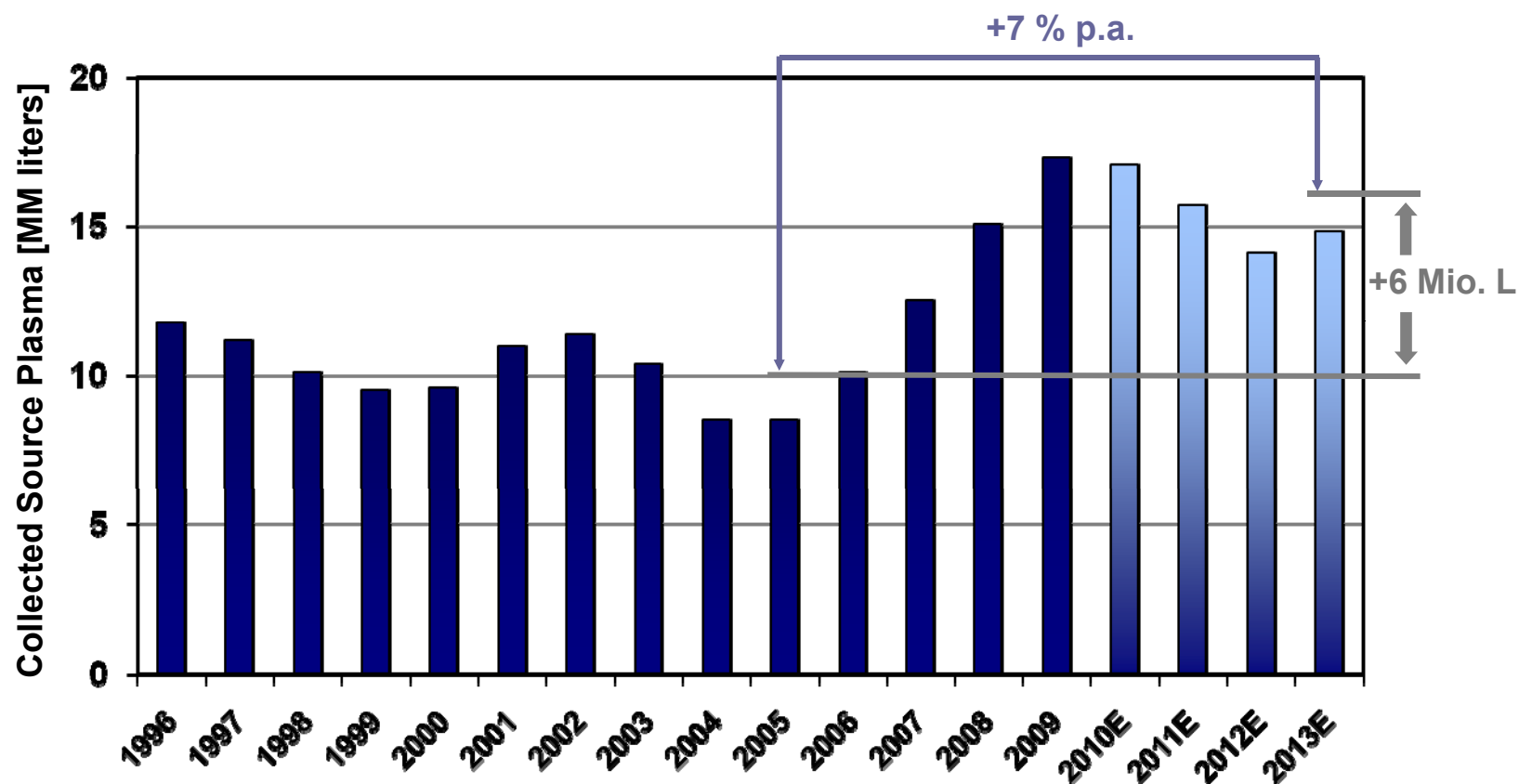
## Development of IVIG markets by regions



- The IVIG market will continue to grow (5% p.a.), particularly by increased demand in emerging markets

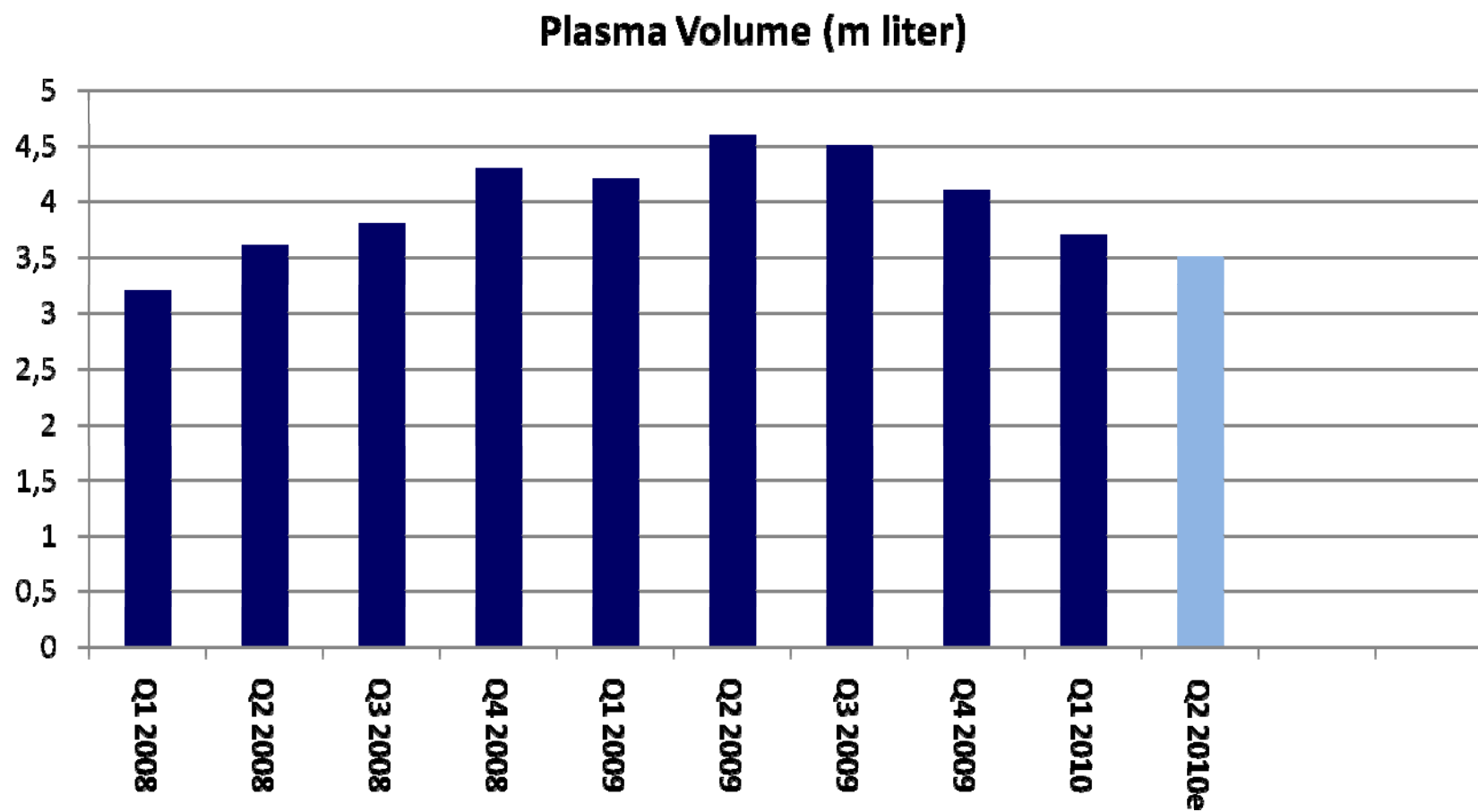
Source: MRB, Analyst Reports, Biotest Market Research

## US source plasma collection forecast, 1996 -2013



Source: MRB "The Plasma Fractions market in the United States", 2007; PPTA; own estimates

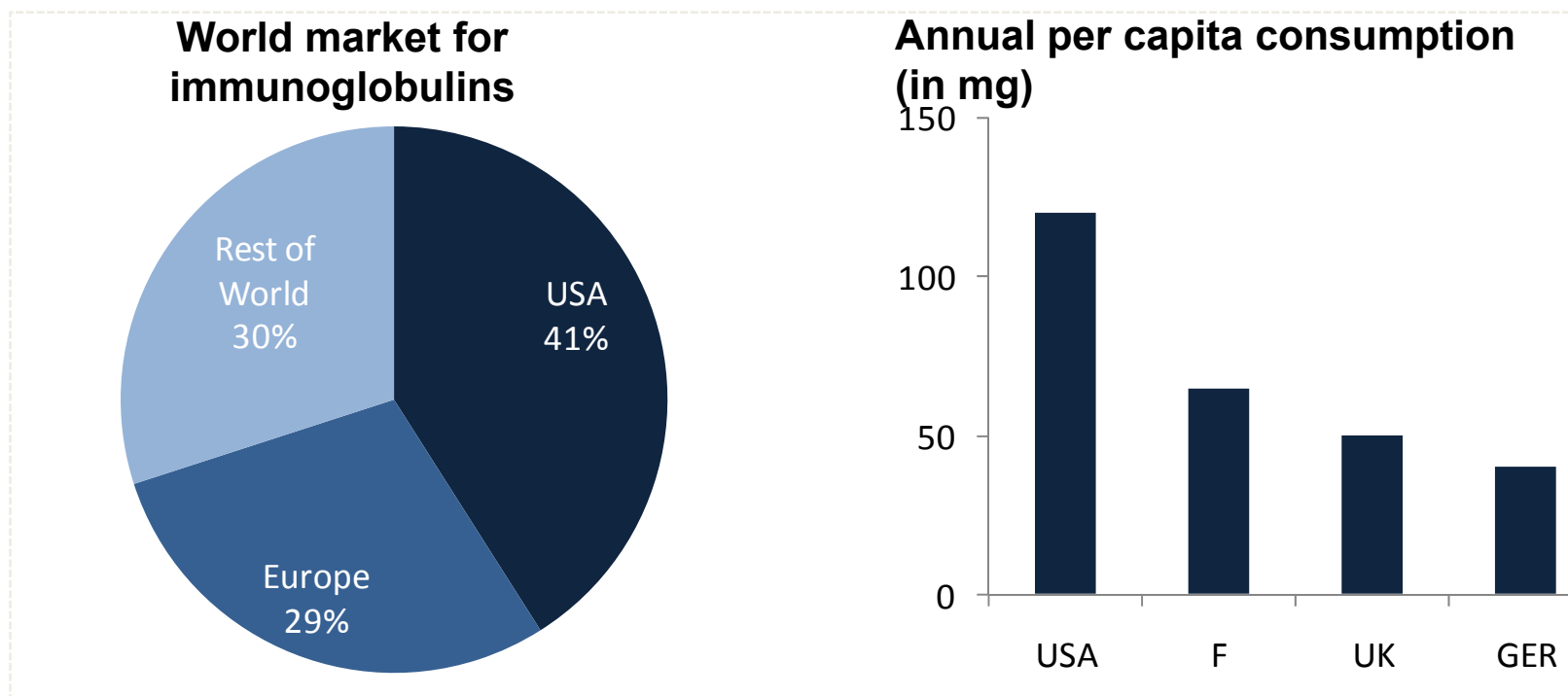
## Quarterly volumes of US source plasma



Source: PPTA (July 2010); Q2 2010e: Biotest AG

## USA: A highly attractive market for Biotest

- World's largest market
- Highest per capita consumption in the world
- High price levels





## US manufacturing plant in operation since end of 2009

- State-of-the-art manufacturing facility at Biotest Pharmaceuticals Corp. (BPC) in Boca Raton, Florida
- Fractionation: 400,000 litres per annum
- Immunoglobulin production: 1.5 tonnes per annum
- Plasma collection at 11 BPC-owned plasma collection centres



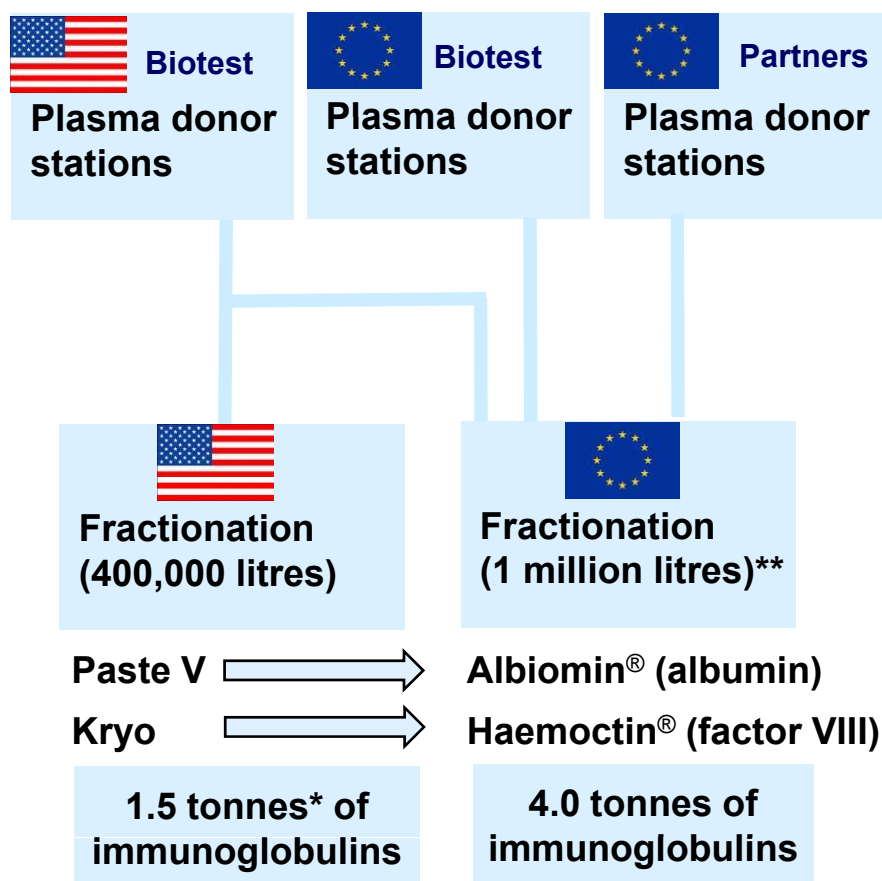
## Bivigam™ (IVIg) development nears successful completion

**Polyspecific immunoglobulin with a wide indication range (incl. antibody deficiency and autoimmune diseases)**



- A polyspecific immunoglobulin comparable to Intratect®
- Clinical development: successful conclusion of phase III
- Production of stability batches completed
- Submission of approval documents in Q3 2010, close to successful completion
- Sales potential after approval: around \$100 million per annum

## Plasma Proteins – Efficient production network



- 21 plasma collection centres
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products from US to Europe from end of 2010
- Network increases EBIT margin

\* Approval will probably be granted end of 2011

\*\* Production in Dreieich and capacities at partners

## Civacir™: Attractive project on track

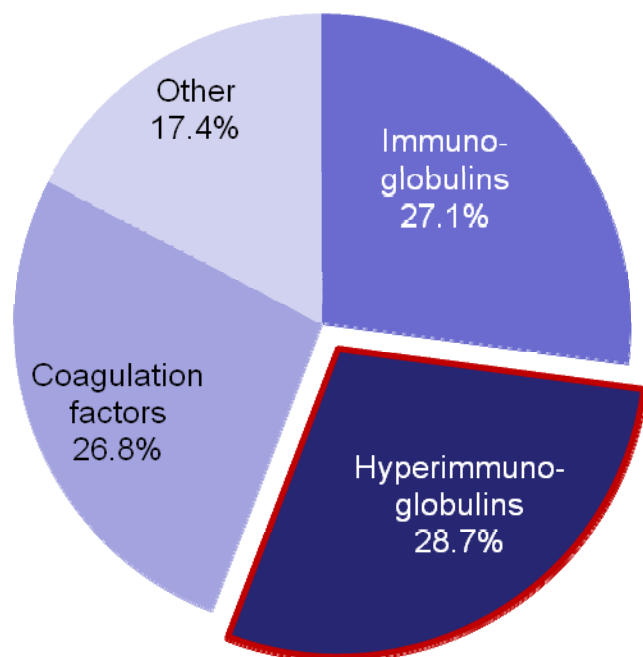
**Hepatitis C  
immunoglobulin for  
reinfection prophylaxis  
after liver transplantation  
due to hepatitis C**



- Hepatitis C: frequent cause of liver transplantations
- Prevalence: 5 to 10 times more frequent than hepatitis B
- Civacir™: Project acquired as part of Nabi Biopharmaceuticals takeover
- Optimisation of manufacturing process, e.g. regarding consistency of neutralising antibodies
- Clinical development expected to be continued in 2011

## Biotest: A market leader in special preparations

Biotest plasma proteins in 2009:  
sales by product category



**Hyperimmunoglobulins and special preparations are a very attractive segment:**

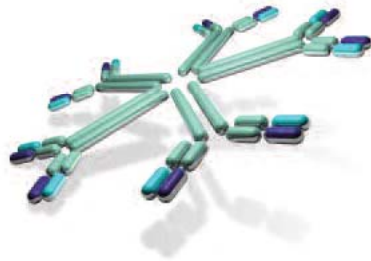
- Stable prices
- High market entry barriers
- Biotest is totally self-sufficient in hyperimmune plasma procurement



\* Including special preparations (e.g. Pentaglobin®)

## IgM Concentrate

**IgM-enriched  
immunoglobulin for  
emergency treatment of  
serious bacterial infections  
(sepsis)**



- Phase I clinical trial successfully completed
- Phase II clinical trial to start from mid of 2011
- Very high functional activity
- Good tolerability
- Improved raw material utilisation

## Cytotect<sup>®</sup>: Trial is progressing

**Prevention of prenatal cytomegalovirus infection of unborn children whose mothers were infected for the first time during the pregnancy**



- International phase III clinical trial to demonstrate efficacy
- Extensive immune screening under way (up to 20,000 tests)
- More than 5,000 pregnant women tested so far
- Interim evaluation planned for end of 2010

## Zutectra®: EU-wide approval of first hepatitis B immunoglobulin for subcutaneous administration

**Hepatitis B reinfection prophylaxis after a liver transplantation**



- EU-wide approval of new form of administration for hepatitis B immunoglobulin
- Administered subcutaneously (under the skin)
- Fast, pain-free, simple and safe
- Developed for self-treatment



## Hepatect® CP and Zutectra® are an ideal combination



**Reinfection prophylaxis  
after a liver trans-  
plantation due to  
hepatitis B infection**



### **Hepatect® CP:**

- Administered intravenously
- Optimal for intensive treatment during and immediately after transplantation

### **Zutectra®:**

- Optimal for self-treatment
- Suitable for long-term prophylaxis as administered subcutaneously

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## **Biotest R&D activity in Plasma Proteins**

### **Hepatitis B immunoglobulin (subcutaneous/ intramuscular) in neonates**

#### **Phase III trial**

- Status: Recruitment completed
- Final Draft of Study Report Dec. 2010
- Marketing Approval: aiming for marketing approval in Germany first, international marketing authorisations to follow

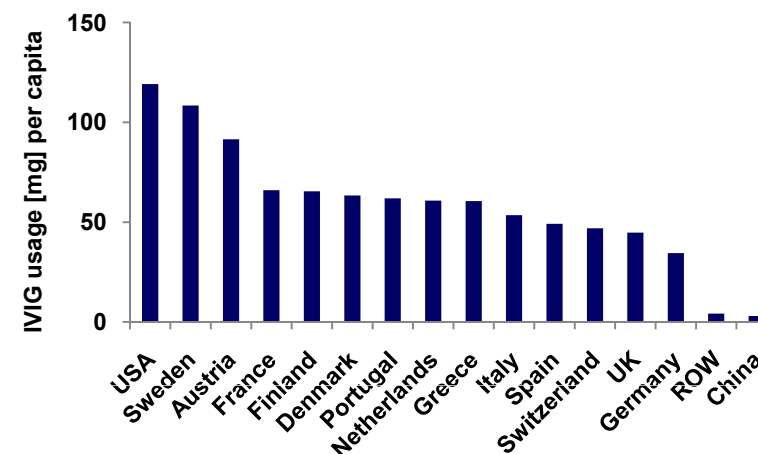
## Further growth of immunoglobulin market expected

### Demand growth driven by

- Favorable demographics: age, weight
- Improved diagnosis, higher dosing level and longer time on therapy
- Continued clinical evidence supporting established and new indications
- Geographical expansion

### Biotest well positioned by diversified portfolio

- Intratect<sup>®</sup> – a premium product concerning tolerability \*
- IVIG available in US 2011
- Speciality Hyperimmunoglobulines: Hepatect<sup>®</sup>, Zutectra<sup>®</sup>, Varitect<sup>®</sup>, Cytotect<sup>®</sup>
- sc application: Zutectra<sup>®</sup>
- Biotest is world market leader in hepatitis B Hyperimmunoglobulin



Source: Global Insight, MRB, PPTA, APFA



\*: Poster: "A European, multicentre, open and prospective study on clinical efficacy, safety, and pharmacological properties of Intratect<sup>®</sup> (human normal immunoglobulin for iv administration) in patients with primary immunodeficiency (PID)"; E. Bernatowska et al., 2006

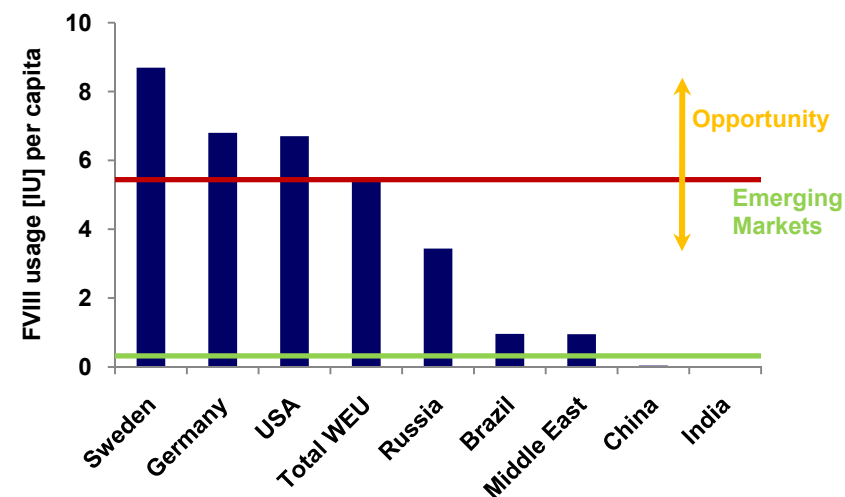
## Opportunities in Haemophilia market

### Increasing global standards of care

- Improving access to care
- Increasing global penetration of hemophilia therapy
- Optimization of compliance, dosing and prophylaxis treatment

### Biotest Products

- Haemonine® (Factor IX) introduced in 2008
- Haemoctin® (Factor VIII) contains high level of von Willebrand factor
- Haemoctin® is stable at RT for 2 years without artificial stabilisers, sugar free
- Haemoctin® has shown to be efficacious in FVIII inhibitor therapy



Source: WFH, PPTA



## Biotest R&D activity in Plasma Proteins

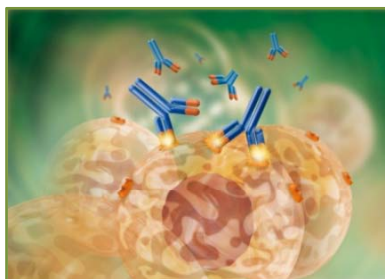
- R&D expenses in 2009 in the Plasma Protein segment: € 25.7 million; in H1 2010: € 14.8 million
- Continuous high investments in R&D in Plasma Proteins will guarantee future growth of the Plasma Proteins business
- Goal:
  - international regulatory registration and approval for all major Biotest products and intermediates



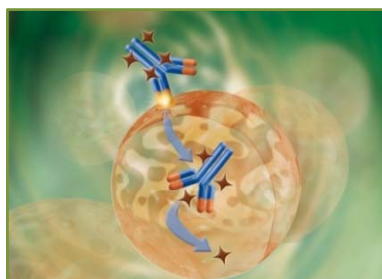


## **Biotherapeutics**

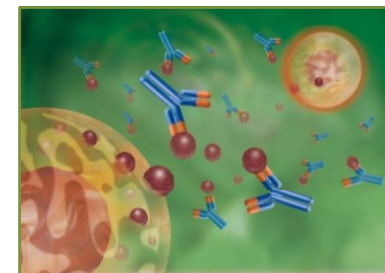
## Biotherapeutics: Attractive development projects



**BT-061:**  
Rheumatoid  
arthritis,  
plaque psoriasis



**BT-062:**  
Multiple myeloma



**BT-063:**  
Systemic lupus  
erythematosus

- Indications with a high medical need for effective and tolerable treatments
- Antibodies with specific mechanism of action



## Biotherapeutics: Focused research

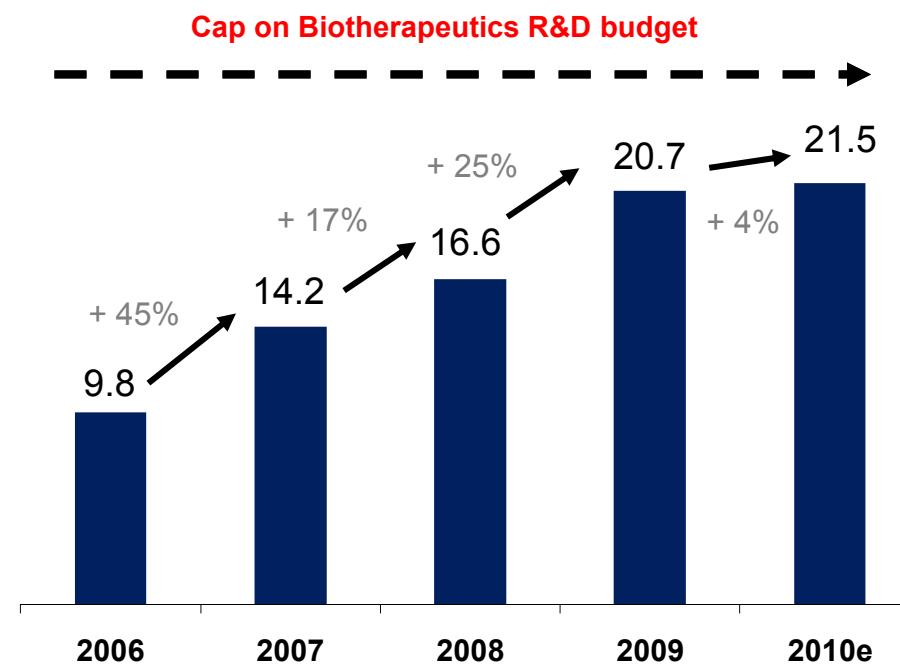
### Biotherapeutics: Focused research

- High medical need
- Rapidly growing markets
- Blockbuster potential

### Lead indications

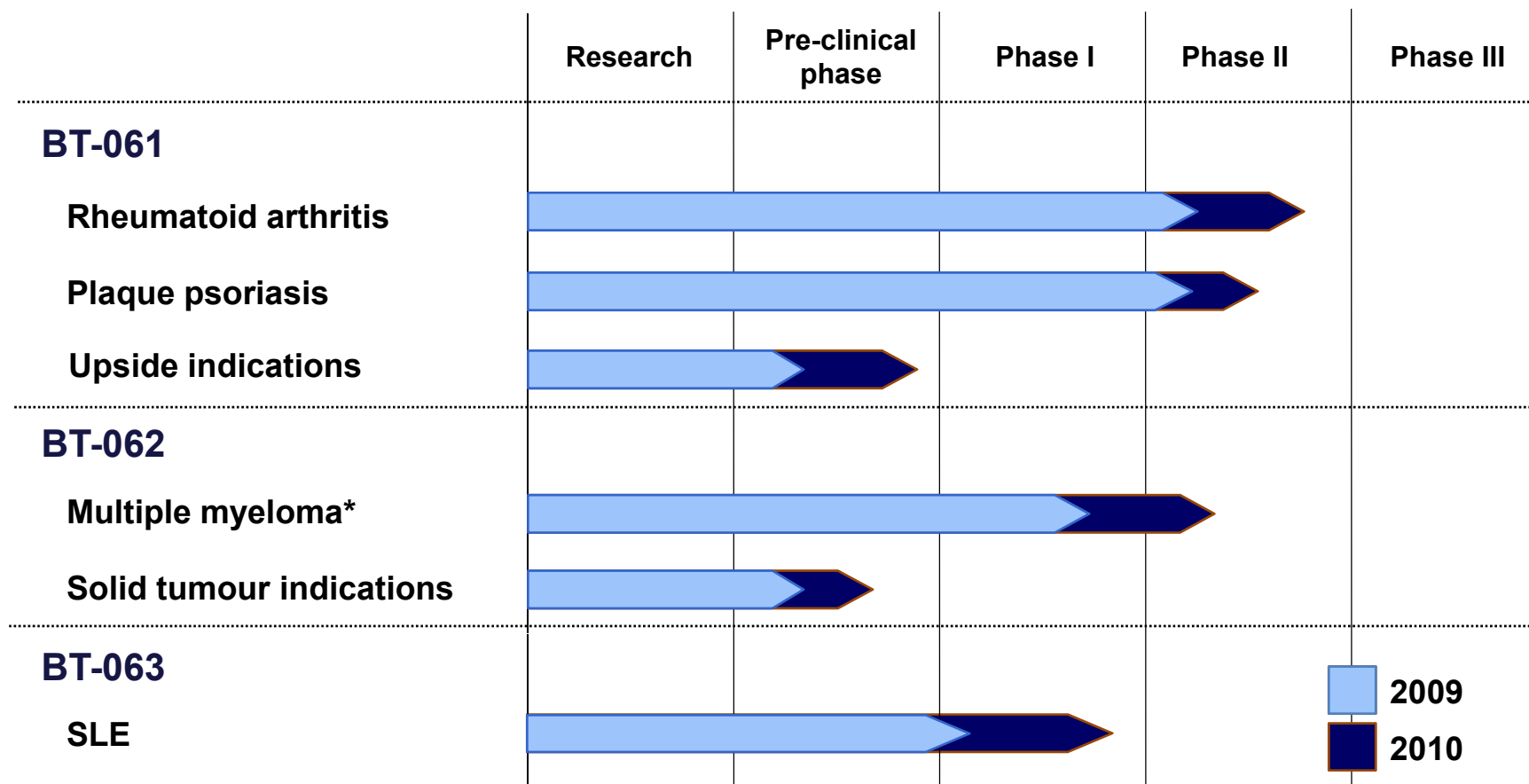
<b>BT-061</b>	Rheumatoid Arthritis, Psoriasis
<b>BT-062</b>	Multiple Myeloma
<b>BT-063</b>	Systemic Lupus Erythematosus

### R&D expense – Biotherapeutics (in € million)



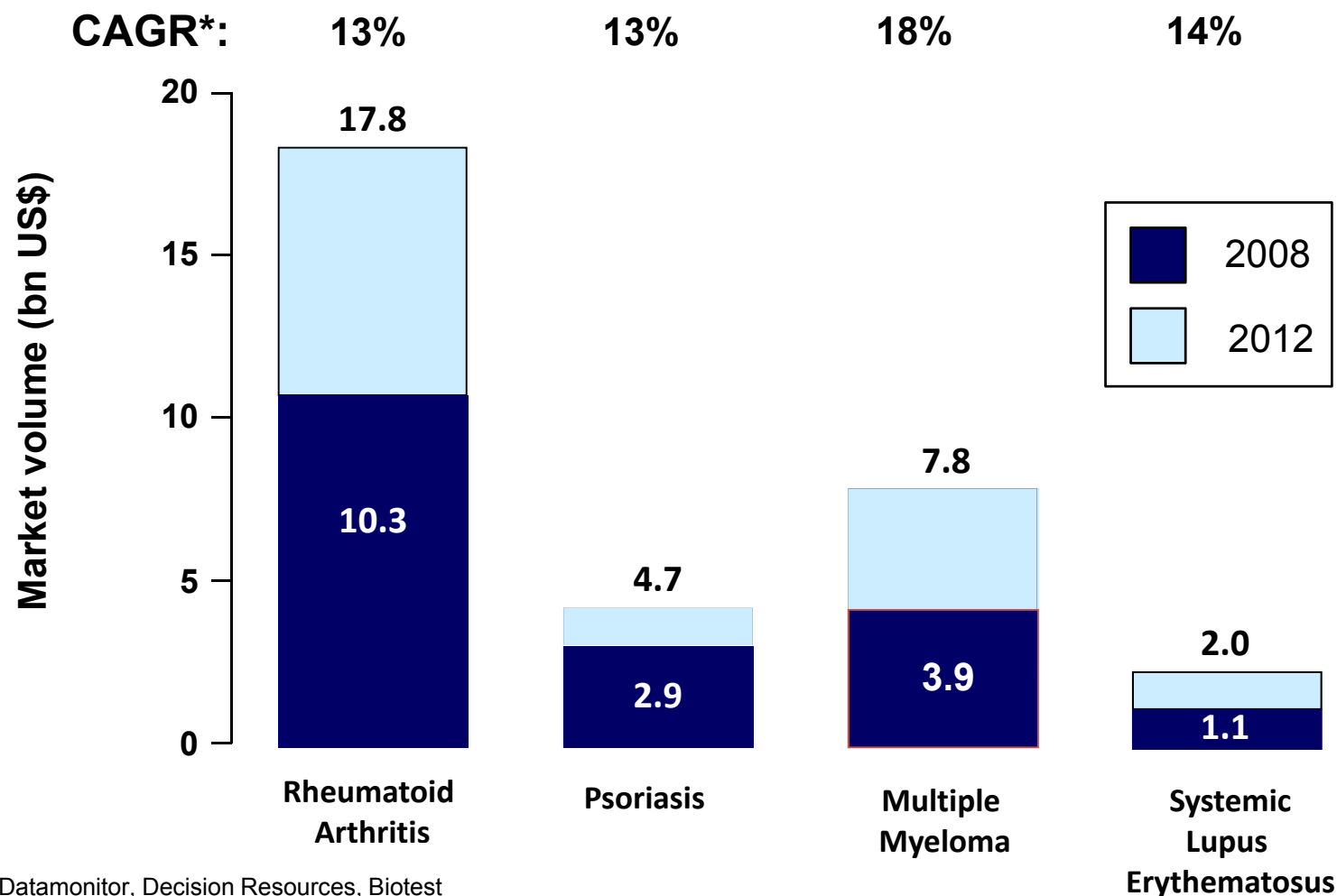


## Biotherapeutics: Significant project progress in financial year 2009 and 2010



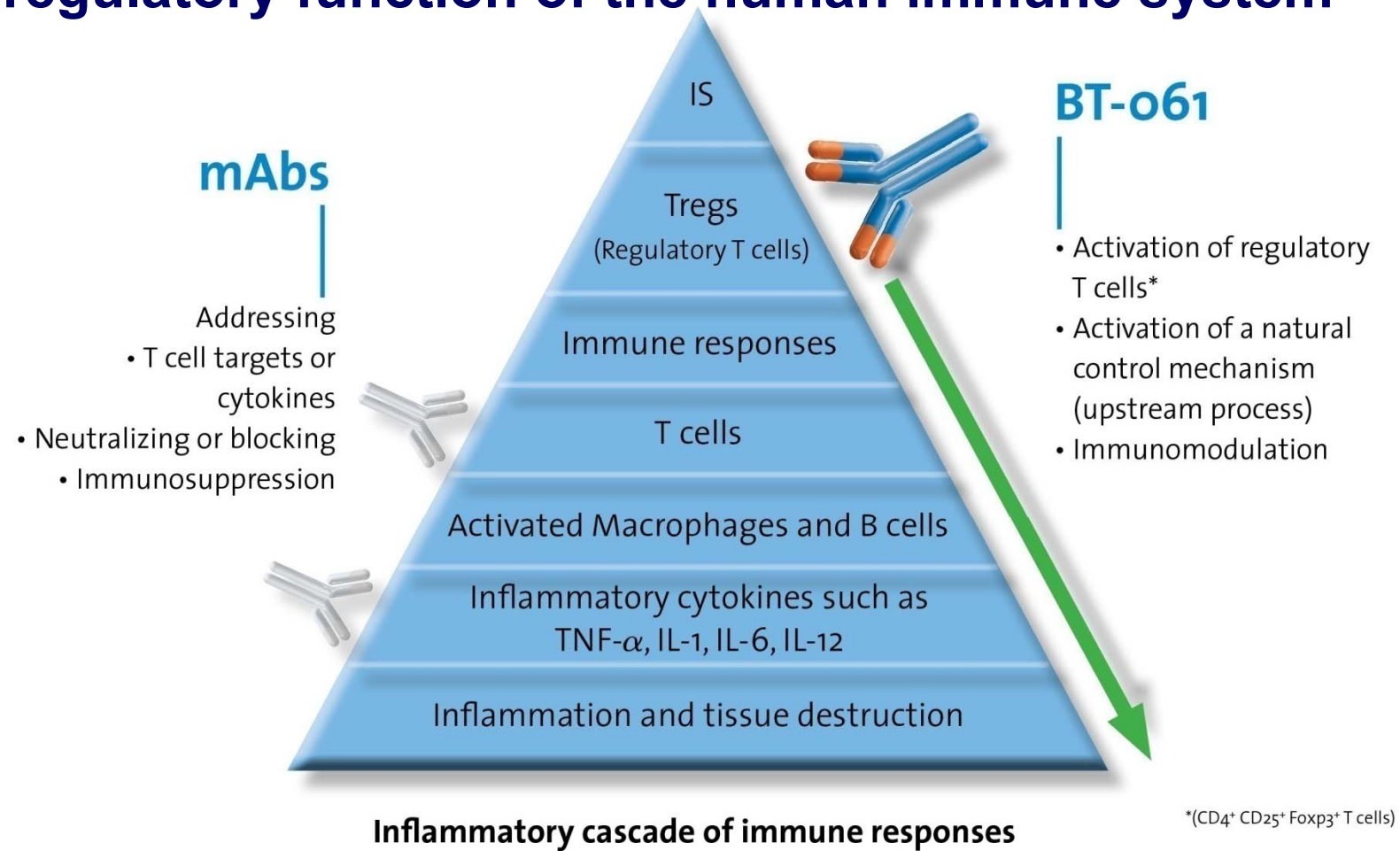
\* Phase I/IIa clinical trial approved by FDA (IND)

## Biotherapeutics: Continuously growing market potential



Quelle: Datamonitor, Decision Resources, Biotest  
\*CAGR: Compound Annual Growth Rate

# BT-061 – Specific mode of action addressing key regulatory function of the human immune system



**Mode of action offers significant potential in several upside indications**

# Rheumatoid Arthritis: Competitive market environment

## Favourable positioning is key to success

	Cytokine neutralizing (TNF $\alpha$ and others)	Targeting B cells or T cells	Targeting Tregs: BT-061
<b>MoA<sup>1)</sup></b>	Neutralization of cytokines	Depletion/inactivation of immune cells	Selective activation of Tregs
<b>Weakness/ Threats*</b>	<ul style="list-style-type: none"> <li>• <b>Black box warning:</b> risk of infection and malignancy</li> <li>• <b>FDA alert</b> for: invasive fungal infections and increased risk of lymphoma in children</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Black box warning</b> for PML<sup>2)</sup></li> <li>• Increased risk of infection</li> <li>• B-cell depletion (up to 1 yr)</li> <li>• Severe infusion reactions</li> </ul>	<ul style="list-style-type: none"> <li>• Late market entry requires clear USP<sup>3)</sup> and positioning</li> </ul>
<b>Strength/ Opportunity*</b>	<ul style="list-style-type: none"> <li>• Market dominance</li> <li>• Broad safety database</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment of TNF non responders</li> </ul>	<ul style="list-style-type: none"> <li>• <b>Superior efficacy</b> expected</li> <li>• Mode of action supports <b>good safety profile</b> (no signs of immunosuppression, cytokine release or lymphocyte depletion)</li> </ul>

## Positioning of BT-061 by new MoA, which translates into superior efficacy and safety

<sup>1)</sup> Mode of Action    <sup>2)</sup> Progressive multifocal leucoencephalopathy    <sup>3)</sup> Unique selling point    \*) with respect to individual compounds

# Current clinical data support targeted product

## Positioning clear proof-of-concept in both indications

### Rheumatoid Arthritis

#### **Proof of Concept (POC)**

**Phase II (No. 962 und 971):**

#### **Mono- and Combinationtherapy**

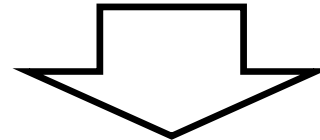
- up to 70% improvement of clinical symptoms (ACR70)
- good tolerability
- Study 962: Final data available
- Study 971: Final data expected in Q4 2010

### Psoriasis

#### **Proof of Concept (POC)**

**Phase I/IIa (No. 967):**

- up to 88% improvement of clinical symptoms (PASI)
  - long duration of therapeutic effect (up to 90 days after single administration)
  - good tolerability
- Study completed

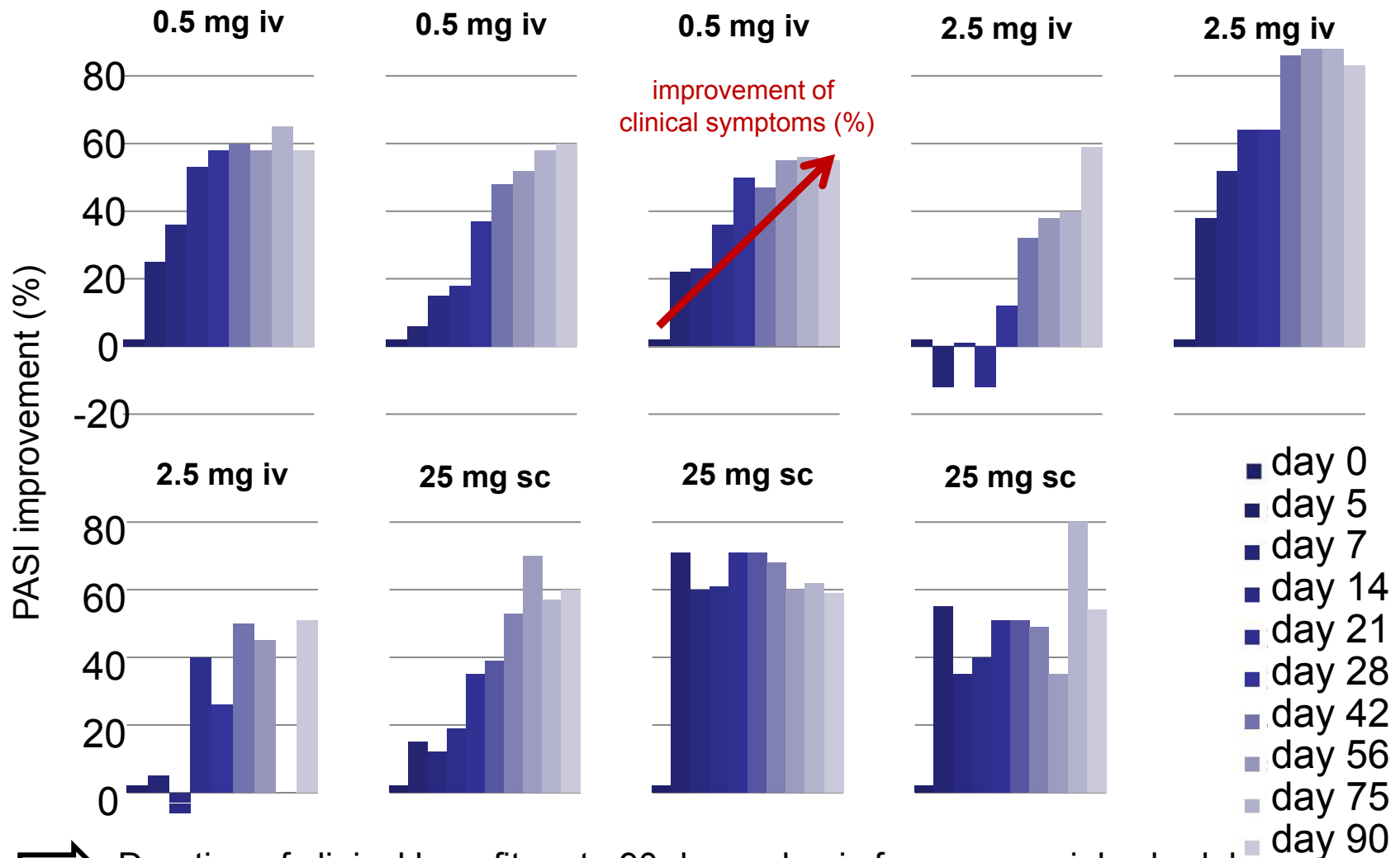


**Potential to position BT-061 via**

- **efficacy**
- **safety**
- **convenient administration**

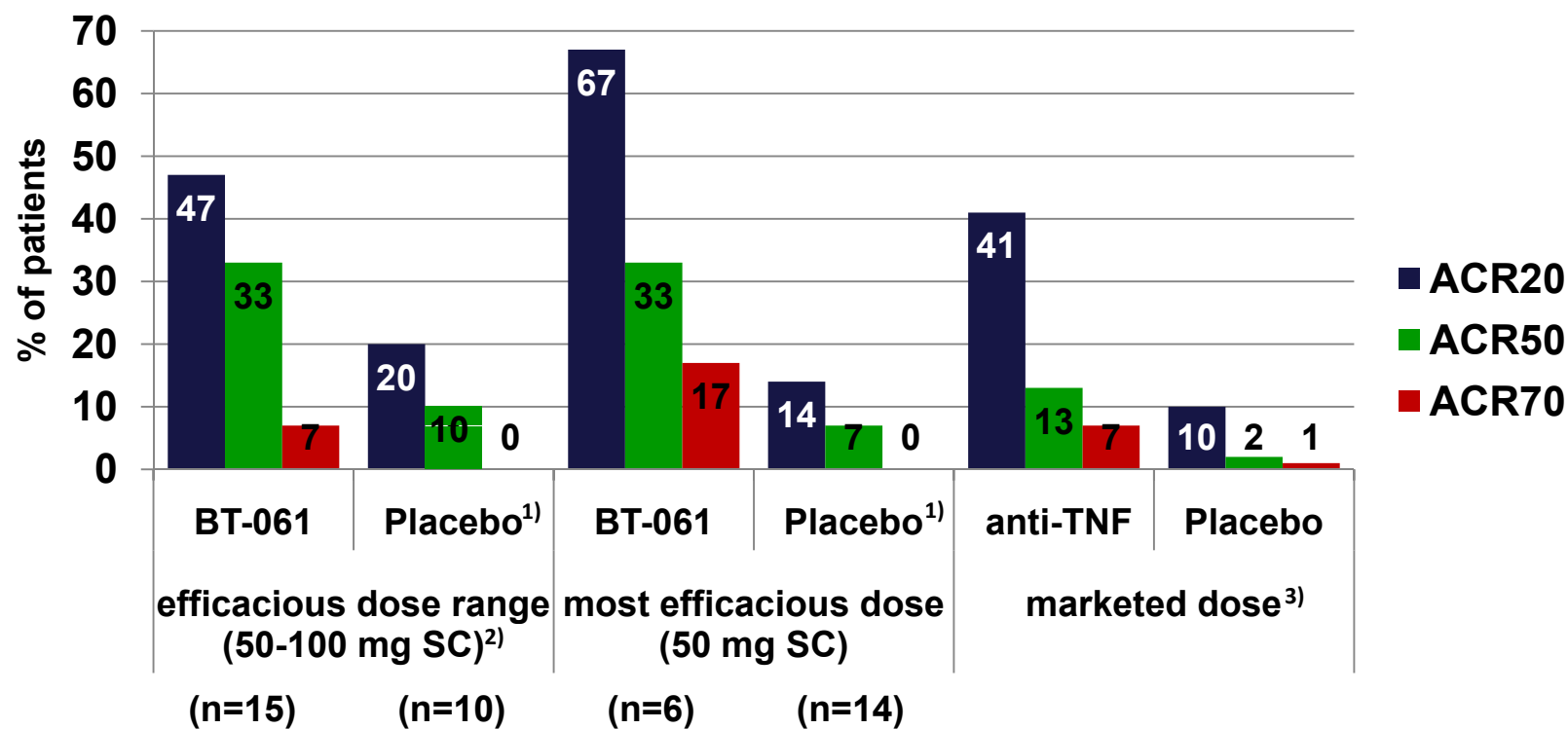
(**self-administration**, every other week, **1 ml subcutaneously**)

## BT-061 in Chronic Plaque Psoriasis: PASI50 and PASI75 responses after single application



## Repeated treatment of RA patients with BT-061 (monotherapy) Benchmarking against gold standard of biologic therapy\*

ACR responses at week 7, monotherapy



1) Two patients from each completed SC dose group; 2) Only patients that received all treatments over the 6 week periode

3) Phase III trial results of anti-TNF monotherapy in DMARD non-responders at week 7 \*) Please note: data from independent trials are not directly comparable as patient characteristics, route of administration, dose levels and treatment frequency are different

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## **BT-061: Goals of clinical trials starting in 2010**

### **Higher patient numbers to confirm product profile seen in early trials**

#### **Psoriasis, Phase II (973)**

- **Goals:**
  - Increase efficacy by completion of dose finding and repeated administration
  - Benchmarking with biologics gold standard
- **Design:** 48 patients in 6 dose groups, 8 weeks treatment, 12 weeks follow-up

#### **Rheumatoid Arthritis, Phase IIb (979)**

- **Goals:**
  - Confirm/establish superior efficacy and tolerability with larger patient basis
  - Establish Proof-of-Differentiation
- **Design:** 175 patients in 3 dose groups, 12 weeks treatment, 12 weeks follow-up



# Clinical development BT-061

## Overview

<b>Study no.</b>	<b>Indication</b>	<b>Design</b>	<b>Subjects/ Patients Planned</b>	<b>Status</b>
<b>961</b>	<b>Healthy volunteers</b>	<b>single dose iv; and sc up to 180 mg</b>	<b>57</b>	<b>Study completed</b>
<b>967</b>	<b>Phase I/IIa:Psoriasis</b>	<b>single dose, placebo controlled iv and sc</b>	<b>55</b>	<b>Study completed</b>
<b>973</b>	<b>Phase II: Psoriasis</b>	<b>multiple dose, placebo controlled</b>	<b>48</b>	<b>Recruitment ongoing</b>
<b>962</b>	<b>Phase IIa: Rheumatoid Arthritis</b>	<b>Multiple dose, Placebo controlled</b>	<b>96</b>	<b>Study completed</b>
<b>971</b>	<b>Phase II: Rheumatoid Arthritis</b>	<b>BT-061 + MTX Multiple dose, Placebo controlled</b>	<b>110</b>	<b>Recruitment completed</b>
<b>979</b>	<b>Phase IIb: Rheumatoid Arthritis</b>	<b>BT-061 + MTX Multiple dose, Placebo controlled</b>	<b>175</b>	<b>Submitted to regulatory authorities</b>

## Biotherapeutics: Established own production capacities



### Development structures in the segment:

- GMP production of monoclonal antibodies established in Boca Raton (BPC)
- Manufactured first large-scale batches of BT-061 in own production facility
- Start of GMP production of BT-062 at BPC in 2011



## BT-061 partnership

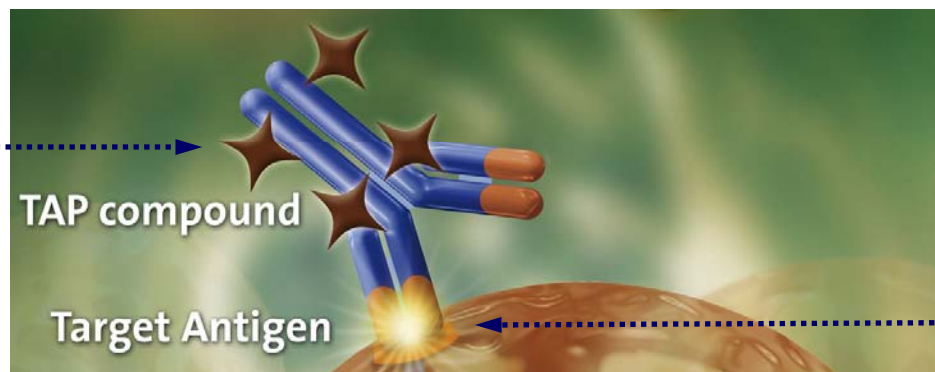


### **Biotest strategy:**

Cooperation with partner  
from clinical phase III

- Negotiations with international pharmaceutical companies ongoing
- High level of interest
- Request for confirmation of positive trial results via further phase II clinical trials
- Stand-alone further development of mAb until agreement is reached

## Competitive edge BT-062: Intrinsic properties provide basis for product positioning



### Toxin moiety mediates high efficacy

- **High potency independent of patient's immune system**
- Toxin technology with best track record: Sanofi Aventis, Biogen Idec, Bayer, Roche/Genentech amongst licensees
- First filing of TAP<sup>1)</sup> mAb expected in 2010 (Genentech)

### Antibody moiety mediates high specificity

- Unique targeting to CD138
- CD138 highly overexpressed in MM and other cancer cells
- **CD138 not expressed on bone marrow stroma cells**
- Good tolerability up to 160 mg/m<sup>2</sup>

<sup>1)</sup> TAP: Tumor activated payload

## BT-062 competitive edge: Specificity and high potency provide potential for competitive positioning

	Small molecules	mAbs	Immunoconjugate BT-062
<b>MoA<sup>1)</sup></b>	Unspecific cellular toxicity	Specific cellular target	Specific targeting combined with high potency drug
<b>Weakness/Threats</b>	AEs in > 30% of patients <ul style="list-style-type: none"> <li>• <b>Myelosuppression</b></li> <li>• <b>Thromboembolic events/ DVT<sup>2)</sup></b></li> <li>• <b>Peripheral neuropathy</b></li> <li>• <b>Gastrointestinal AEs<sup>3)</sup></b></li> </ul>	<ul style="list-style-type: none"> <li>• <b>Dependent on patients immune system</b></li> <li>• Broad tissue expression/ potential cross reactivity</li> </ul>	<ul style="list-style-type: none"> <li>• Limited safety data basis</li> </ul>
<b>Strength/Opportunity</b>	<ul style="list-style-type: none"> <li>• Dominant market position</li> <li>• Validated targets</li> <li>• Comprehensive safety data base</li> </ul>	<ul style="list-style-type: none"> <li>• High specificity</li> </ul>	<ul style="list-style-type: none"> <li>• <b>High potency</b> independent from patient's immune system</li> <li>• <b>High specificity</b></li> <li>• <b>No myelosuppression</b> and liver toxicity expected</li> </ul>

<sup>1)</sup> Mode of Action    <sup>2)</sup> Deep Vein Thrombosis · <sup>3)</sup> Adverse events

## BT-062: Single-dose study 969 in Multiple Myeloma

### First efficacy data, August 2010

Number of patients	Total	Percentage	Objective response	Clinical benefit (%)
treated with BT-062*	32			
efficacy data available	<b>25</b>	<b>100%</b>		
- disease progression within 6 weeks	11	44%		
- stable disease $\geq$ 9 weeks	12	48%		<b>56%</b>
- minor response	1	4%	8%	
- partial response	1	4%		

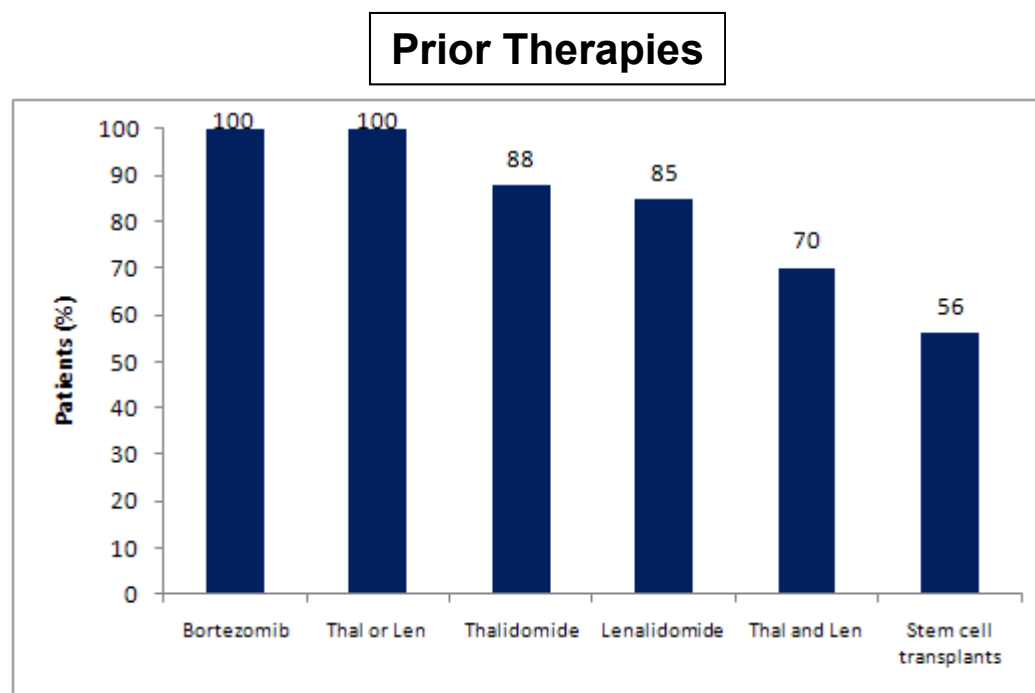
- **BT-062 shows anti-tumor activity already in repeated single dose schedule**
- **Further patients were enrolled in MTD\*\* cohort up to a total of 13**

\*Median number of prior chemotherapies: 7 (range: 2-15); 33% of patients had 10 or more prior chemotherapies

\*\*MTD: Maximum tolerated dose; Response criteria as defined by International Myeloma Working Group

## BT-062: Repeated single dose study 969 in Multiple Myeloma - Baseline characteristics

Patients have been heavily pre-treated; median age of about 65 years and about 6 years median time since initial diagnosis



- All patients have been treated with Bortezomib and at least one Immunomodulator
- About 70% have been pre-treated with both Lenalidomide and Thalidomide
- More than 50% have undergone an autologous stem cell transplantation (ASCT)

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## **BT-062: Next steps**

### **Establishment of commercial treatment schemes**

#### **Phase I/II: Repeated Dosing / Monotherapy – USA** (Recruitment started August 2010)

- **Goals:**

- Selection of commercial treatment scheme
- Establish Proof-of-Differentiation in mono therapy

- **Design:**

- Up to 70 patients, open label escalation study with intensified dosage scheme
- Extension cohort of up to 29 patients

#### **Phase II: Repeated Dosing / Combination – Europe** (Planned start: 2011)

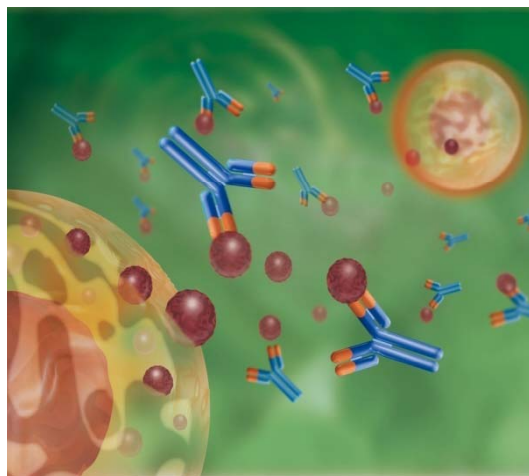
- **Goal:** Establish Proof-of-Differentiation in combination therapy

- **Design:** Open label combination study

**Due to lower number of pre-treatments, patients are expected to show improved response rate and longer duration of benefit**



## BT-063: Phase I study on track



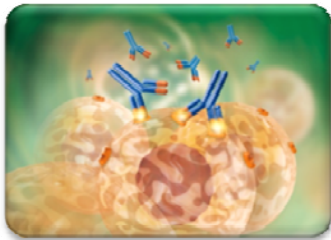
### BT-063 lead indication

- Systemic Lupus Erythematosus (SLE)
- High medical need: SLE incurable today, no new approval since ~ 40 years
- 2.5 million patients are suffering from SLE worldwide today

### Status Phase I

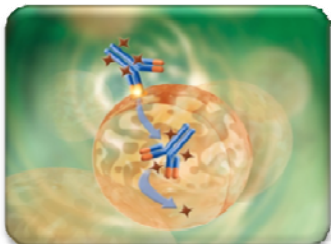
- Dose escalation in healthy volunteers ongoing
- 23 volunteers treated
- So far study medication well tolerated

## Outlook Biotherapeutics: Next steps in clinical development initiated



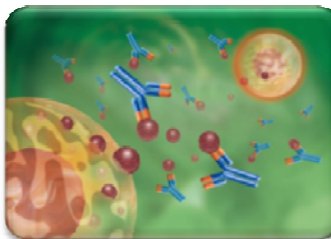
### **BT-061:**

- First encouraging clinical data from both lead indications
- Phase II trial in Psoriasis started
- Phase IIb in RA initiated
- Discussion with strategic partners ongoing



### **BT-062:**

- First indications of efficacy from dose-escalating study
- Multiple dose phase I/IIa trial approved by FDA
- Study initiated



### **BT-063:**

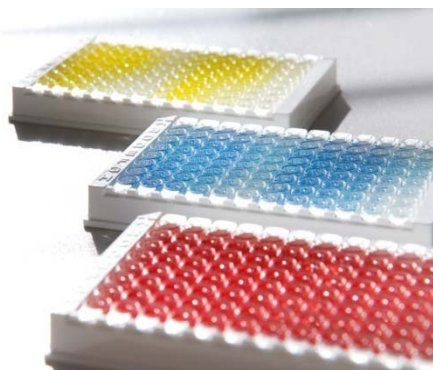
- Phase I study approved in Sept. 2009
- Treatment at 7th dose level completed (02 2010)



## **Microbiological Monitoring**

## Segment continues to be successful

- H1 2010 revenue growth of 10.0%, achieved mainly by heipha, but also Biotest HYCON products contributed to the growth
- Expansion of logistics capacities at heipha in Eppelheim
- Investment in research and development
- Strengthening of sales structures in the United States and Japan



**Thank you for your attention!**



## Contact and Financial Calendar 2010/2011

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### Financial Calendar 2010/ 2011

<b>Nov 08, 2010</b>	<b>Q3 Report 2010/ Analyst's Conference</b>
<b>Mar 22, 2011</b>	<b>FY 2010/ Analyst conference</b>
<b>May 10, 2011</b>	<b>Q1 Report 2011</b>
<b>May 12, 2011</b>	<b>Annual General Meeting</b>
<b>Aug 11, 2011</b>	<b>Q2 Report 2011</b>
<b>Nov 10, 2011</b>	<b>Q3 Report 2011/ Analyst conference</b>

# Biotest Plasma Proteins – premium products





# Intratect®

## Human immunoglobulin for intravenous use (IVIg)



### Therapeutic indications:

- Replacement therapy in:
  1. Primary Immunodeficiency Syndromes
  2. Myeloma or chronic lymphocytic leukaemia
  3. Children with congenital AIDS and recurrent infections
- Treatment of autoimmune diseases:  
ITP (idiopathic thrombocytopenic purpura), Guillain-Barré-Syndrome, and Kawasaki Syndrome

### Properties:

- Storage at room temperature
- Ready-to-use solution
- Well tolerated (Sugar free)

### Clinical trials:

- Patients with a primary antibody deficiency
- Patients with idiopathic thrombocytopenic purpura (ITP)



## Pentaglobin® / IgM-Concentrate

**IgM-enriched immunoglobulin  
for severe bacterial infections**



### Therapeutic indications:

- Adjunctive therapy of severe bacterial infections in addition to antibiotic therapy
- Immunoglobulin replacement in immunocompromised patients

### Properties:

- Unique in elimination of pathogens and their toxins
- Excellent immunomodulator for controlling inflammation and severe bacterial infections
- Excellent tolerability

### Clinical trial:

- **IgM-Concentrate** in clinical Phase I:  
Further developed IgM-enriched immunoglobulin

## Hepatect® CP

**Human Hepatitis B immunoglobulin manufactured from plasma of donors with high anti-HBs antibody titres**



### Therapeutic indications:

- Prophylaxis against hepatitis B (HBV) in adults and children over 2 years who have not been vaccinated and who are at risk of infection
- Prophylaxis of HBV re-infection after liver transplantation (gold standard)
- Prophylaxis after exposure to HBs Antigen positive material, e.g. needle stick injuries
- HBV prophylaxis in newborns from HBV carrier mothers

### Properties:

- Contains high purity anti-HBs antibodies, standardised to 50 IU/ml
- Ready-to-use infusion solution, sugar-free
- Natural function and activity of specific immunoglobulins is preserved

# Cytotect®Biotest

**Human CMV immunoglobulin  
manufactured from plasma of  
donors with high CMV antibody  
titres**



## **Therapeutic indications:**

- Prophylaxis against the clinical manifestation of CMV infections in immunosuppressed patients, especially transplant recipients

## **Properties:**

- Contains anti-CMV antibodies, standardised to 50 U/ml with reference to the standard of the Paul-Ehrlich-Institute
- Natural function and activity of specific immunoglobulin is preserved
- Ready-to-use solution, sugar-free

## **Clinical trial:**

- Phase III study to prevent CMV infection in newborns of mothers who acquired a primary CMV infection during pregnancy
- Orphan Drug Designation (Europe, U.S., CH)

## Haemoctin<sup>®</sup> / Haemonine<sup>®</sup>

**Chromatographically purified,  
double virus inactivated  
coagulation factors  
concentrated from plasma**



### Therapeutic indications:

- Prevention and treatment of bleeding in:
  1. Haemophilia A (Haemoctin<sup>®</sup>)
  2. Haemophilia B (Haemonine<sup>®</sup>)

### Properties:

- High viral safety standard
- Stable for two years at room temperature
- Haemoctin contains a high level of von Willebrand factor (VWF)
- Haemoctin has been shown to be efficacious in FVIII inhibitor therapy - in general VWF-containing FVIII preparations are the first choice in inhibitor treatment with high dosages of FVIII.

## Zutectra® – increased patient compliance

**Human Hepatitis B immunoglobulin for subcutaneous administration. Manufactured from plasma of donors with high anti-HBs antibody titres.**



**First subcutaneous injectable HBIG for self-administration**

### **Therapeutic indication:**

- Prophylaxis of HBV re-infection after liver transplantation

### **Properties:**

- Subcutaneous administration – ready for self-administration by patients
- Ready-to-use solution in pre filled syringe
- High specific anti-HBs activity of 500 IU/ml

⇒ Safe and convenient HBV re-infection prophylaxis for liver transplant patients

### **Clinical results:**

- Protective anti-HBs-serum levels achieved in all patients in the registration trial with weekly Zutectra® applications, no HBV re-infection occurred

## International myeloma working group response criteria

	Major characteristics of response criteria*
<b>Progressive Disease (PD)</b>	Increase of 25% from lowest response value in any one or more of the following: Serum M-component (absolute increase must be $\geq 0.5\text{g}/100\text{ml}$ ) <sup>c</sup> and /or Urine M-component (absolute increase must be $\geq 200$ mg per 24 h)
<b>Stable disease (SD)</b>	Not meeting criteria for CR, VGPR, PR or progressive disease
<b>Minor response (MR) in patients with relapsed refractory myeloma</b>	$\geq 25\%$ but $< 49\%$ reduction of serum M protein and reduction in 24 h urine M protein by 50–89%, which still exceeds 200mg per 24 h
<b>Partial response (PR)</b>	$\geq 50\%$ reduction of serum M-Protein and reduction in 24-h urinary M protein by $\geq 90\%$ or to $< 200$ mg per 24 h If the serum and urine M-Protein are unmeasurable, a $\geq 50\%$ decrease in the difference between involved and uninvolved FLC levels is required in place of the M-Protein criteria
<b>Maximum Tolerated Dose (MTD)</b>	The highest dose level at which $< 2$ of 6 subjects experience a DLT (Dose Limiting Toxicity) is defined as the MTD.

\* according IMWG, International Myeloma Working Group; Source: Kyle and Rajkumar, 2009;

# Plasma Proteins: Production process

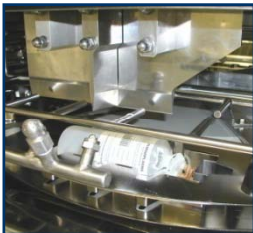


## 1. Plasma Sourcing

Plasmapheresis: Plasma collection

### Virus Safety

**Donor selection**  
**Testing of donations**



## 2. Fractionation

From Plasma to intermediates

- Cryo
- Paste II, III
- Paste V

**Virus removal**



## 3. Purification

From Intermediates to Final Bulk

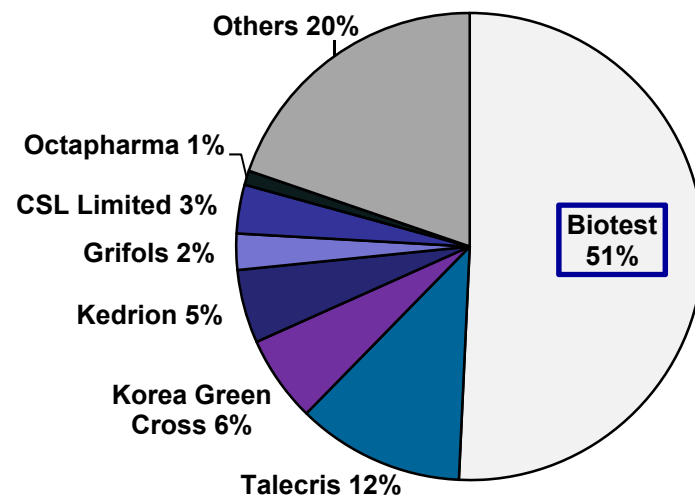
**Virus inactivation**



## 4. Filling and Packaging

## Biotest is a mayor player in Hepatitis B Immunoglobulin (HBIG) market

### HBIG Market worldwide (i.m. & i.v.) in \$



(Marketing Research Bureau, Inc.)

- Use of HBIG after transplantation is mandatory
- Biotest is world wide market leader with Hepatect® in Europe and Nabi HB™ in USA
- Zutectra® enhances Biotest competence and engagement in the HBIG market
- Zutectra® will strengthen and defend current strong market position by preventing possible switch to i.m. and future i.v. drugs
- Further Launches for Zutectra® and Nabi HB™ already scheduled in attractive world wide markets