

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



Management Presentation

**Biotest AG**

May 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	Q1 2010
<b>Sales</b>	€ 440.2 m (+14.1%)	€ 115.0 m (+5.2%)
Thereof Plasma Proteins	€ 390.1 m (+14.9%)	€ 101.9 m (+4.6%)
<b>EBIT</b>	€ 61.5 m (+4.2%)	€ 12.3 m (-18.0%)

### 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 11 countries worldwide
- Employees (FTE)\*: 1,831\*\*  
    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

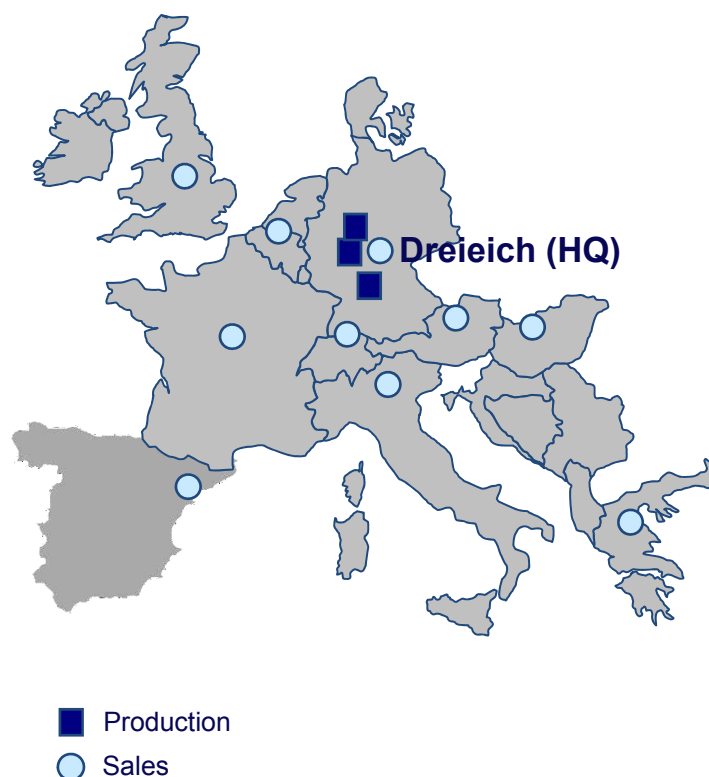
\*: as of 31 March 2010    \*\*: Continued Operations



Headquarter, Dreieich

# Biotest Group overview

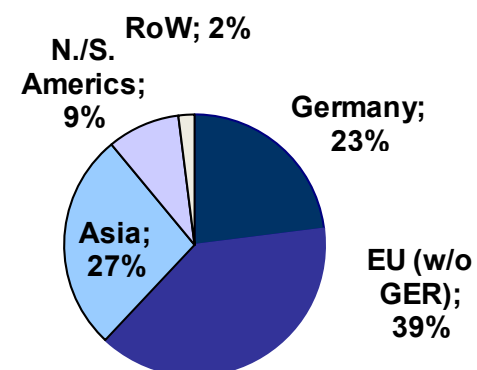
## European production and distribution sites



## Additional sites overseas:

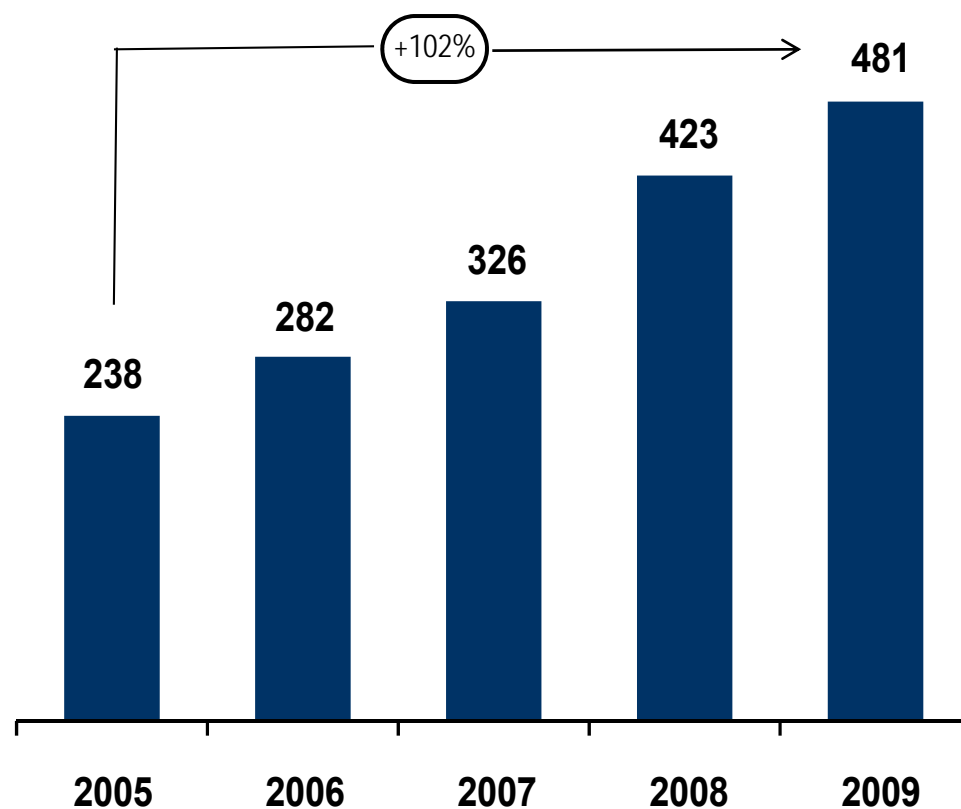
- USA: Florida (■ ○), Rockaway (○)
- Japan: Tokyo (○)
- Distribution also via 138 distributors in 76 countries

## Sales by region (Q1 2010):



## About Biotest – strong track record

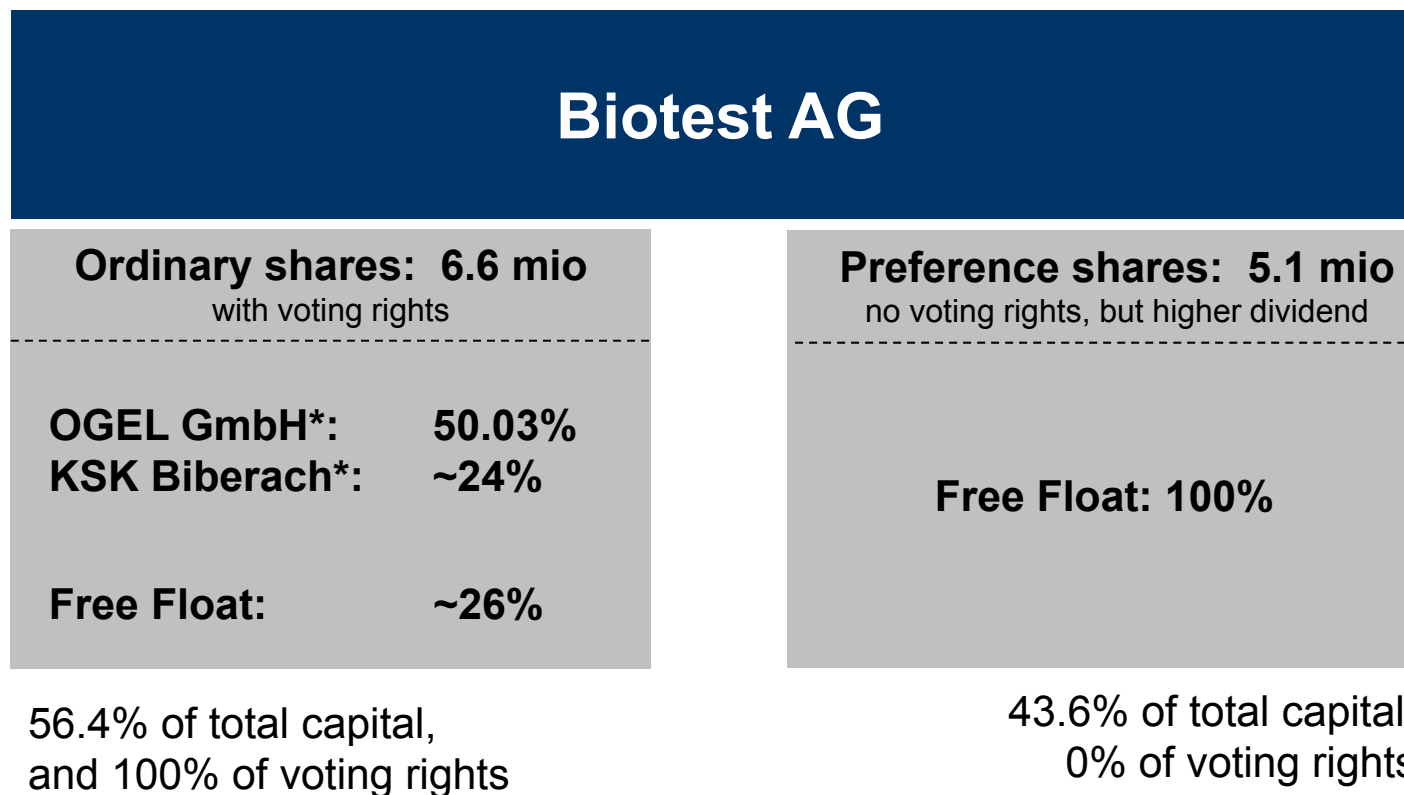
**Sales of Biotest Group (in € million)\***



- 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

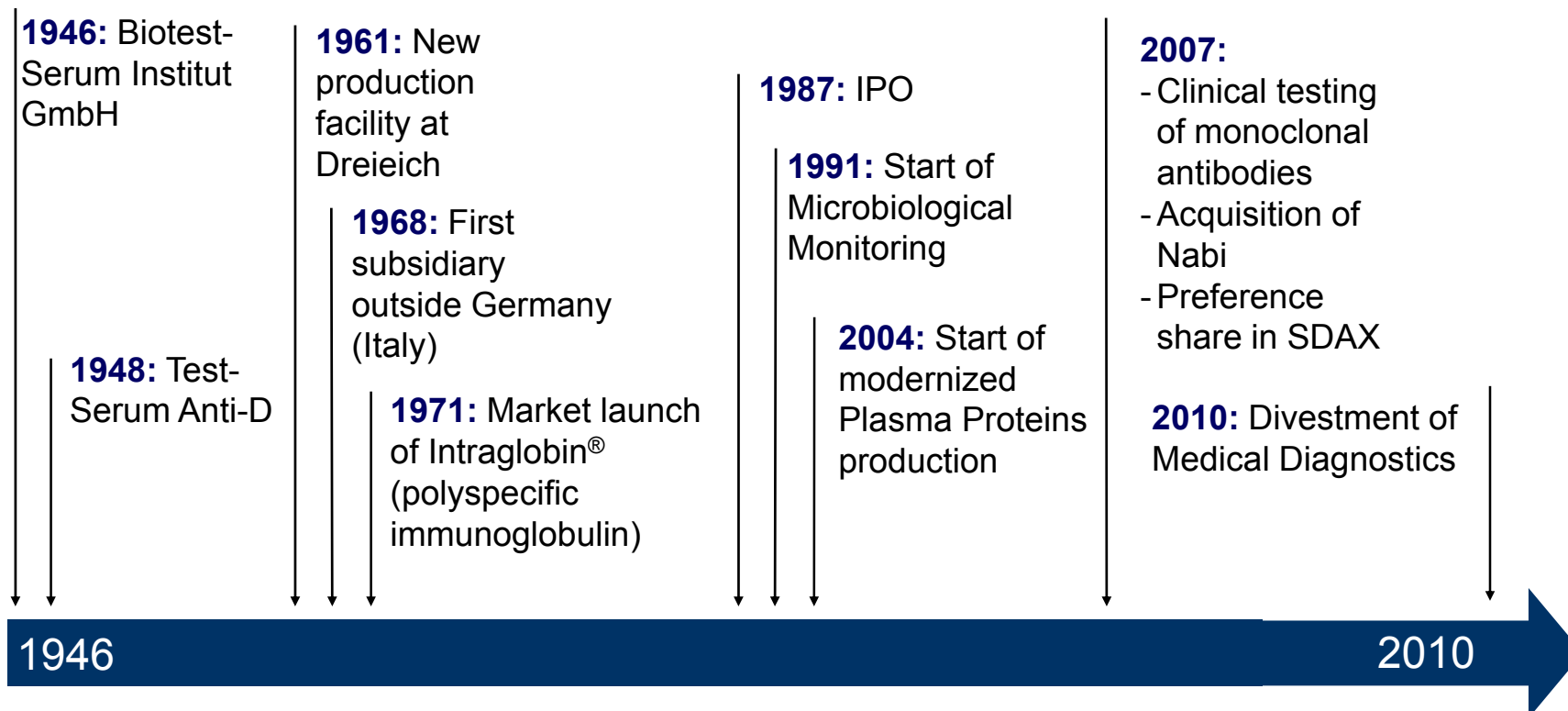
\*: Biotest Group incl. Discontinued Operations

## Shareholder structure



\* as of May 2010

## Biotest: History and milestones achieved







## **Financials Q1 2010**

## Q1 2010 – The Highlights

- Q1 Sales increase + 5.2% to € 115.0 million ; increase of R & D expenses by € 3.5 million (+34%), EBIT € 12.3 million (-18%)
- Earnings after tax (incl. Discont. Operations) € 22.6 million including the extraordinary income of the sale of Medical Diagnostics
- Plasma protein production in US: stability batches of Bivigam™ (IVIg) completed
- First sales of Zutectra®
- Biotherapeutics: clear indications of clinical efficacy of BT-061 in Psoriasis in a Phase I/IIa trial



## Medical Diagnostics sold to Bio-Rad

- Sale of transplantation and transfusion diagnostic activities
- Buyer: Bio-Rad Laboratories, Inc.
- Contract signed: 23 October 2009
- Closing on 6 January 2010
- Sale price: €45 million
- Preliminary sales proceeds: €18.1 million (EBIT)
- Preliminary EAT: € 15.1 million

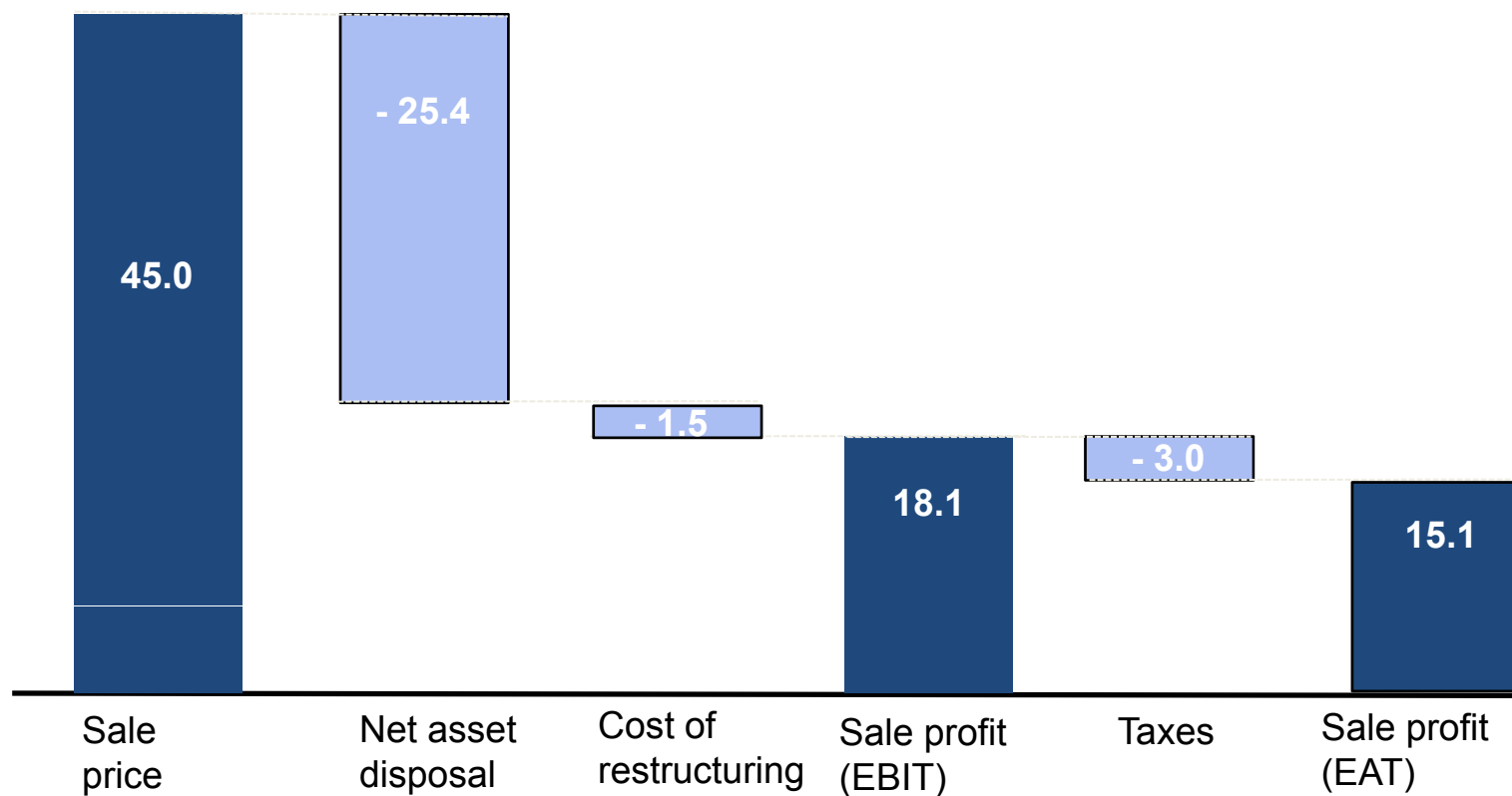


### Transaction comprised:

- Biotest Medical Diagnostics GmbH
- Biotest Diagnostics Corp.
- Activities of international affiliates

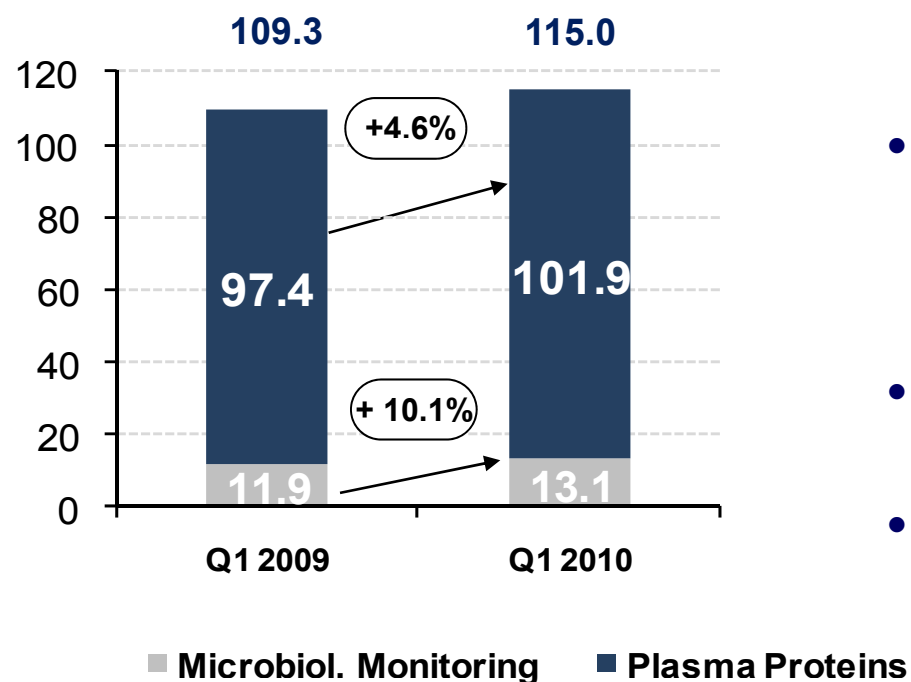
## Probable sale profit of €15.1 million after taxes (EAT)

in € million



## Sales growth despite difficult environment

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



- Sales in the first quarter of 2010 were up by 5.2% to 115.7 million vs. Q1 2009
- The Microbiological Monitoring segment grew at a rate of 10.1%, mainly through products manufactured by heipha
- The Group's Plasma Proteins business grew with 4.6%
- Leading position of Biotest products in several European countries

## Sales Plasma Proteins

Sales Plasma Proteins Q1 2009	€	97.4 m
Volume effect	+ €	12.2 m
Price effect	- €	7.7 m
<hr/>		
<b>Sales Plasma Proteins Q1 2010</b>	<b>€</b>	<b>101.9 m</b>

## EBIT Plasma Proteins Q1 2010 vs Q1 2009

EBIT Plasma Proteins Q1 2009	€	19.8 m
EBIT from increase volume	+ €	5.7 m
EBIT loss from reduced prices	- €	7.7 m
Net changes of other costs/expenses	+ €	0.2 m
<b>EBIT Plasma Proteins Q1 2010</b>	<b>€</b>	<b>18.0 m</b>

## Q1 2010: EBIT Biotest Group (€ million)

	Q1 2009	Q1 2010	Δ
Plasma Proteins	19.8	18.0	- 9 %
Biotherapeutics	- 3.7	- 5.1	- 38 %
Microbiological Monitoring	1.3	1.7	+ 31 %
Corporate	-2.4	- 2.3	+ 4 %
<b>Biotest Group</b>	<b>15.0</b>	<b>12.3</b>	<b>- 18 %</b>



## Lower EBIT due to higher R & D Expenses (€ million)

- EBIT Q1 2010** (actual)
- △ R & D Plasma Proteins
  - △ R & D Microbiology
  - △ R & D Biotherapeutics

**EBIT Q1 2010** (adjusted for increased R&D expenses)

	2010	△	to 2009
<b>EBIT Q1 2010</b> (actual)	<b>12.3</b>		<b>- 18 %</b>
△ R & D Plasma Proteins	2.0		
△ R & D Microbiology	0.1		
△ R & D Biotherapeutics	1.4		
<b>EBIT Q1 2010</b> (adjusted for increased R&D expenses)	<b>15.8</b>		<b>+ 5.3%</b>

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## Reasons for increased R & D expenses

### **Plasma Proteins:**

- BPC has produced IVIG consistency batches

### **Biotherapeutics:**

- 5 Clinical studies ongoing with BT-061, BT-062 and BT-063

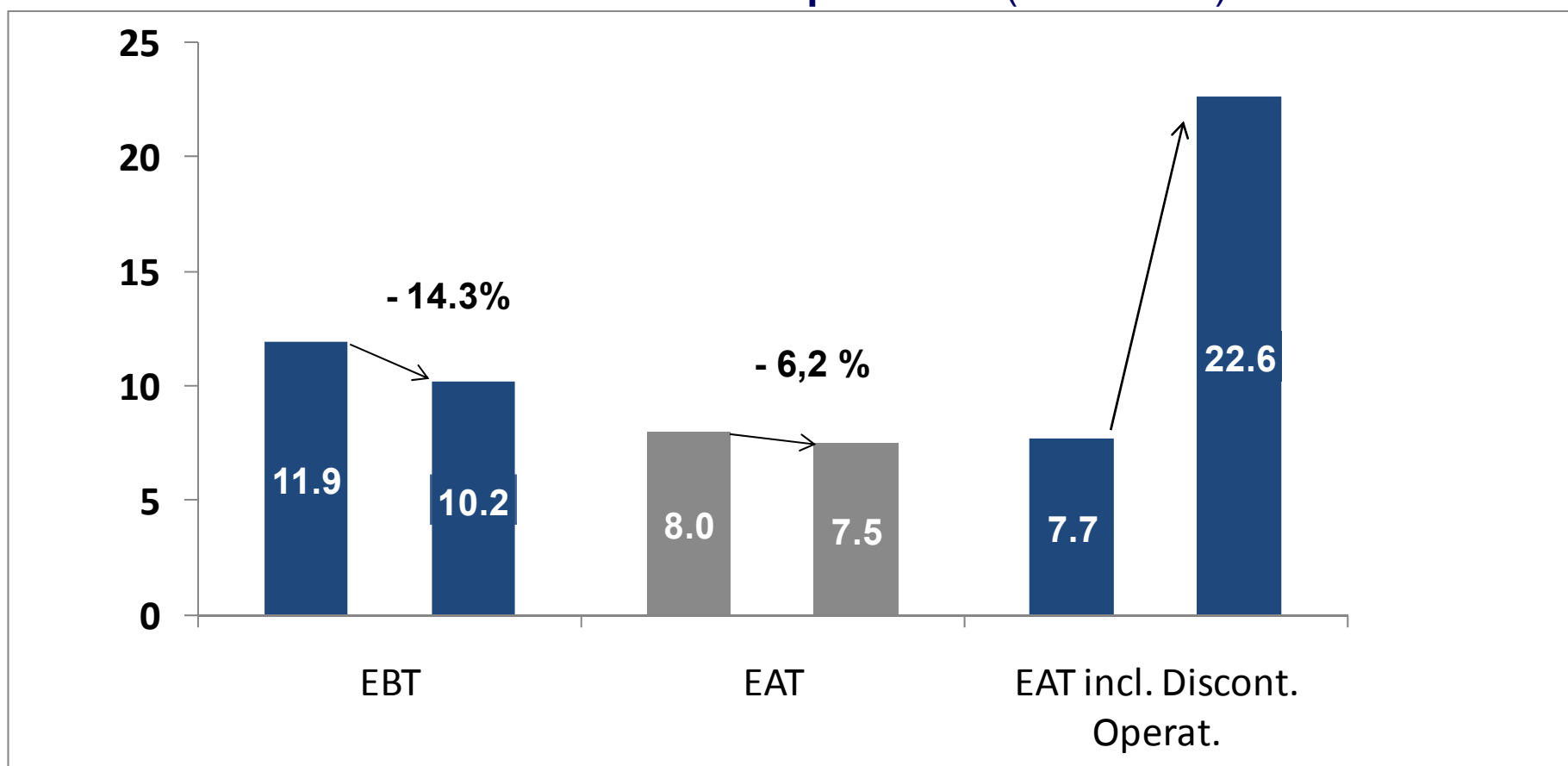
### **Microbiology:**

- Development of new pyro detect systems

## Decrease in profit in Q1 2010

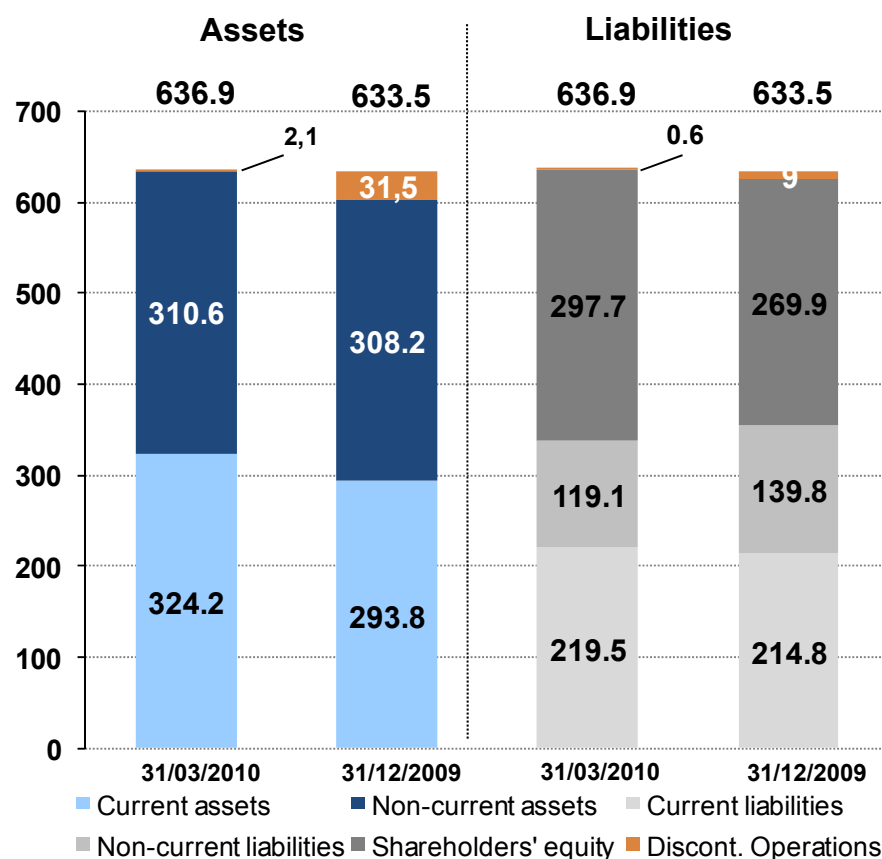
### Strong increase in Profit incl. Discont. Operations

**EBT and EAT and EAT incl. Disc. Operations (in € million)**



## Strong balance sheet

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



### Assets

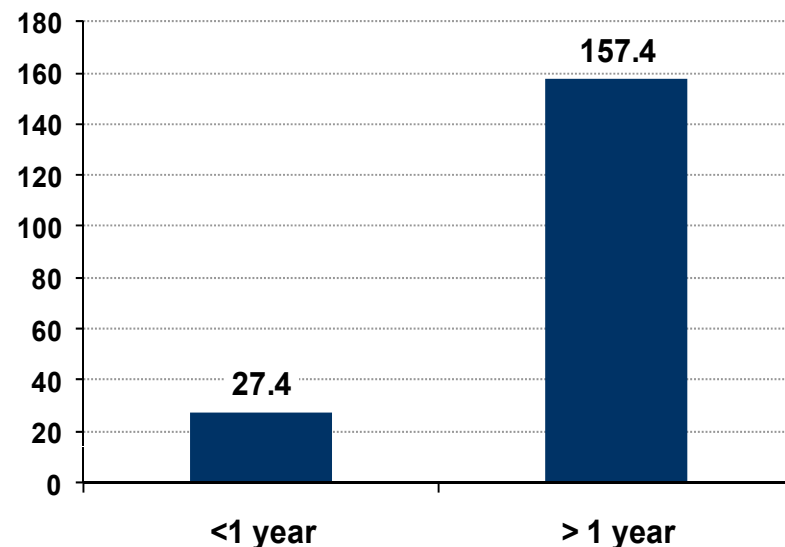
- Higher inventories driven by expected growth in 2010
- Higher Trade receivables due to higher sales volumes mainly in the plasma proteins segment

### Liabilities

- Increase in current financial liabilities, primarily corresponding to working capital development
- Equity ratio as of 31 Mar. 2010: 46.7% ( 31 Dec. 2009: 42.6%)

## Long term secure debt financing

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



- Total financial liabilities as of 31 March 2010: € 184.8 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



## **Outlook for 2010**

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## Outlook for 2010

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

- Products often life-saving treatments – long-term demand independent of cyclical effects
- Biotest's business is regionally diversified
- Growth opportunities in industrialised countries and emerging markets

### **But there are grounds for caution:**

- Difficult funding situation of public sector healthcare systems
- Higher credit and default risks in some markets

### **Our targets for 2010:**

- Low single-digit percentage sales growth
- EBIT at 2009 level

Prerequisite:



- No further price decreases
- More sales in high-margin markets



## Plasma Proteins



## Our strategy for Plasma Proteins: Expand position as specialist in innovative immunology and haematology

- Develop new preparations, approvals in further indications
- Open up new international markets
- Demand-based development of capacities



**Coagulation factors – Immunoglobulins – Hyperimmunoglobulins – Intensive and emergency medicine**

## Major progress in development of Plasma Proteins



**Zutectra<sup>®</sup>**

Europe-wide approval  
(centralised procedure)



**Hepatect<sup>®</sup>**

Approvals in seven  
other European countries  
(mutual recognition procedure)



**Albiomin<sup>®</sup>**

Approvals in six  
other European countries

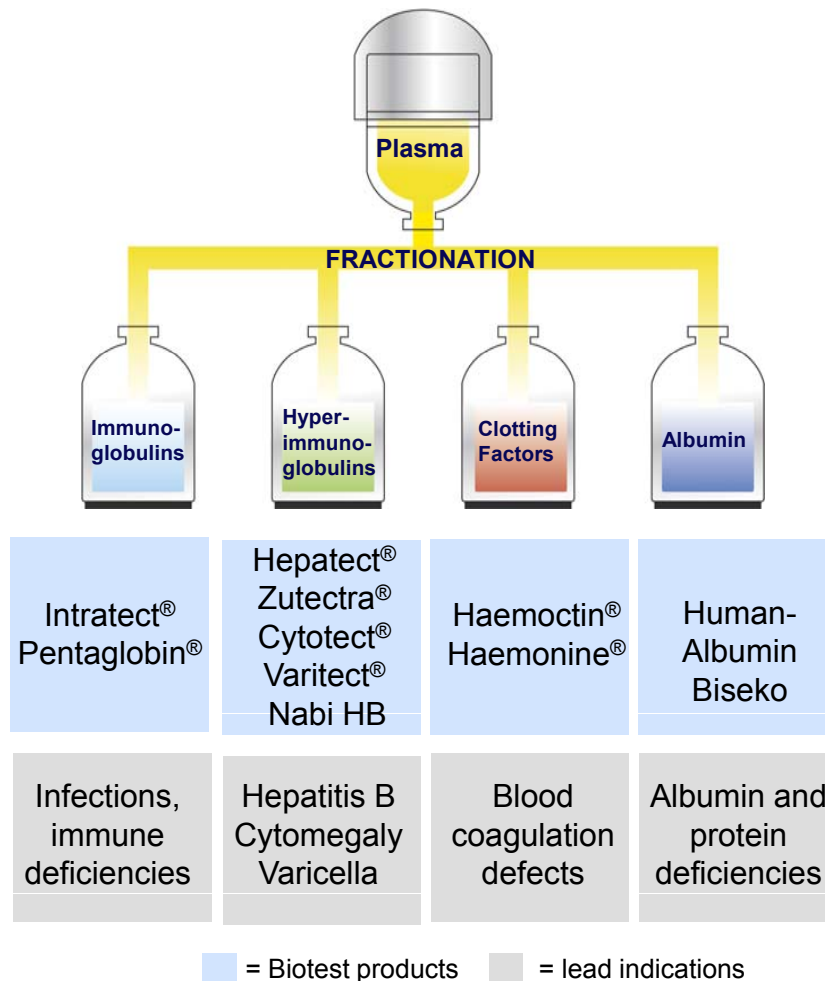


**Intratect<sup>®</sup>**

Use in fibromyalgia indication:  
trial completed –  
scientific publications finalised

# Plasma Proteins business at a glance

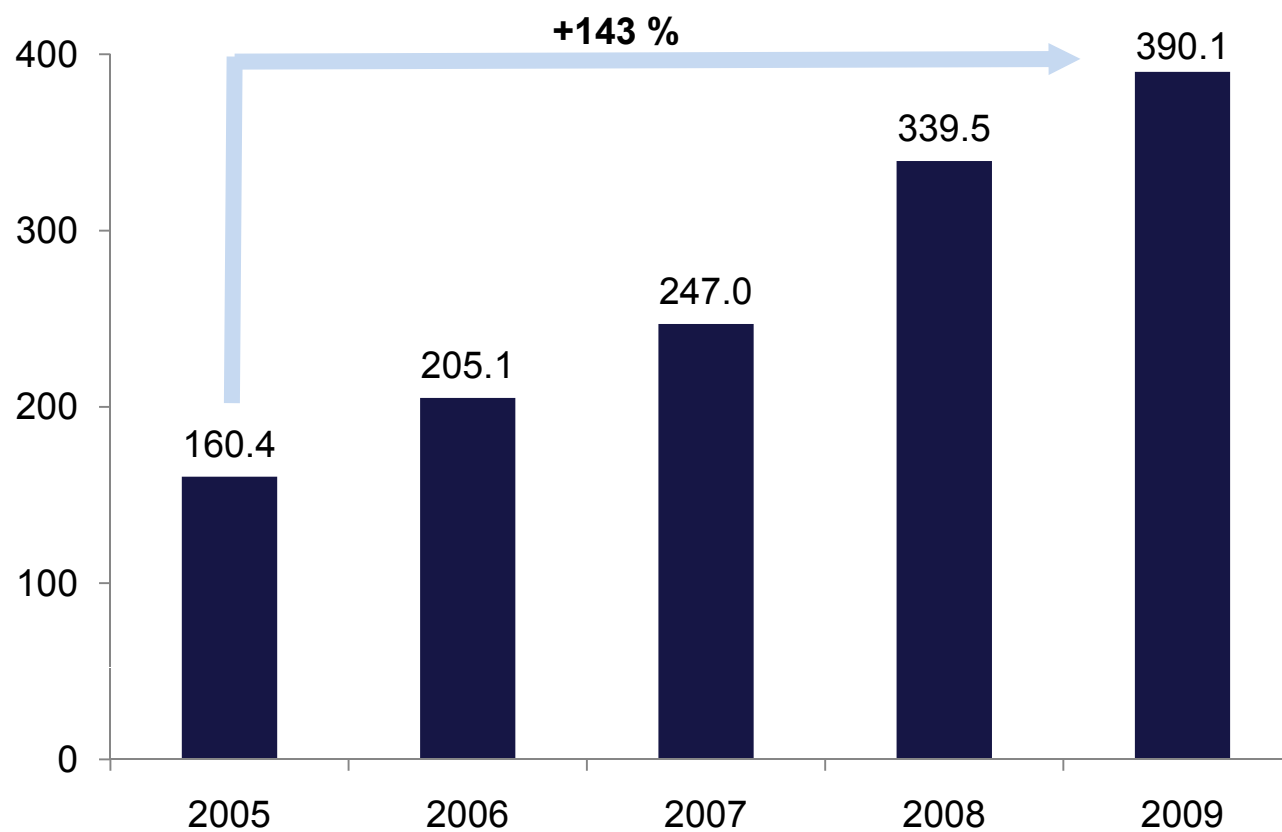
## Biotest Plasma Protein products



- Global market share: 3%
- Market share in relevant markets (GER, AUT, CH, GRE, UK): 14%
- Intratect® market share in GER, AUT, CH: > 13%, in UK: > 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

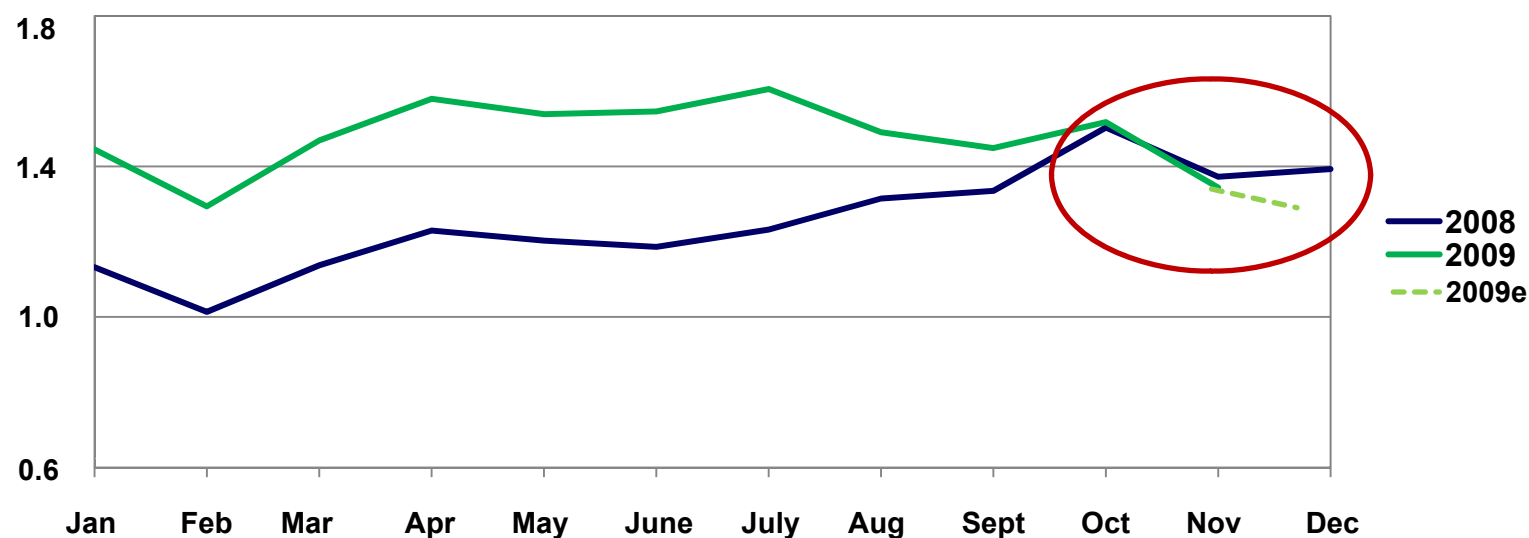
## Plasma Proteins: Impressive growth

Plasma Proteins: revenue (in € million)



## Development of plasma supply in the United States 2008/2009

Volume of US-sourced plasma (in million litres)

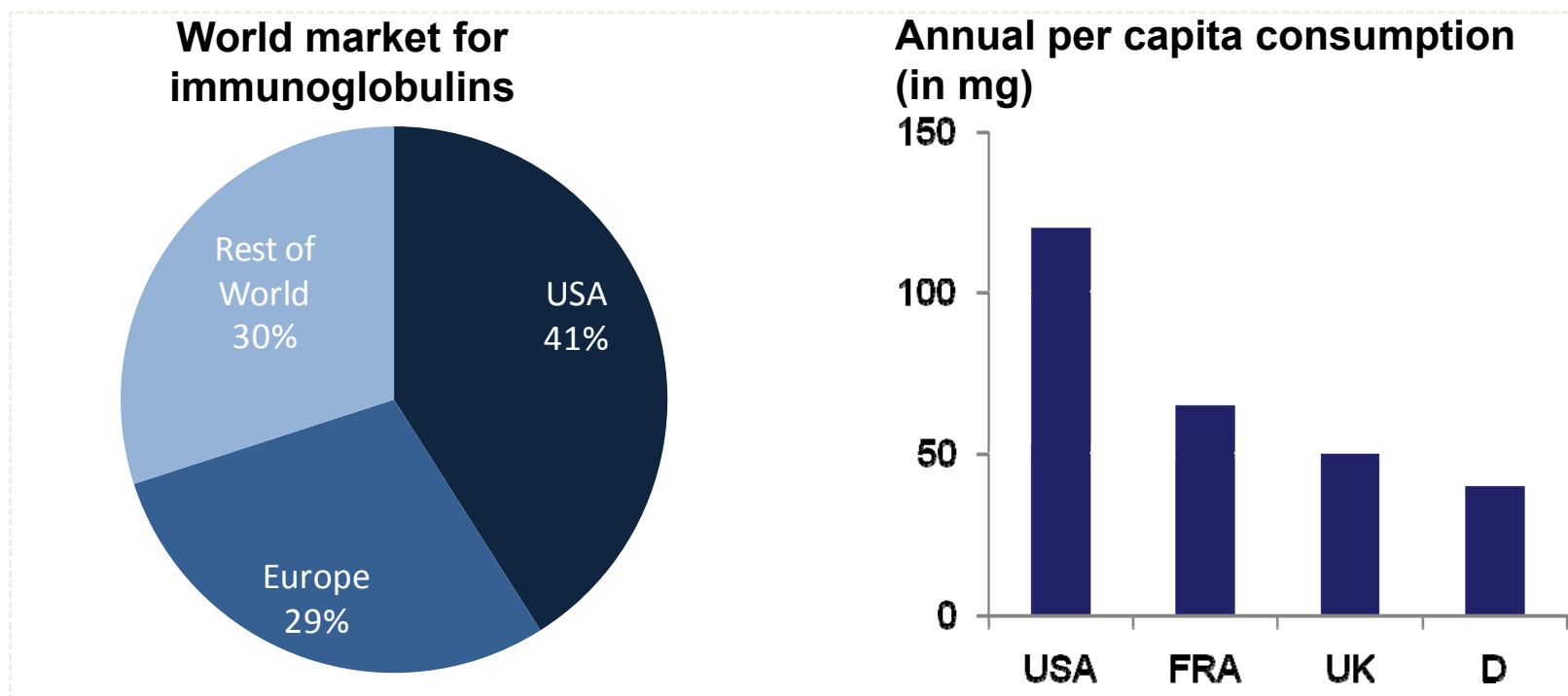


- Adjustment of US-sourced plasma volumes to changed market environment end of 2009
- Further decline in plasma volumes expected in 2010; market recovery from 2011
- Biotest recognised trend early and was able to adjust its plasma sourcing strategy accordingly

Source: PPTA

## 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 10 BPC-owned plasma collection centres



## Bivigam™ (IVIg) development nears successful completion

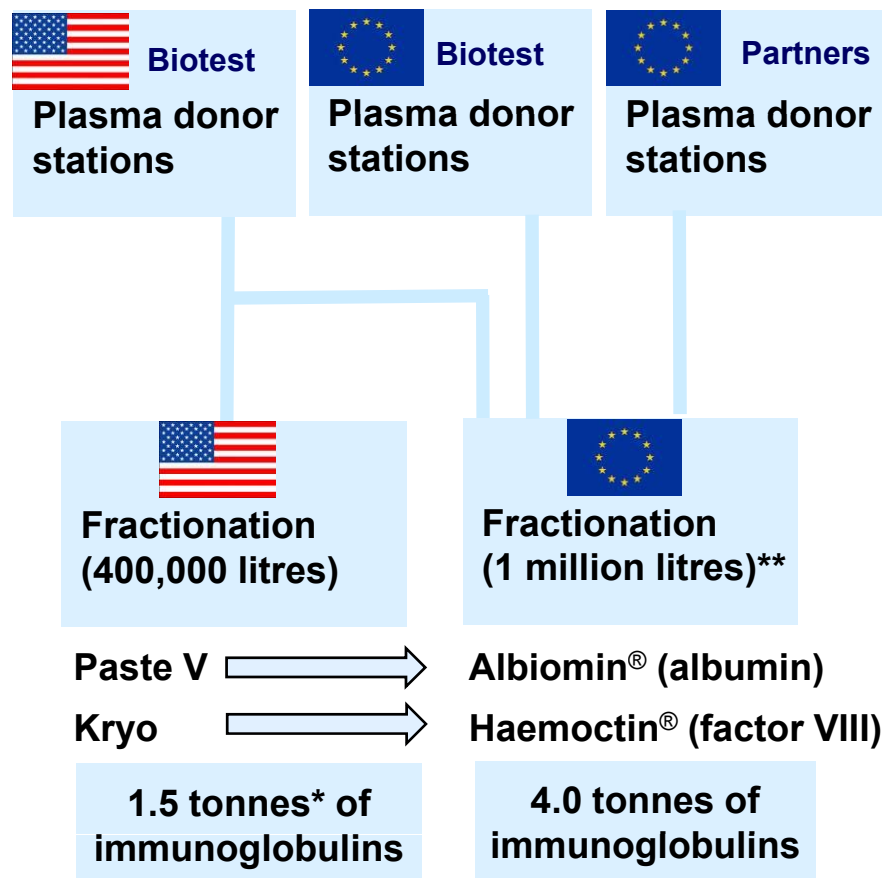
**Polyspecific immunoglobulin with a wide indication range (incl. antibody deficiency and autoimmune diseases)**



- 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, approval likely in Q3 2011
- Sales potential after approval: around \$100 million per annum



## Plasma Proteins – Efficient production network



- 20 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

## Civacir™: Attractive project is put on course

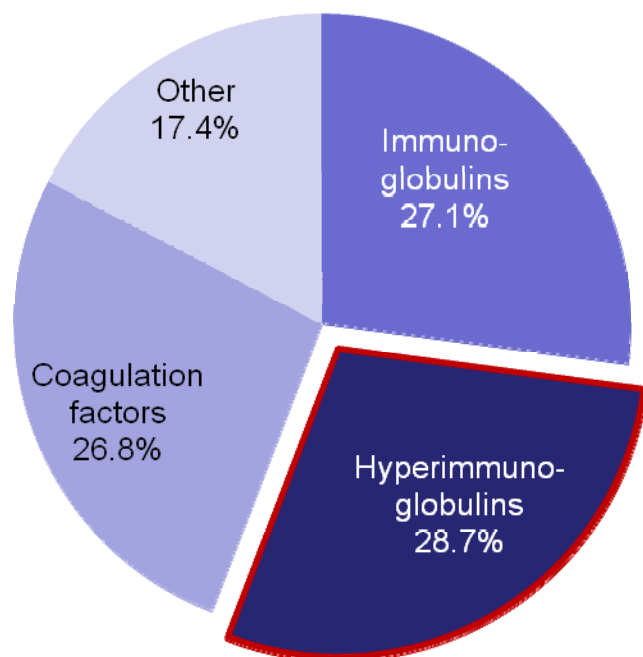
**Hepatitis C  
immunoglobulin for  
reinfection prophylaxis  
after liver transplantation  
due to hepatitis C**



- 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:**

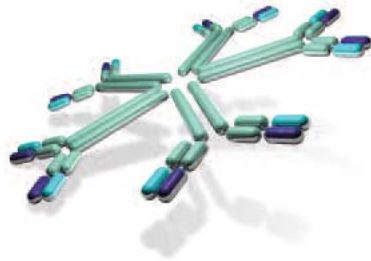
- Stable prices
- High market entry barriers
- Biotest is totally self-sufficient in hyperimmune plasma procurement



\* 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 end of 2010
- Indication spectrum comparable to that of Pentaglobin®
- 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 confirm positive findings of pilot study
- 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<sup>®</sup>: Europe-wide approval of first hepatitis B immunoglobulin with subcutaneous administration

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



- Europe-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<sup>®</sup> CP and Zutectra<sup>®</sup> are an ideal combination



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



### **Hepatect<sup>®</sup> CP:**

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

### **Zutectra<sup>®</sup>:**

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

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

### **Hepatitis B immunoglobulin in neonates**



#### **Phase III trial**

- Status: Recruitment ongoing (5 sites have recruited 30 patients)
- End of Study planned for Q3 2010
- Marketing Approval: aiming for marketing approval in Germany first, international marketing authorisations to follow



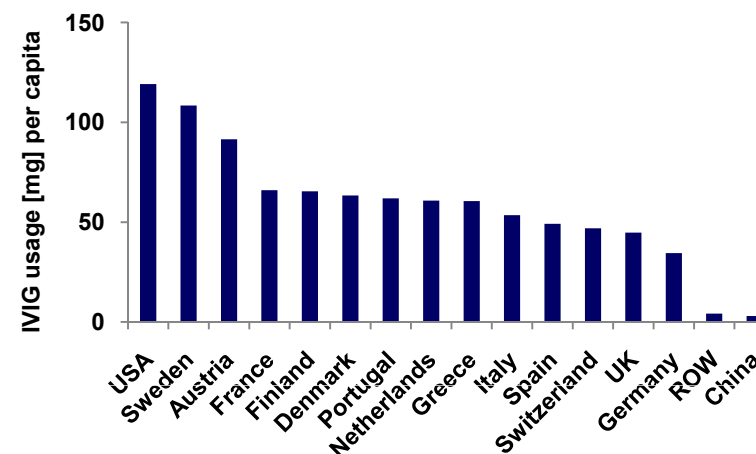
## Further growth of immunoglobulin market expected

### 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® – 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

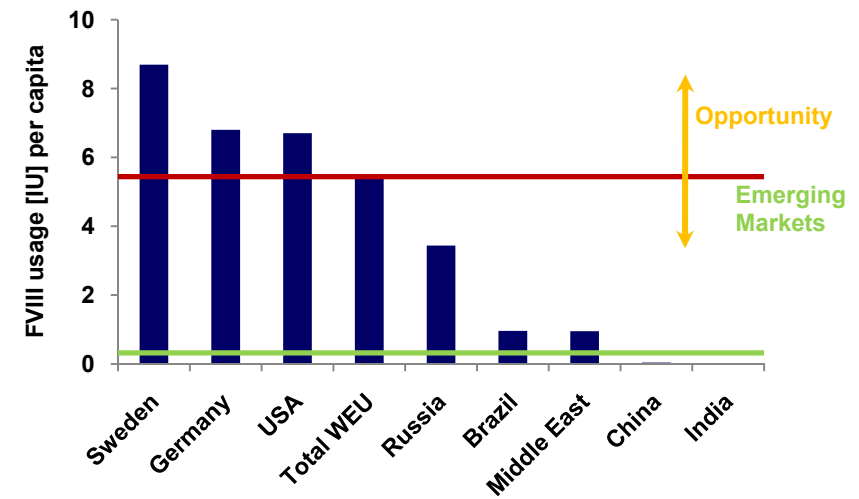
## Opportunities in Haemophilia market

### 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



## Biotest R&D activity in Plasma Proteins

- R&D expenses in 2009 in the Plasma Protein segment: € 25.7 million; in Q1 2010: € 8.4 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



## Investment in capacity at Biotest with a long-term horizon

- World demand continues to increase
- Biotest will continue to grow with the plasma segment
- Opening up the attractive US market by means of own production
- Bivigam™ (IVIG) approval expected in Q3 2011

 Additional market potential of \$100 million



## Interim conclusion: Biotest is well positioned in plasma proteins

- US market entry with Bivigam™ (IVIg) in 2011
- Product range expanded systematically
- Attractive pipeline
- Increased efficiency due to production network

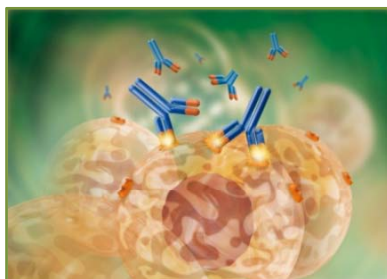




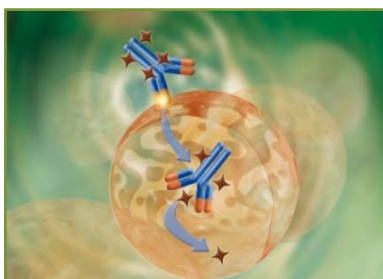
## **Biotherapeutics**



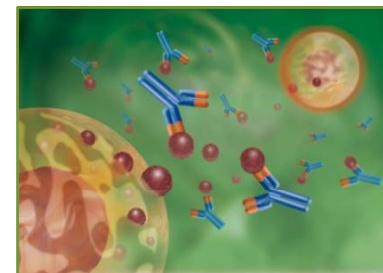
## Biotherapeutics: Attractive development projects



**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

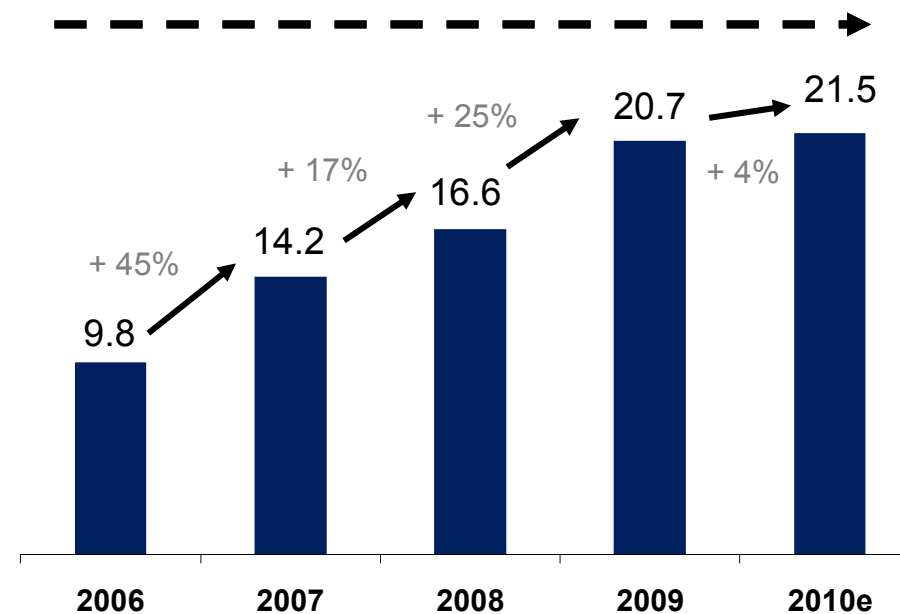
- High medical need
- Rapidly growing markets
- Blockbuster potential

### Lead indications

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

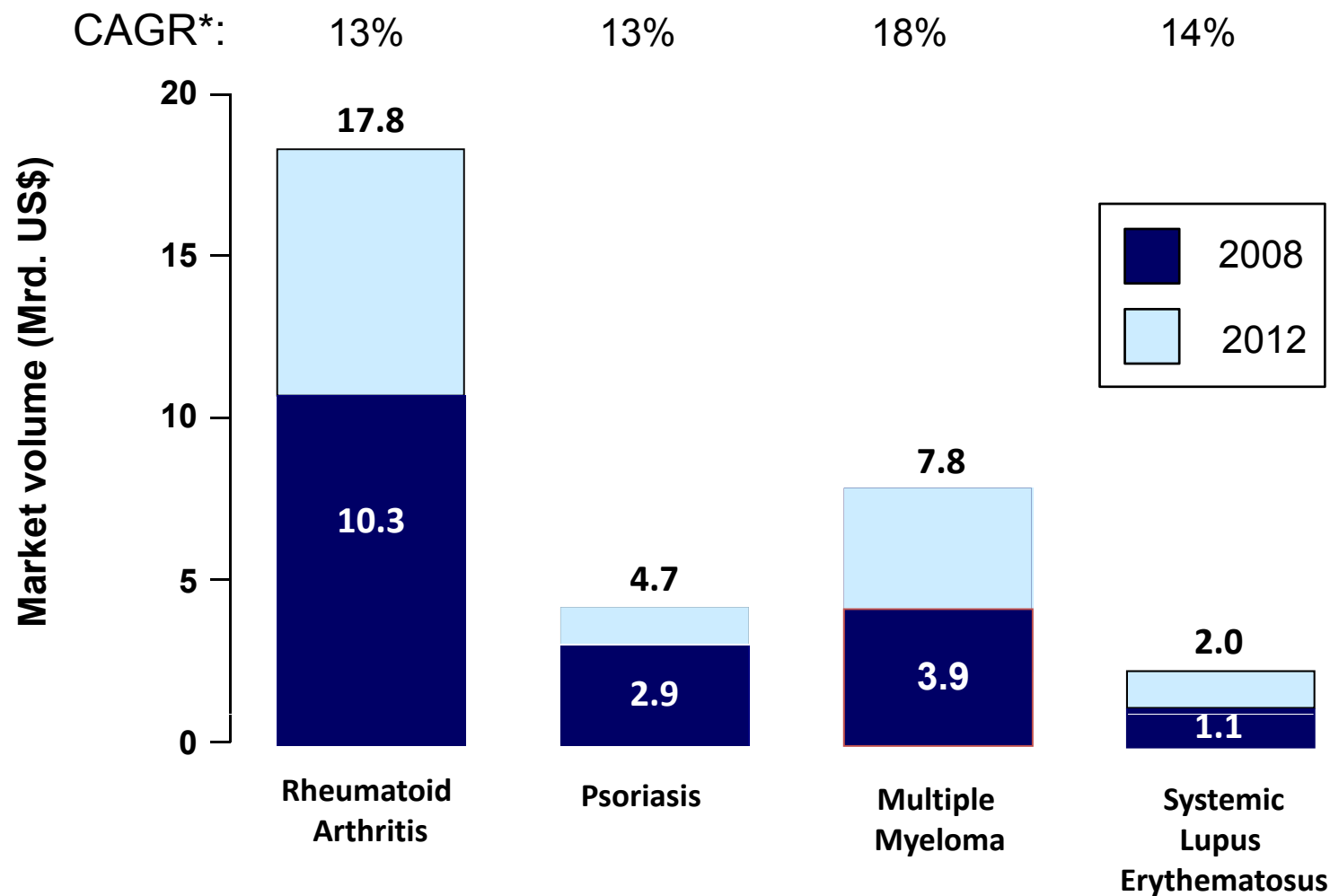
### R&D expense – Biotherapeutics (in € million)

Cap on Biotherapeutics R&D budget



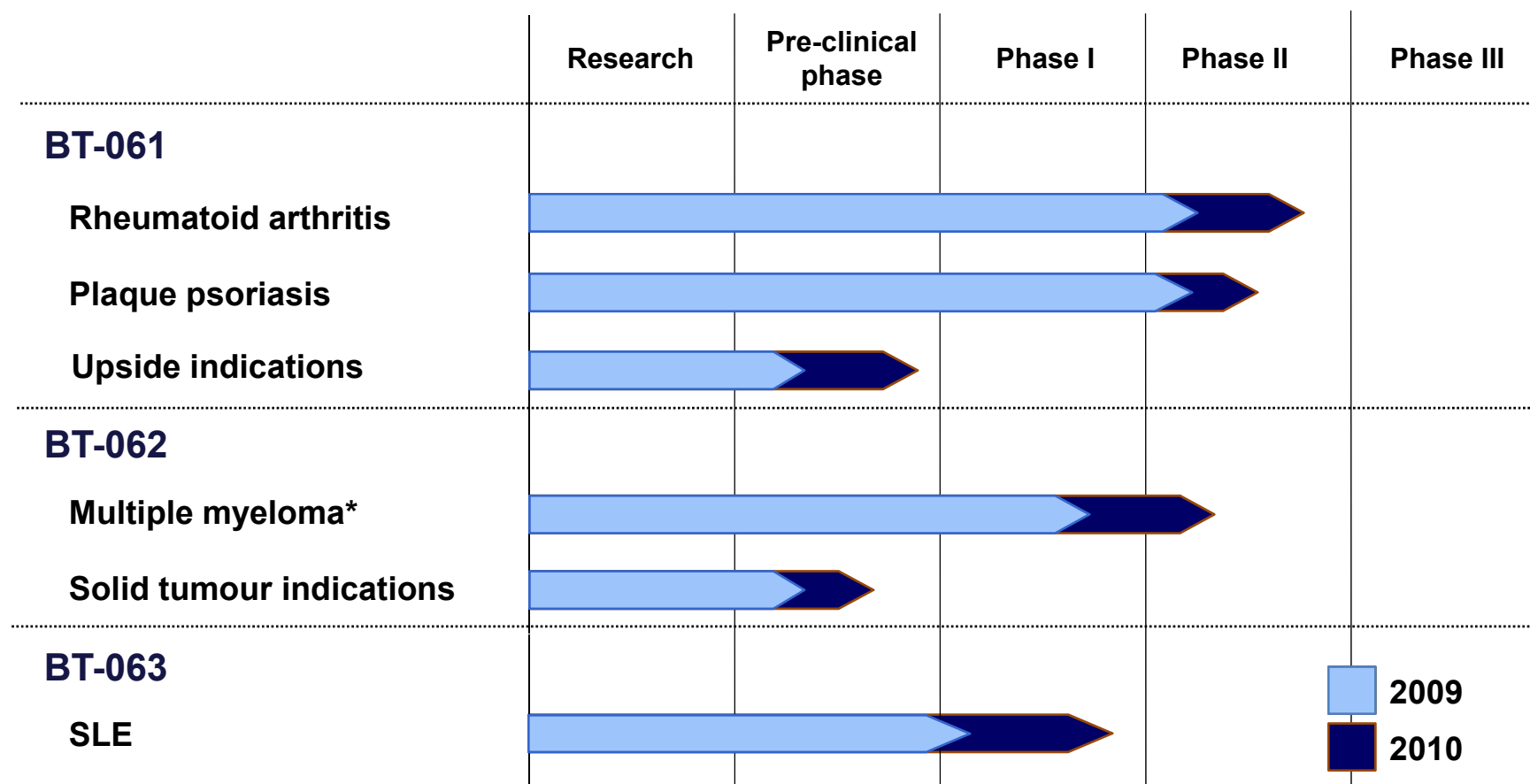


## Biotherapeutics: Continuously growing market potential



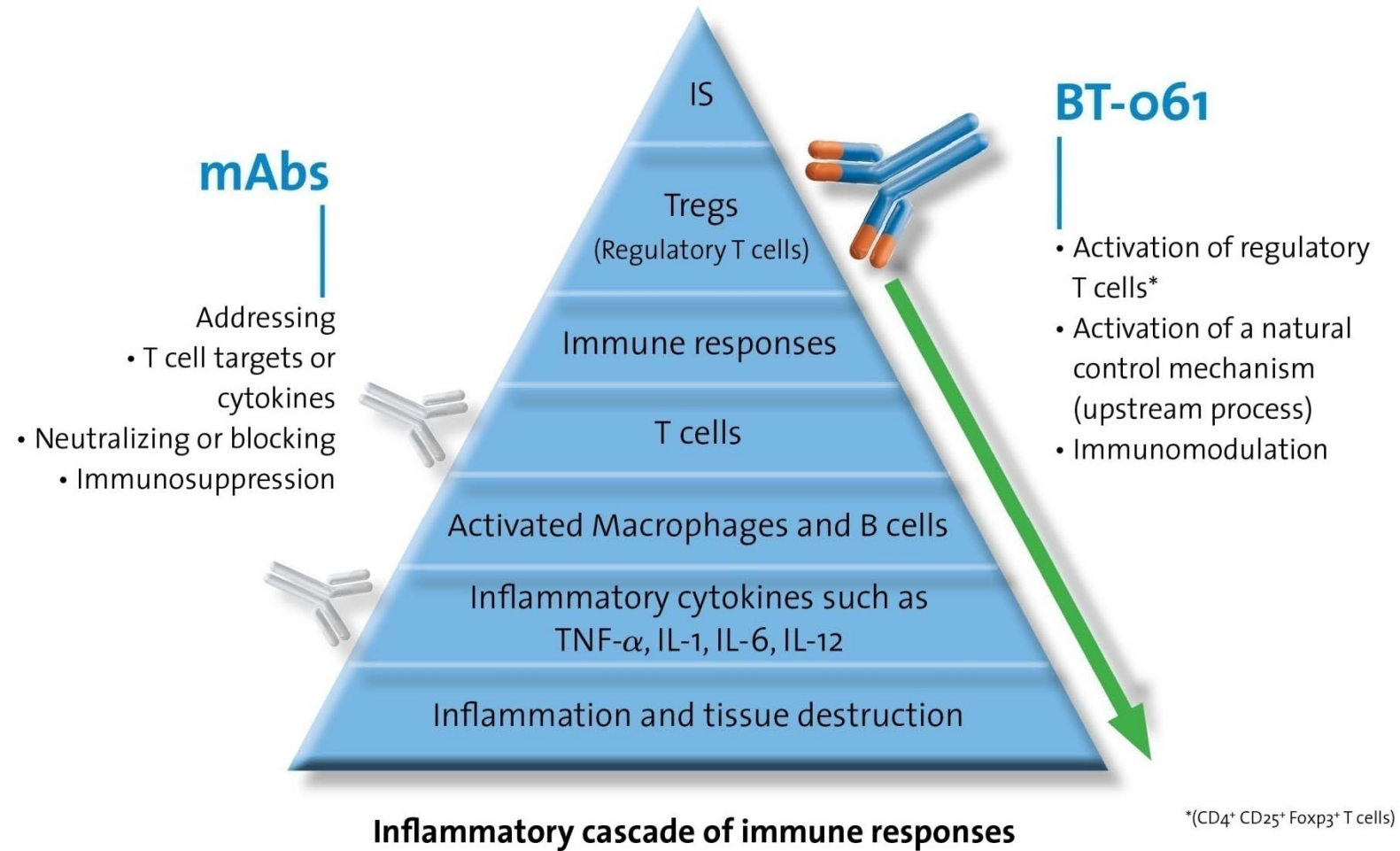
Quelle: Datamonitor, Decision Resources, Biotest  
\*CAGR: Compound Annual Growth Rate

## Biotherapeutics: Significant project progress in financial year 2009



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

## 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**

# Clinical development BT-061

## Overview

<b>Study no.</b>	<b>Indication</b>	<b>Design</b>	<b>Subjects/ Patients Planned</b>	<b>Status</b>
961	Healthy volunteers	single dose iv; and sc up to 180 mg	57	Study completed
967	Phase I/IIa:Psoriasis	single dose, placebo controlled iv and sc	55	Study completed
973	Phase II: Psoriasis	multiple dose, placebo controlled	48	Recruitment Started (Q1- 2010)
962	Phase IIa: Rheumatoid Arthritis	Multiple dose, Placebo controlled	96	Recruitment completed
971	Phase II: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	110	Part I (iv) finalized Part II (sc) ongoing
979	Phase IIb: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	~ 200	Submission: Q2-2010

## BT-061: Results of clinical trials deliver proof of concept for rheumatoid arthritis



Phase IIa trial:  
BT-061  
vs. placebo

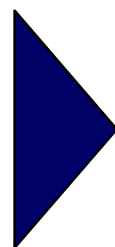
Phase II trial:  
BT-061 + MTX\*  
vs. MTX\* alone

Initial results\*:

- Clear improvement in symptoms (ACR 20–70)
- Generally good tolerability



Phase IIb trial (mid-Q2 2010)



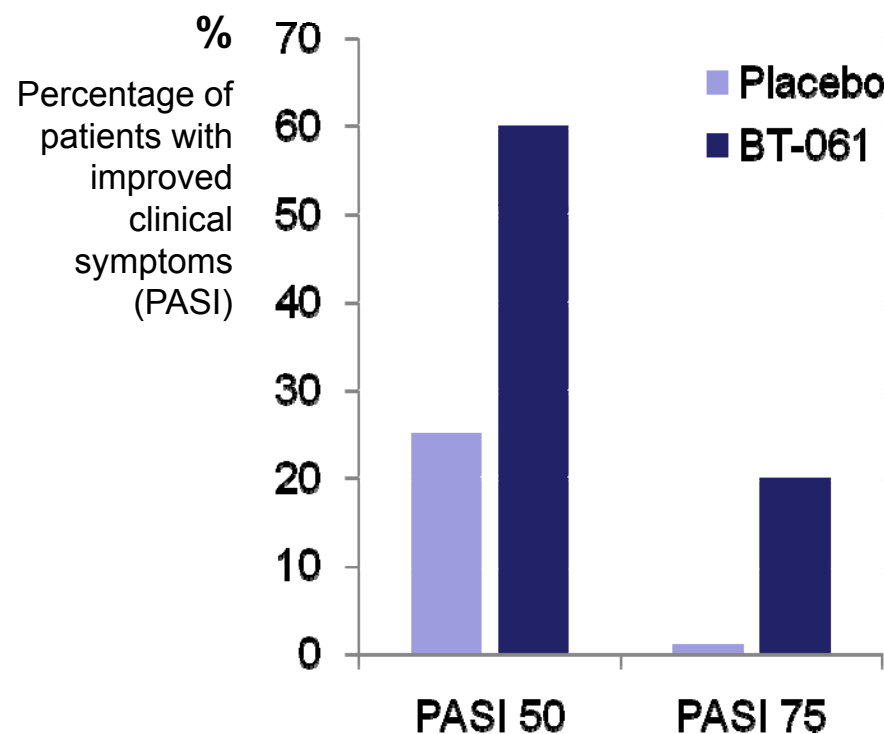
- BT-061 + MTX\*\* vs. MTX\*\* alone
- About 200 patients
- Basis for phase III trial (in 2012 at the earliest)

\* Interim analyses / final results in Q3/Q4 2010

\*\* MTX = methotrexate, a drug used in primary rheumatoid arthritis therapy

## BT-061: Proven efficacy in treating psoriasis\*

PASI\*\* score after single administration  
(25 mg, subcutaneously)

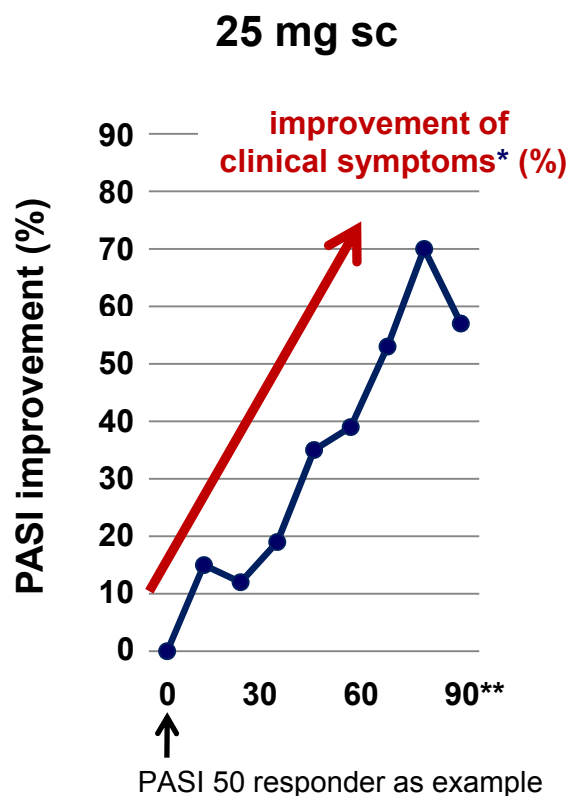


- Substantial improvement in symptoms (PASI\*\* score) after single administration
- Best effect when administered subcutaneously
- Proof of concept

\* Final result of trial 967

\*\* **PASI** = Psoriasis Area and Severity Index, a measurement of the extent and severity of psoriasis condition

## Psoriasis Phase I/IIa Study (No. 967) Results: Improvement of clinical symptoms - a characteristic time course



- Highest response rate (improvement of clinical symptoms) in 25 mg sc group
- Duration of clinical benefit up to 90 days after single application of BT- 061
- Good safety and tolerability

↑ single injection

\* PASI (Psoriasis Area and Severity Index) measures the average redness, thickness and scaliness of the lesions, weighted by the area of involvement.

\*\* days past treatment

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## **BT-061: Summary clinical results Psoriasis**

### **Psoriasis Phase I/IIa (single dose administration)**

- Highest response rates by subcutaneous administration (25 mg)
- Duration of clinical benefit up to 90 days
- Proof-of-concept achieved in Psoriasis
- Good safety and tolerability

➤ **Improvement of clinical symptoms and Proof-of concept in Phase I/IIa**



### **Psoriasis Phase II (multiple dose administration)**

- Recruitment has started
- Goals:
  - Further improvement of efficacy by repeated dosing (8 weeks)
  - Finalization of dose finding/ frequency of administration
  - Focus on subcutaneous administration



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## **BT-061: Summary clinical results Rheumatoid Arthritis**

### **Rheumatoid Arthritis Phase Ia and Phase II:**

Phase Ia:        Monotherapy: up to 70% improvement (ACR70) after 6 weeks of treatment (50 mg sc and 2 mg iv)

Phase II:        Combination with methotrexate (MTX): up to 70% improvement (ACR70) after 8 weeks of treatment (2 mg iv + MTX)

- Proof-of concept achieved in Rheumatoid Arthritis
- Good safety and tolerability



### **Rheumatoid Arthritis Phase IIb (submission Q2/2010):**

- ~ 200 patients
- Combination with MTX
- 12 weeks treatment
- Subcutaneous administration
- Goals:
  - Generate statistical basis for phase III
  - Determine final dose schedule

## 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
- Gradual further establishment of teams in Drug Development



## BT-061 partnership

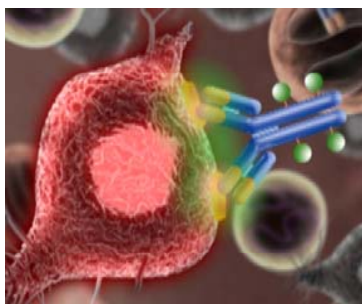


### **Biotest strategy:**

Cooperation with partner  
from clinical phase III

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

## BT-062 : Clinical efficacy in Multiple Myeloma



- BT-062: specific and highly effective immunotoxin: toxin part mediates high efficacy – antibody part mediates high specificity
- Phase I Study: Repeated single dose, dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
  - Indications of efficacy already with low dosages:
    - **Disease progression halted in some patients for several months**
    - **Clinical benefit for 53% of patients lasting 6 weeks or longer**
    - **Maximum treatment dose defined and cohort extension ongoing**
  - Good safety and tolerability

## BT-062: Single-Dose Study 969 in Multiple Myeloma

### First Efficacy Data

Number of patients	Total	Percentage	Objective response	Clinical benefit (%)
treated with BT-062*	25			
efficacy data available	<b>17</b>	<b>100%</b>		
- disease progression	1	6%		
- no disease progression > 3 weeks	7	41%		
- stable disease $\geq$ 6 weeks	7	41%		<b>53%</b>
- minor response	1	6%	12%	
- partial response	1	6%		

➤ **BT-062 shows anti-tumor activity already in repeated single dose schedule**

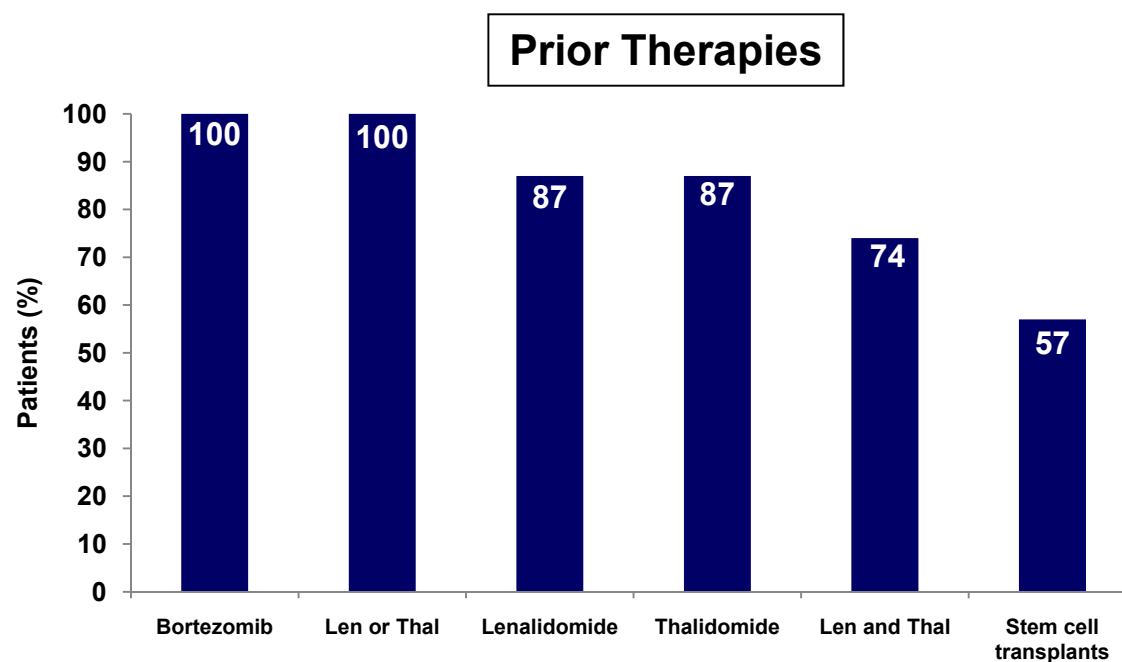
➤ **Further patients to be enrolled in MTD\*\* cohort up to a total of 15**

\*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 75% have been pre-treated with both Lenalidomide and Thalidomide
- More than 50% have undergone an autologous stem cell transplantation (ASCT)

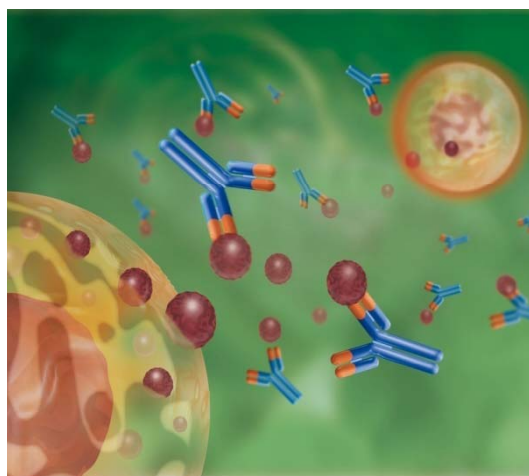
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## **BT-062 : Next steps initiated**

- Based on positive results from Phase I study, study documents for next clinical phase I/IIa have been submitted
- Phase I/IIa Study: Multi dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
  - Study approved by FDA (IND\*-submission)
  - Trial initiation expected in Q2 2010
- Goal: Further definition of dose schedule

\*IND = Investigational New Drug

## BT-063: Phase I study on track



### BT-063 lead indication

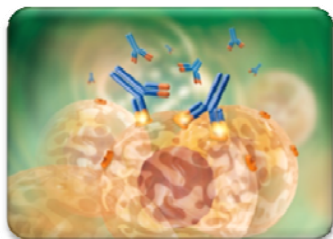
- Systemic Lupus Erythematosus (SLE)
- High medical need: SLE incurable today, no new approval since ~ 40 years
- 2.5 million patients are suffering from SLE worldwide today

### Status Phase I

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

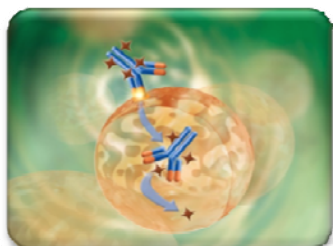


## Outlook Biotherapeutics: Next Steps in Clinical Development Initiated



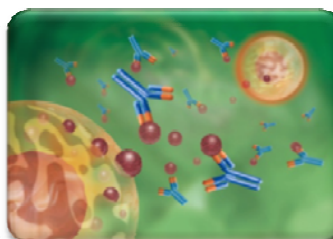
### **BT-061:**

- First encouraging clinical data from both lead indications
- Phase II trial in Psoriasis started
- Phase IIb in RA in preparation
- 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 start expected Q2 2010



### **BT-063:**

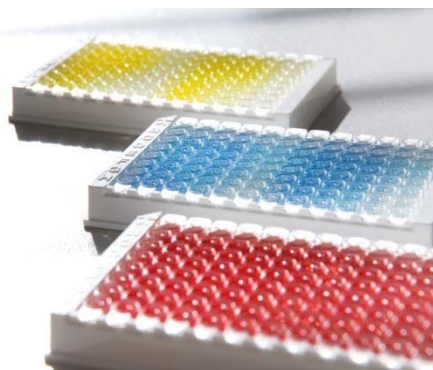
- Phase I study approved in Sept. 2009
- Treatment at 7th dose level completed (02 2010)



## Microbiological Monitoring

## Segment continues to be successful

- Q1 2010 revenue growth of 10.1%, 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!**



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## Contact and Financial Calendar 2010

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### Financial Calendar 2010

**May 06, 2010**      **Annual General Meeting**

**May 11, 2010**      **Q1 Report 2010**

**Aug 12, 2010**      **Q2 Report 2010**

**Nov 08, 2010**      **Analyst's Conference**

**Nov 08, 2010**      **Q3 Report 2010**

# 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

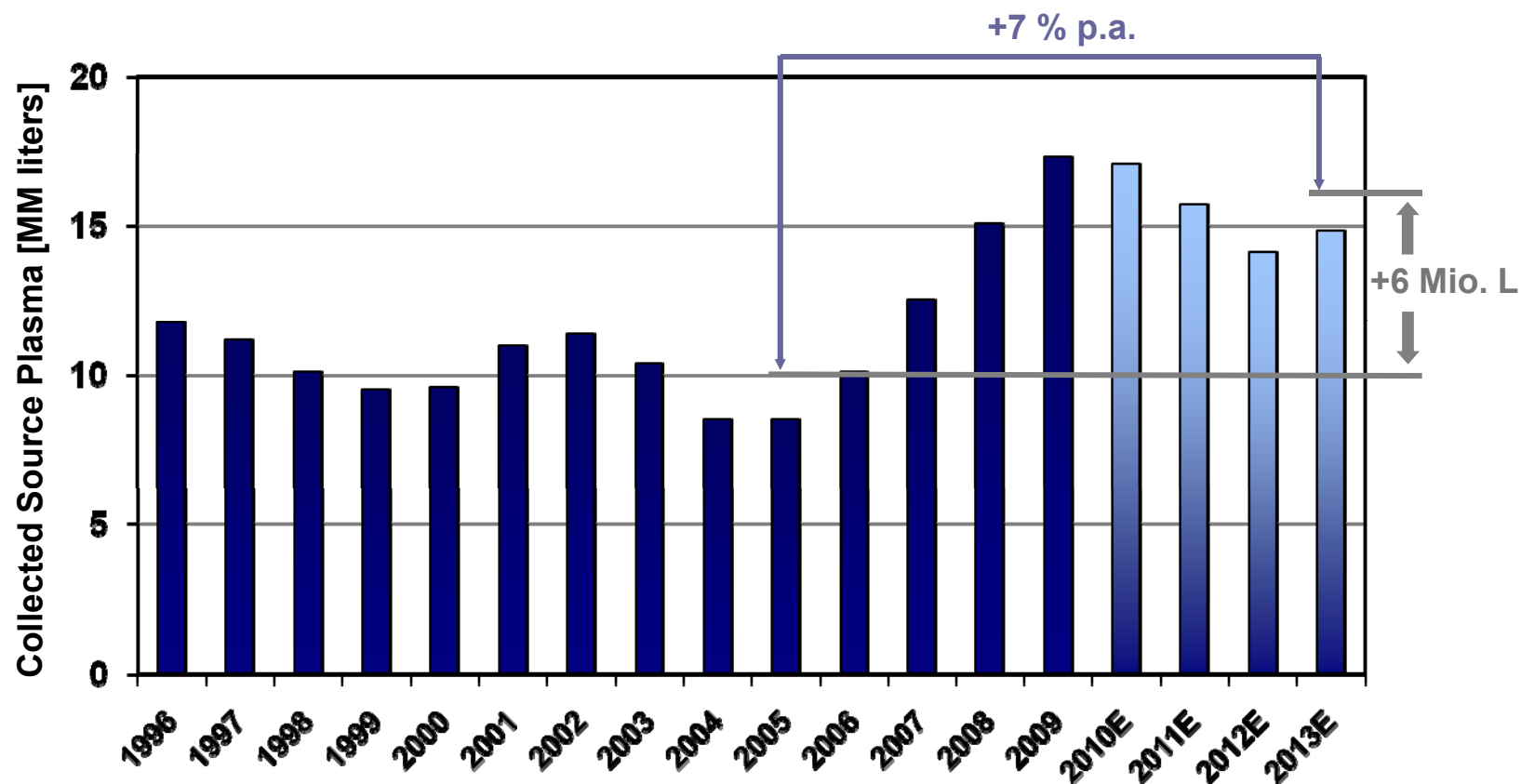
From Intermediates to Final Bulk

**Virus inactivation**



## 4. Filling and Packaging

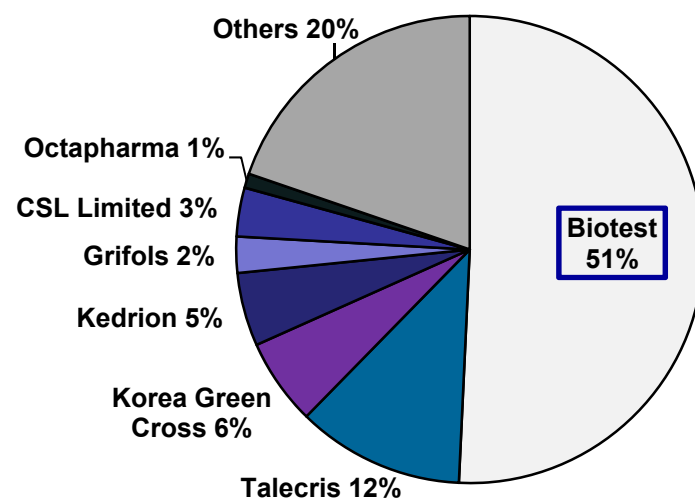
## US source plasma collection forecast, 1996 -2013



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

## 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<sup>®</sup> in Europe and Nabi HB<sup>™</sup> in USA
- Zutectra<sup>®</sup> enhances Biotest competence and engagement in the HBIG market
- Zutectra<sup>®</sup> will strengthen and defend current strong market position by preventing possible switch to i.m. and future i.v. drugs
- Further Launches for Zutectra<sup>®</sup> and Nabi HB<sup>™</sup> already scheduled in attractive world wide markets