

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



Roadshow Stockholm

**Biotest AG**

August 19, 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

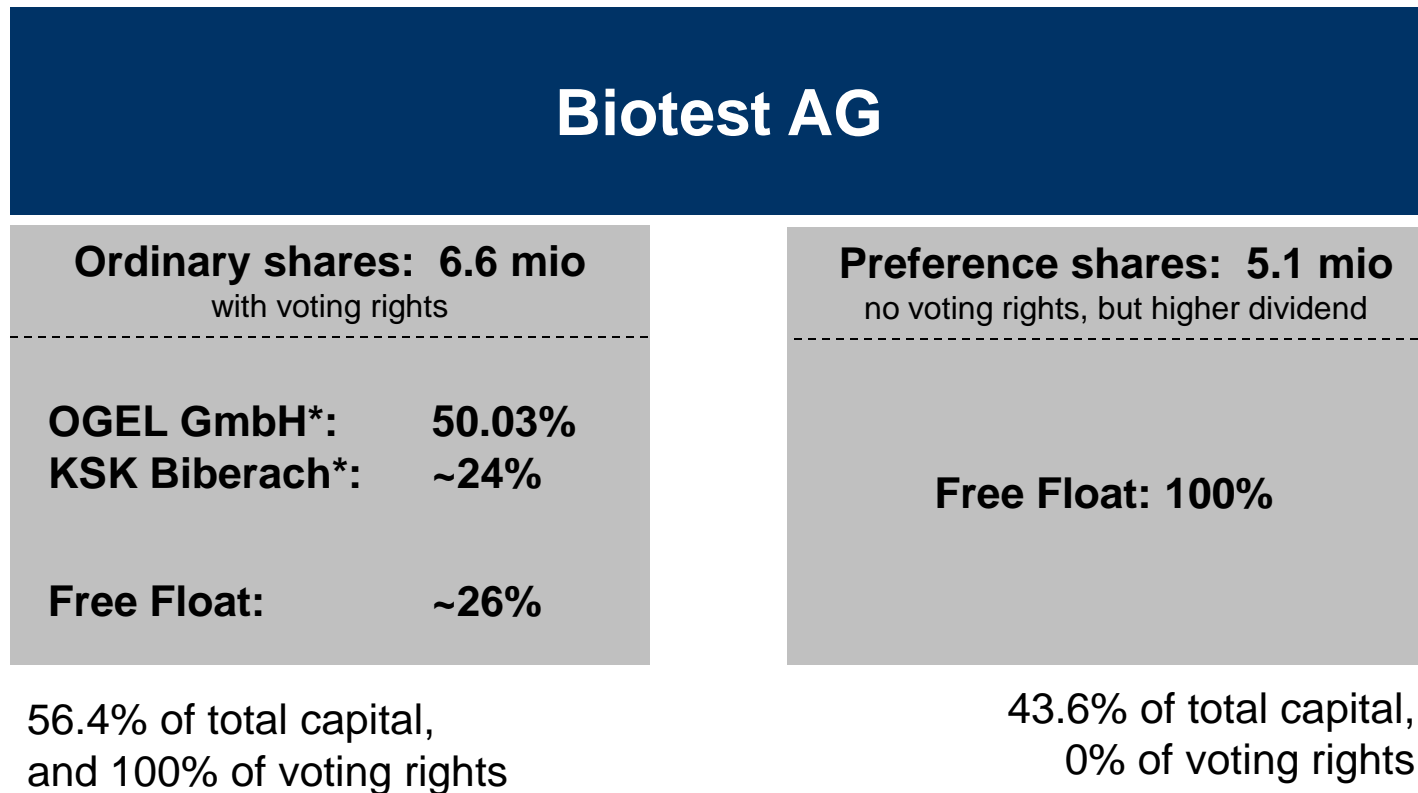
#### Biotherapeutics

- Monoclonal antibodies

#### Microbiological Monitoring

- Hygiene monitoring

## Shareholder structure



\* as of August 2010



## **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



## 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



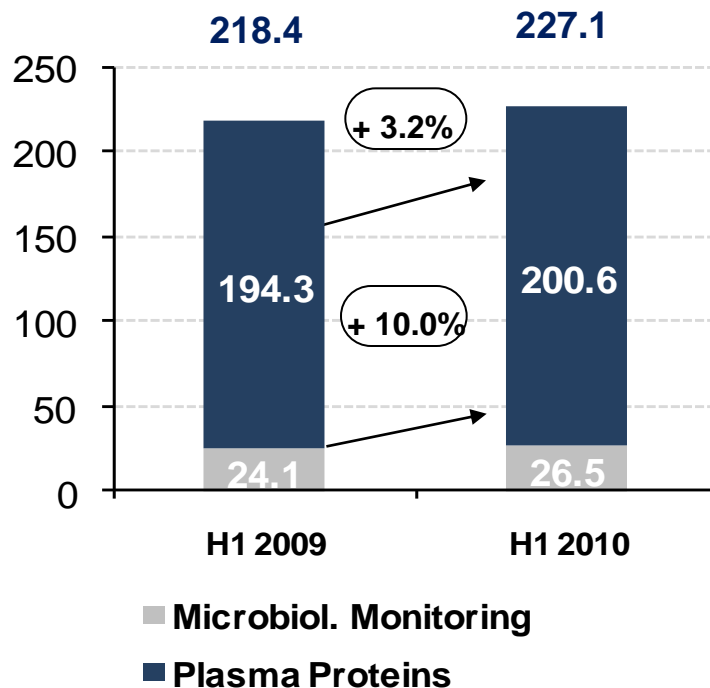
New EBIT guidance: € 45 million +/- 10%

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
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<b>Sales Plasma Proteins H1 2010</b>	<b>€</b>	<b>200.6 m</b>

## EBIT Plasma Proteins H1 2010 vs H1 2009

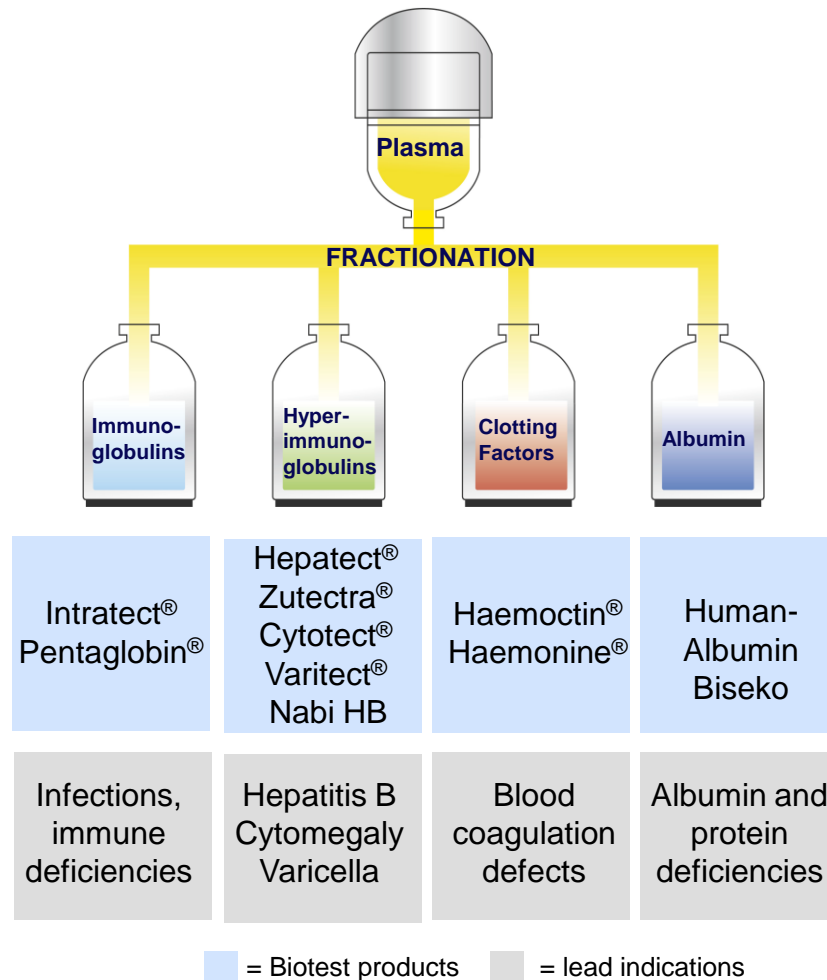
EBIT Plasma Proteins H1 2009	€	42.7 m
EBIT from increased volume	€	8.7 m
EBIT loss from reduced prices	€	- 14.6 m
Net changes of other costs/expenses	€	- 1.2 m
<b>EBIT Plasma Proteins H1 2010</b>	<b>€</b>	<b>35.6 m</b>



## 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®**

EU-wide approval  
(centralised procedure)



**Hepatect®CP**

Approvals in 13  
other European countries  
(mutual recognition procedure)



**Albiomin®**

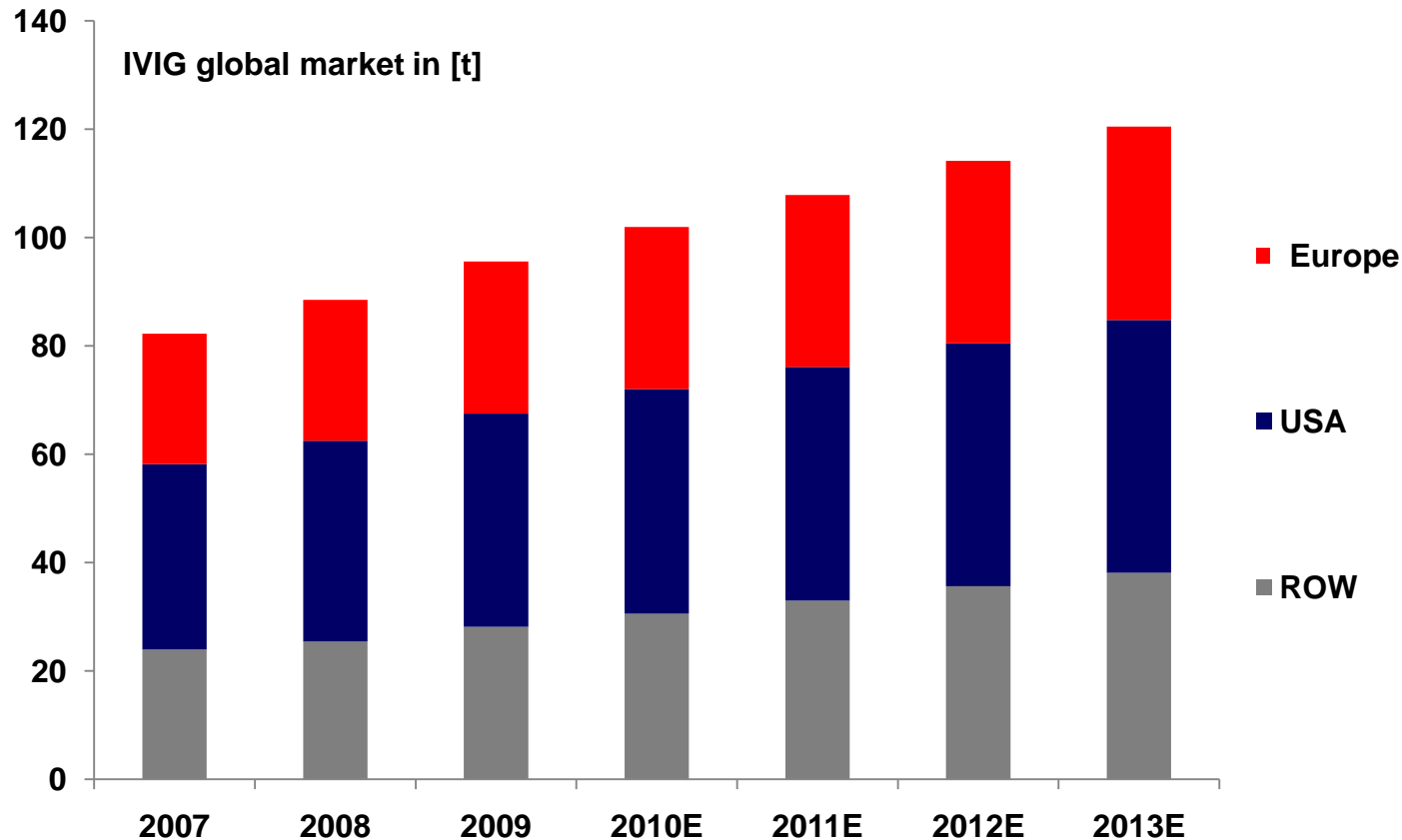
Approvals in Germany and 10  
other European countries



**Intratect®**

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

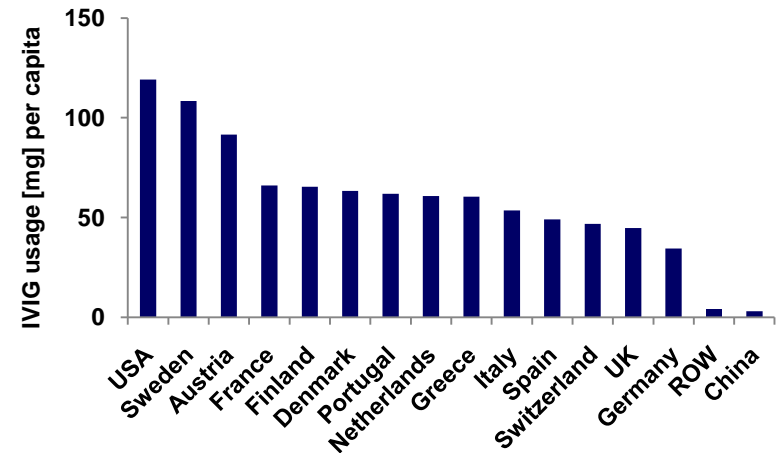
# Further growth of immunoglobulin market expected

## 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® – a premium product concerning tolerability \*
- IVIG available in US 2011
- Speciality Hyperimmunoglobulines: Hepatect®, Zutectra®, Varitect®, Cytotect®
- sc application: Zutectra®
- 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® (human normal immunoglobulin for iv administration) in patients with primary immunodeficiency (PID)"; E. Bernatowska et al., 2006

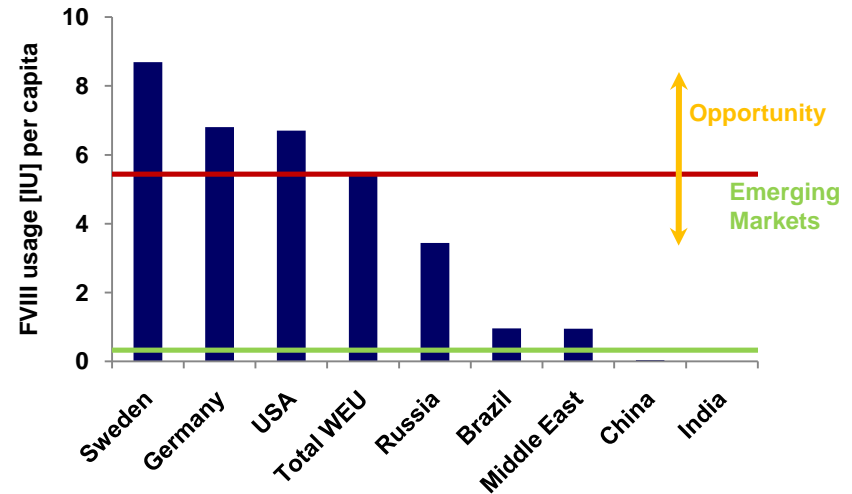
# Opportunities in Haemophilia market

## 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

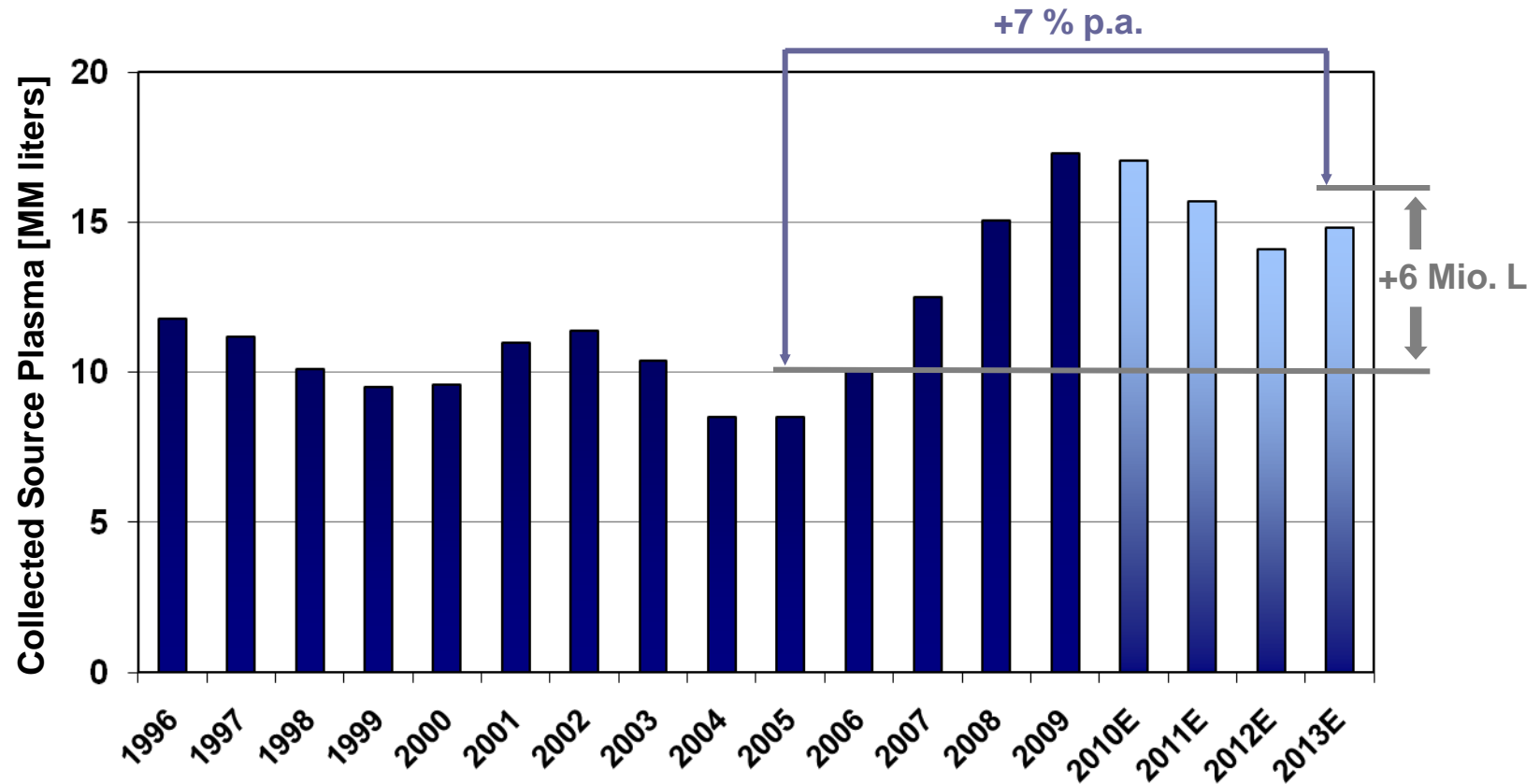


Source: WFH, PPTA



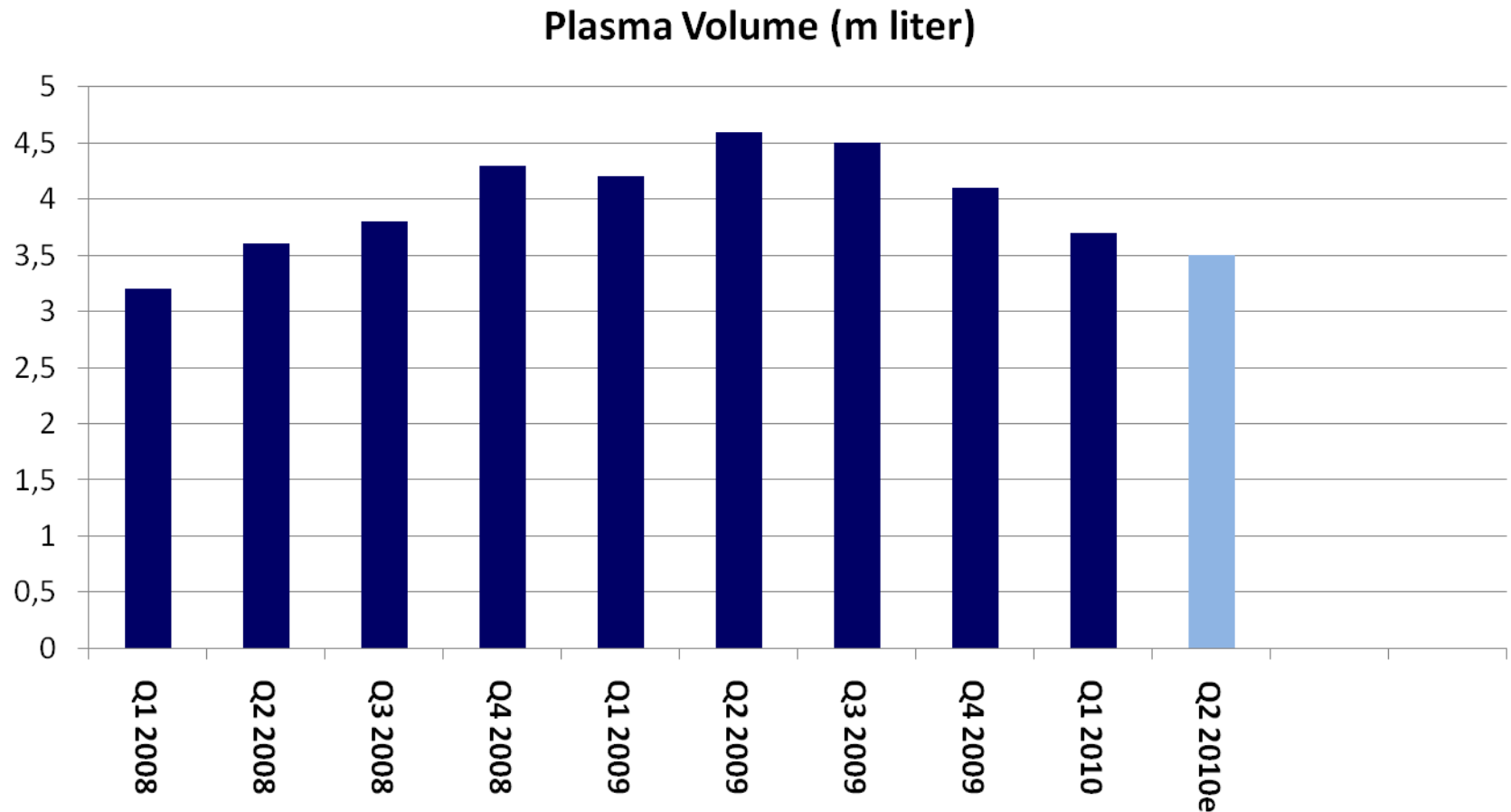


# US source plasma collection forecast, 1996 -2013



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

## 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



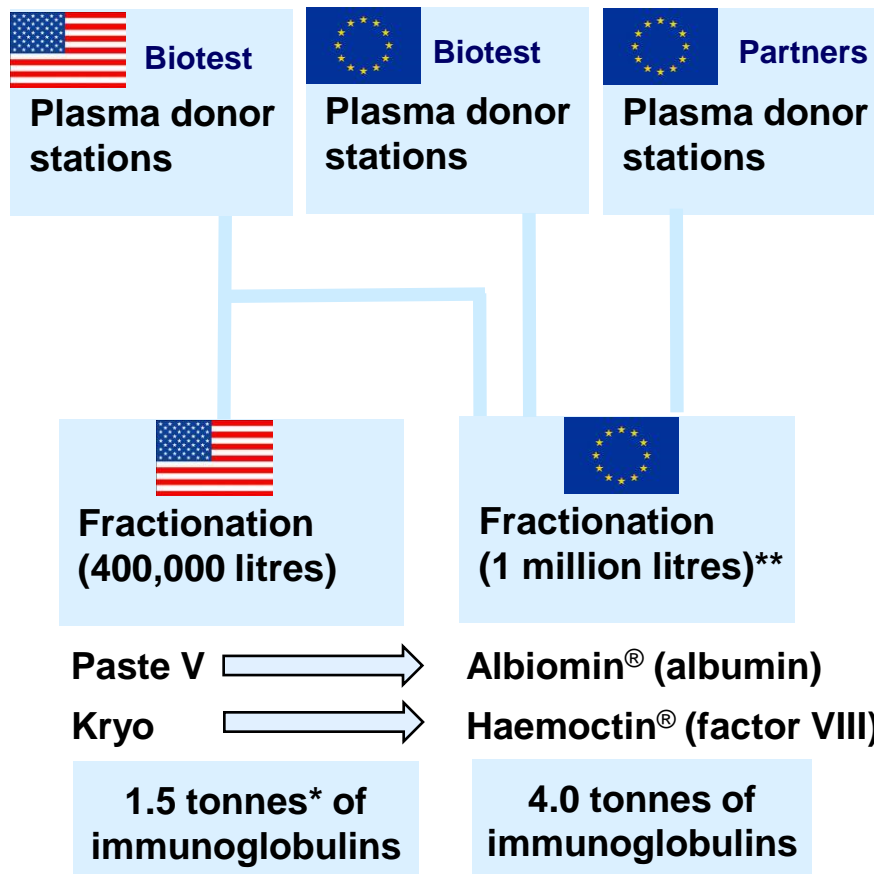
# Bivigam™ (IVIg) development nears successful completion

**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



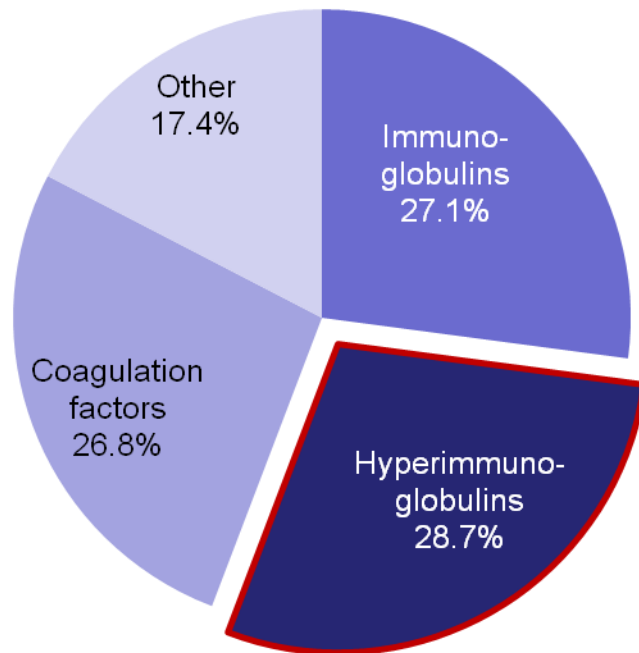
- 21 plasma collection centres
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products from US to Europe from end of 2010
- Network increases EBIT margin

\* Approval will probably be granted in 2011

\*\* Production in Dreieich and capacities at partners

## 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®)

# 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®:**

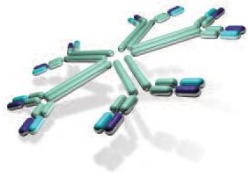
- Optimal for self-treatment
- Suitable for long-term prophylaxis as administered subcutaneously

## Major R&D progress of Plasma Protein projects



### **Zutectra<sup>®</sup>**

Post approval trial to examine convenience and self-medication at home with 70 patients



### **IgM Concentrate**

Phase II to start mid of 2011  
Treatment of serious bacterial infections  
High functional activity, good tolerability



### **Cytotect<sup>®</sup>**

Phase III clinical trial ongoing  
Prevention of prenatal CMV infection  
Interim evaluation planned for end of 2010

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

Phase III trial, recruitment completed  
Final Draft of Study Report end of 2010  
Marketing approval: aiming at Germany first



## 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: Focused research

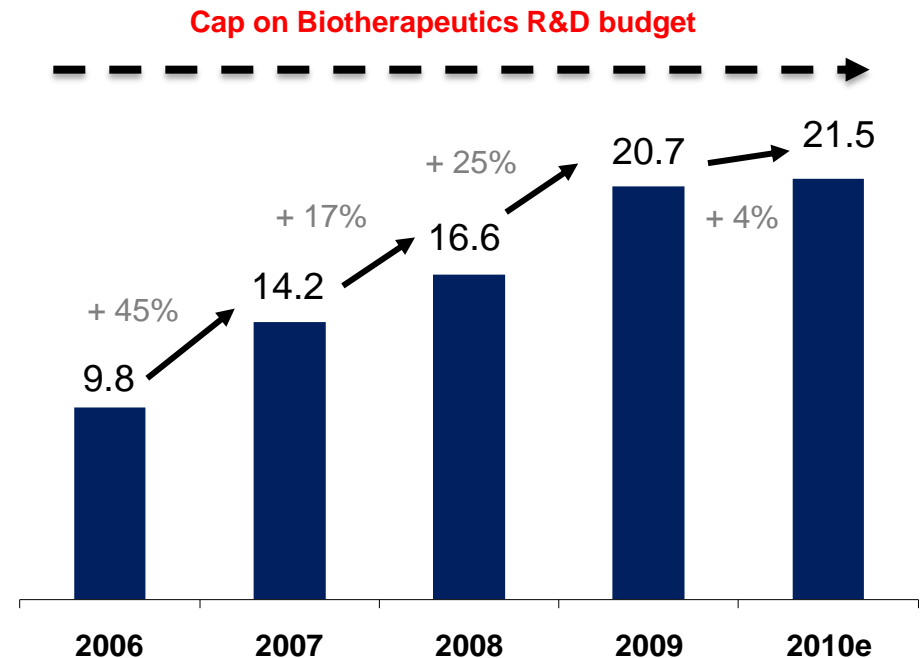
## Biotherapeutics: Focused research

- High medical need
- Rapidly growing markets
- Blockbuster potential

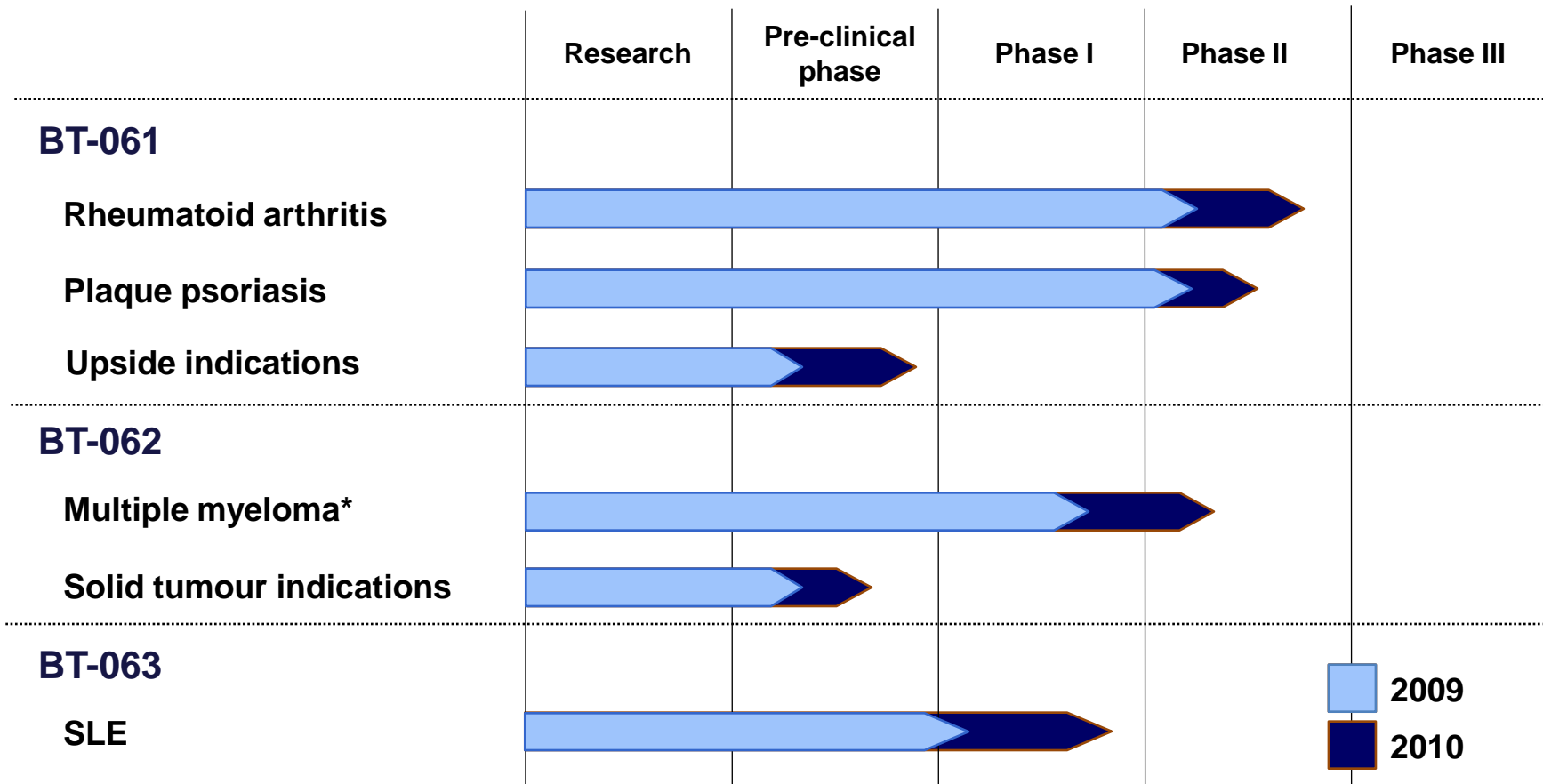
## Lead indications

<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)

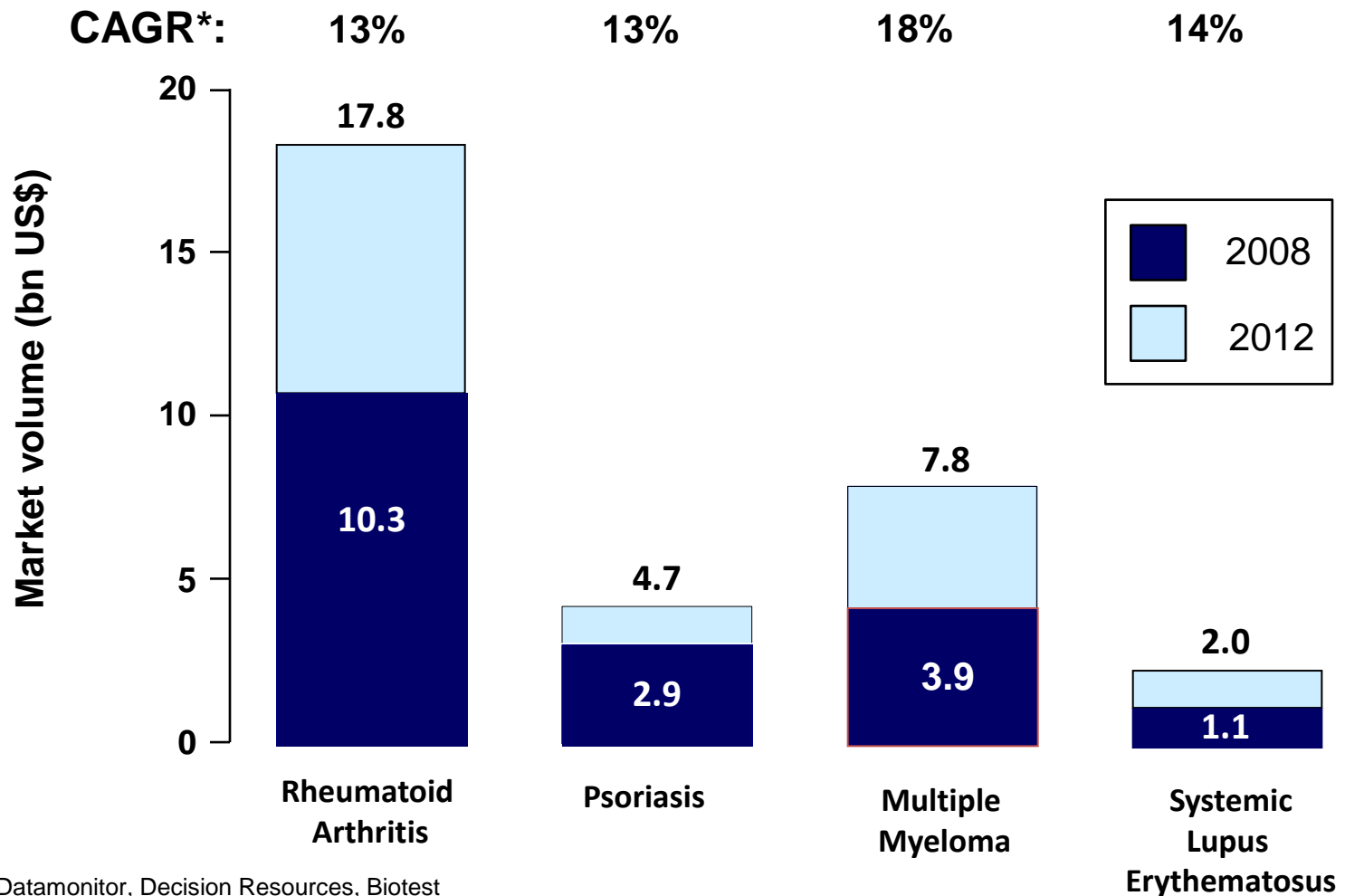


# Biotherapeutics: Significant project progress in financial year 2009 and 2010



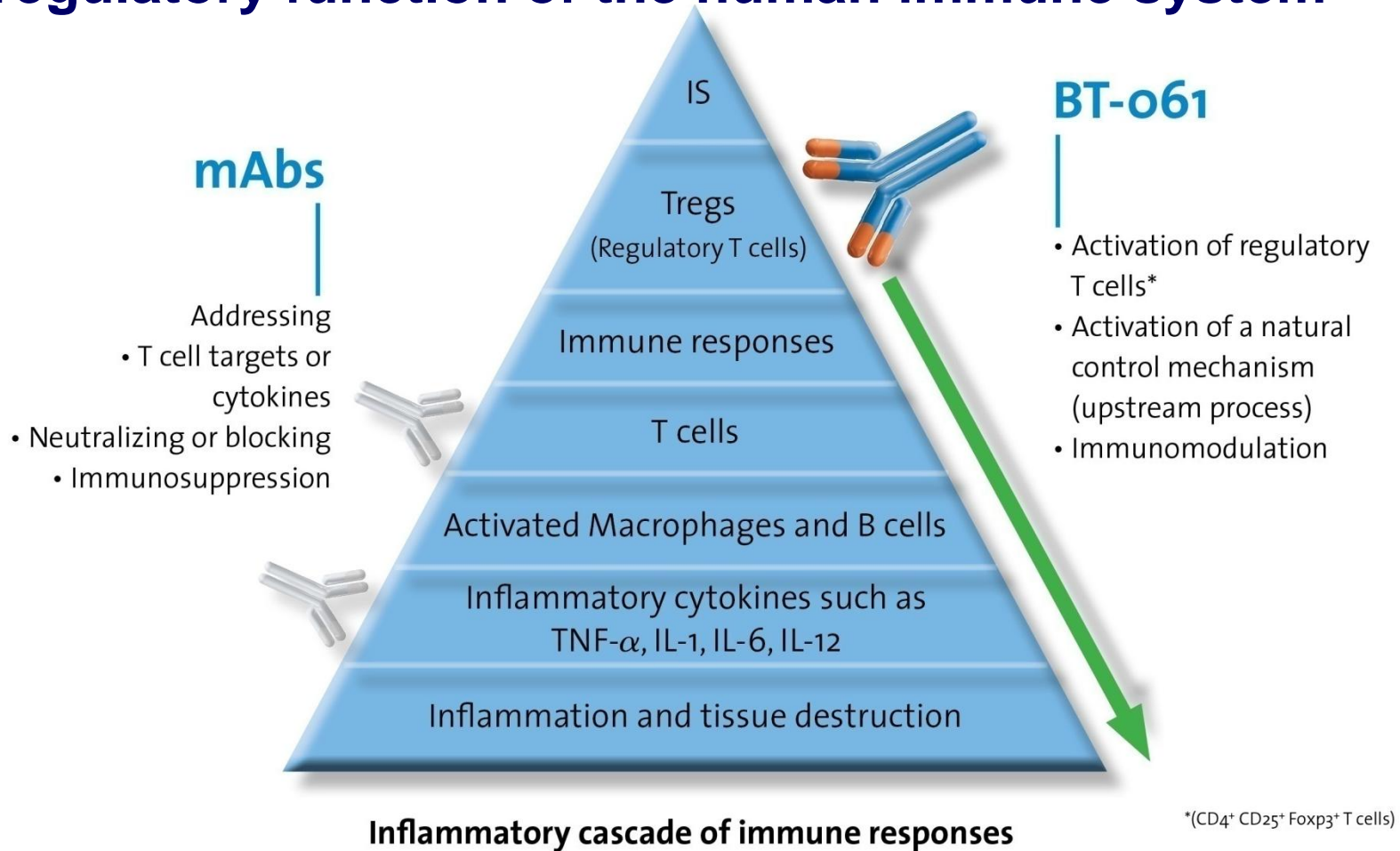
\* Phase I/IIa clinical trial approved by FDA (IND)

# 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

# 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

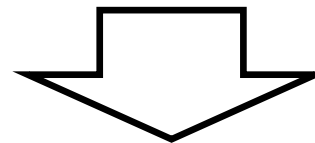
- up to 70% improvement of clinical symptoms (ACR70)
- good tolerability
- Study 962: Final data available
- Study 971: Final data expected in Q4 2010

### 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

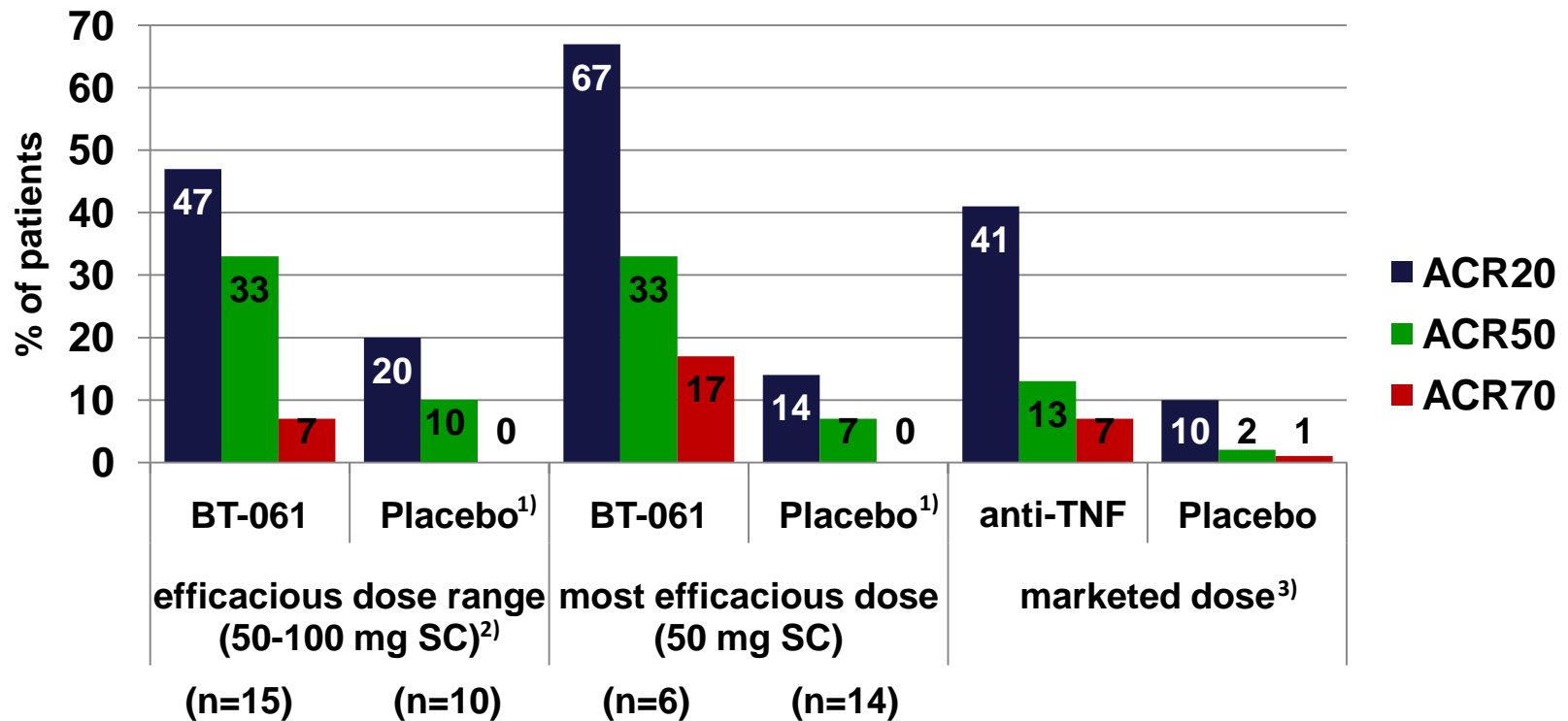
- efficacy
- safety
- convenient administration

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



## 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

# 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 first half of 2011



## BT-061 partnership

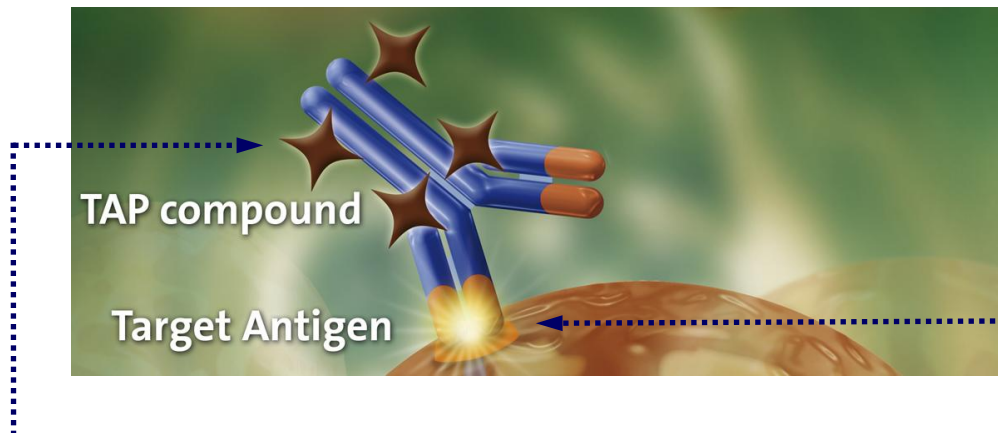


### **Biotest strategy:**

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**

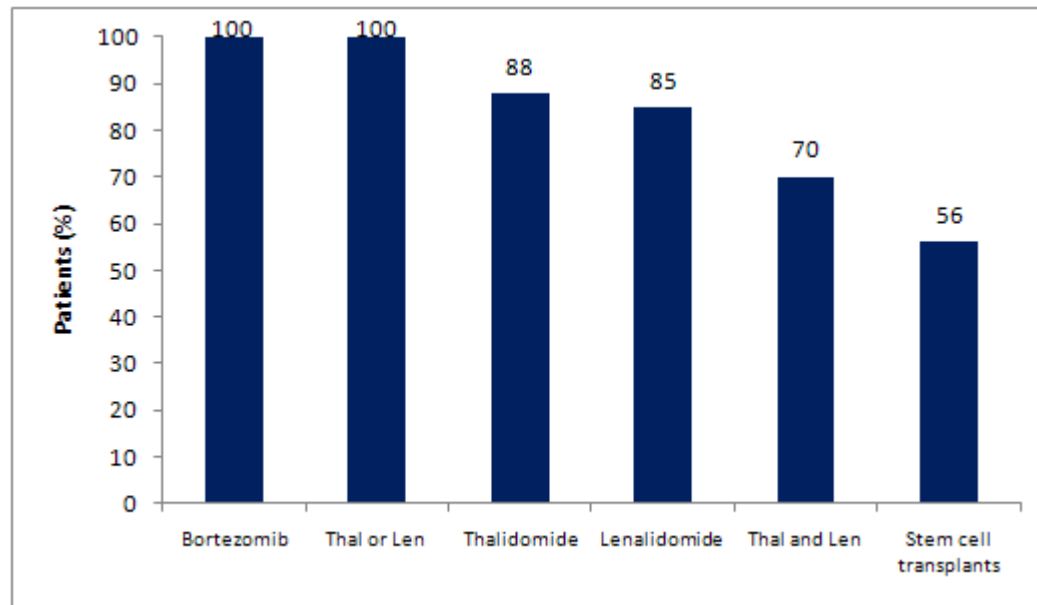
\*Median number of prior chemotherapies: 7 (range: 2-15); 33% of patients had 10 or more prior chemotherapies

\*\*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

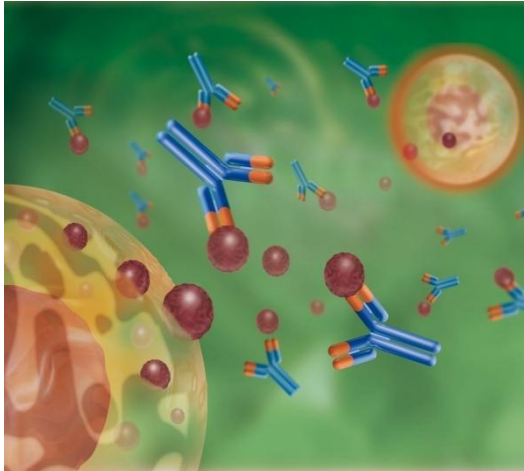
### Prior Therapies



- 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)



## BT-063: Phase I study on track



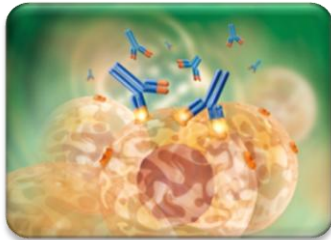
### BT-063 lead indication

- 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

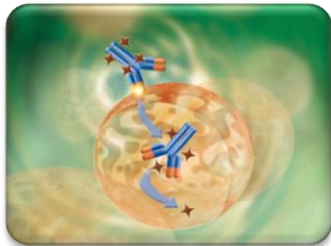
- Dose escalation in healthy volunteers ongoing
- 23 volunteers treated
- So far study medication well tolerated

## Outlook Biotherapeutics: Next steps in clinical development initiated



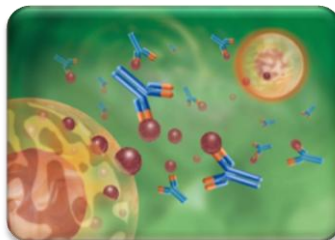
### **BT-061:**

- 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)



## **Outlook for 2010**

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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

## Contact and Financial Calendar 2010/2011

### Investor Relations Biotest AG:

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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>