

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



## **Management Presentation**

**Biotest AG**  
**August 2009**

## Biotest at a glance

### Figures H1 2009:

<b>Sales</b>	€ 239.2 m	(+13.4%)
Thereof Plasma Proteins	€ 194.3 m	(+14.6%)
<b>EBIT</b>	€ 29.4 m	(+6.5%)

### Business sectors

**Pharmaceuticals**

**Diagnostics**

### Divisions

#### Plasma Proteins

- Immunoglobulins
- Hyper-immunoglobulins
- Clotting factors
- Albumin

#### Biotherapeutics

- Monoclonal antibodies

#### Medical Diagnostics

- Transfusion
- Transplantation
- Infectious disease

#### Microbiological Monitoring

- Hygiene monitoring

## Biotest – key figures

- Headquarters in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 10 countries worldwide
- Employees (FTE)\*: 2,099  
    Thereof 60% 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



Headquarters, Dreieich

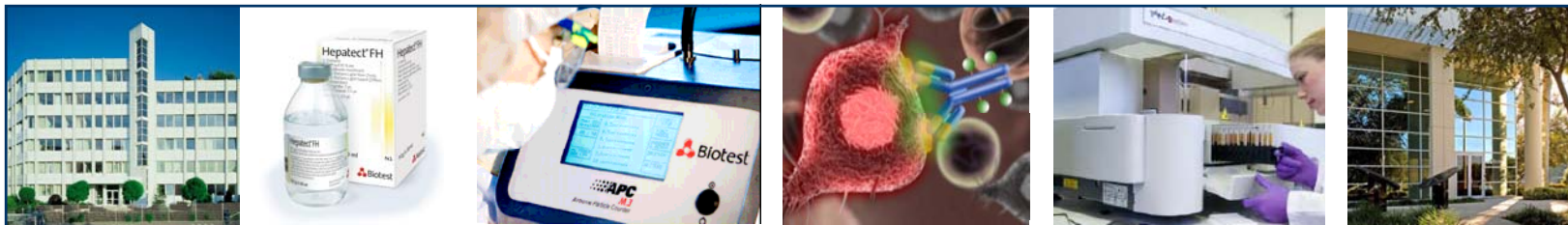
\*: as of 30 June 2009

## Biotest strategy

- Internationalisation
- Focus on markets with special needs
- Research and development

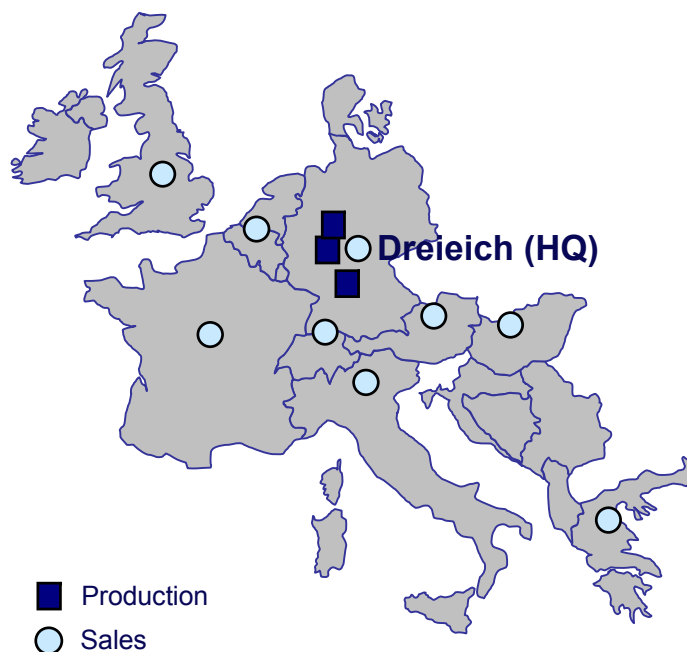


Sustained profitable growth



## Biotest Group overview

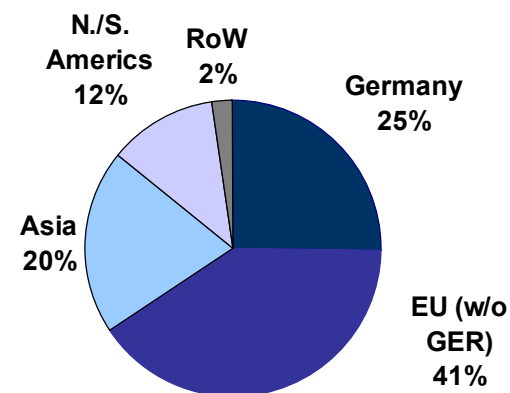
### European production and distribution sites



### Additional sites overseas:

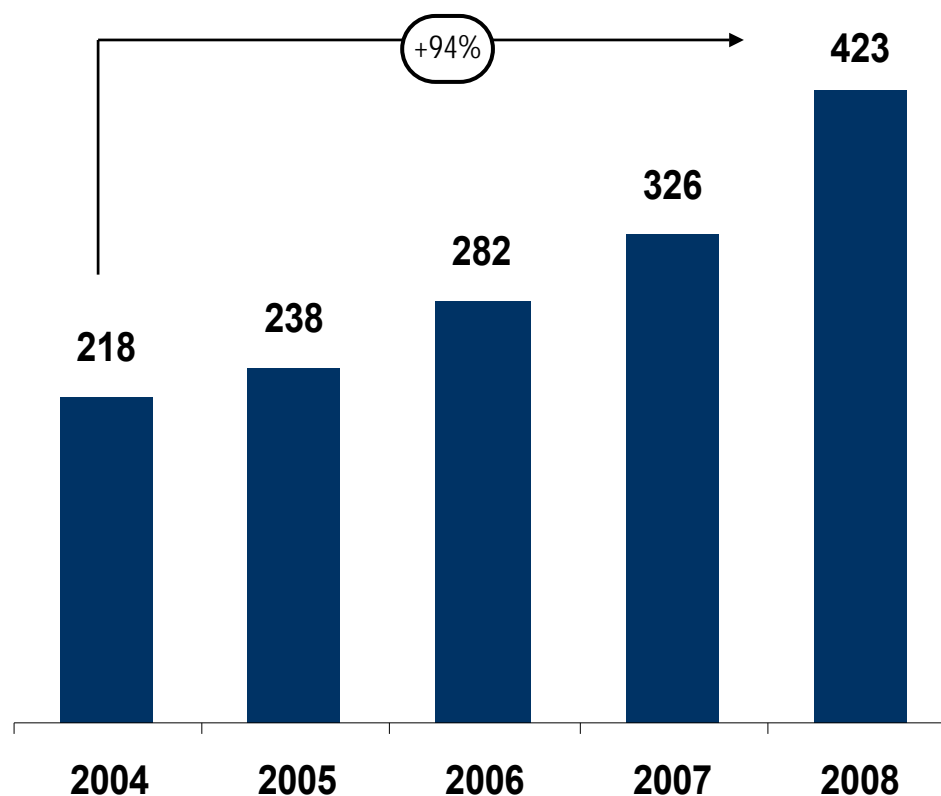
- USA: Florida (■ ○), New Jersey (○)
- Japan: Tokyo (○)
- Distribution also via 138 distributors in 76 countries

### Sales by region (H1 2009):



## About Biotest – strong track record

Sales of Biotest Group (in € million)



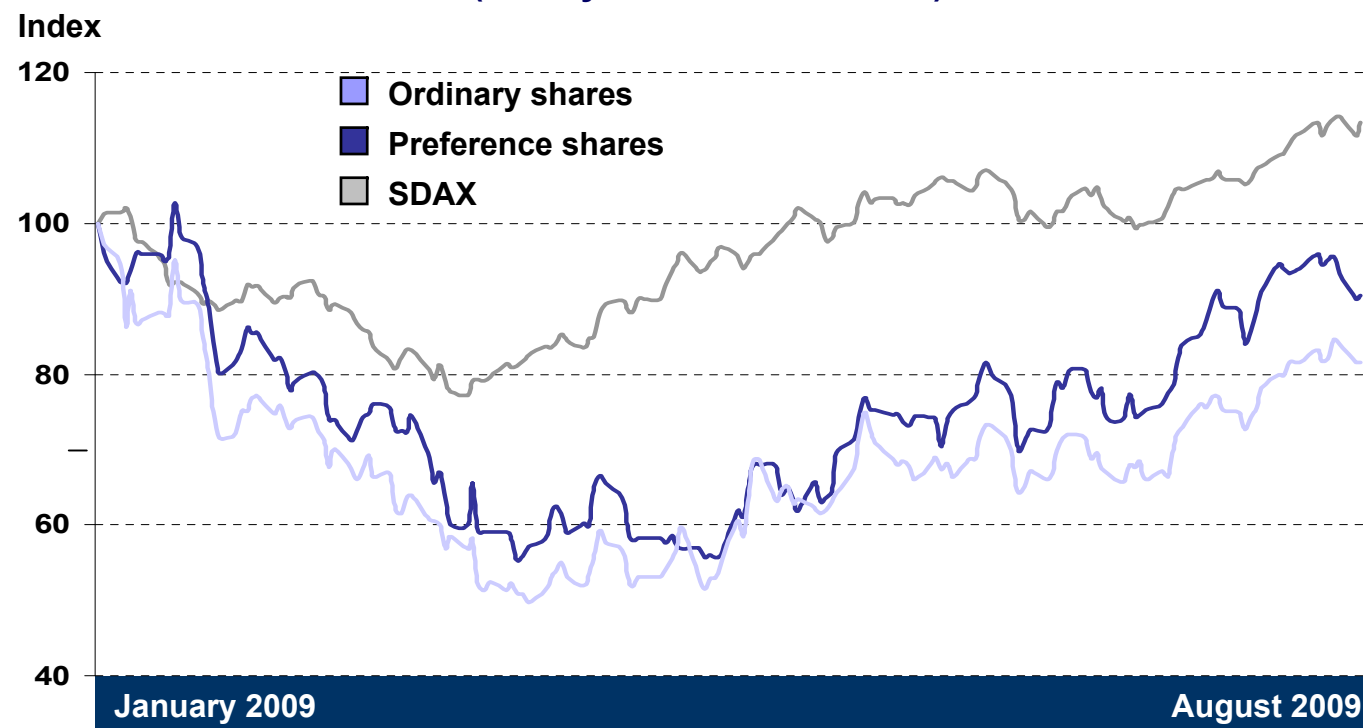
- Strong revenue growth, particularly in Plasma Proteins business
- Plasma Proteins account for 80% of Group's sales in 2008
- EBIT increase by 199% from 2004 to 2008

## Biotest share – rise again since May 2009

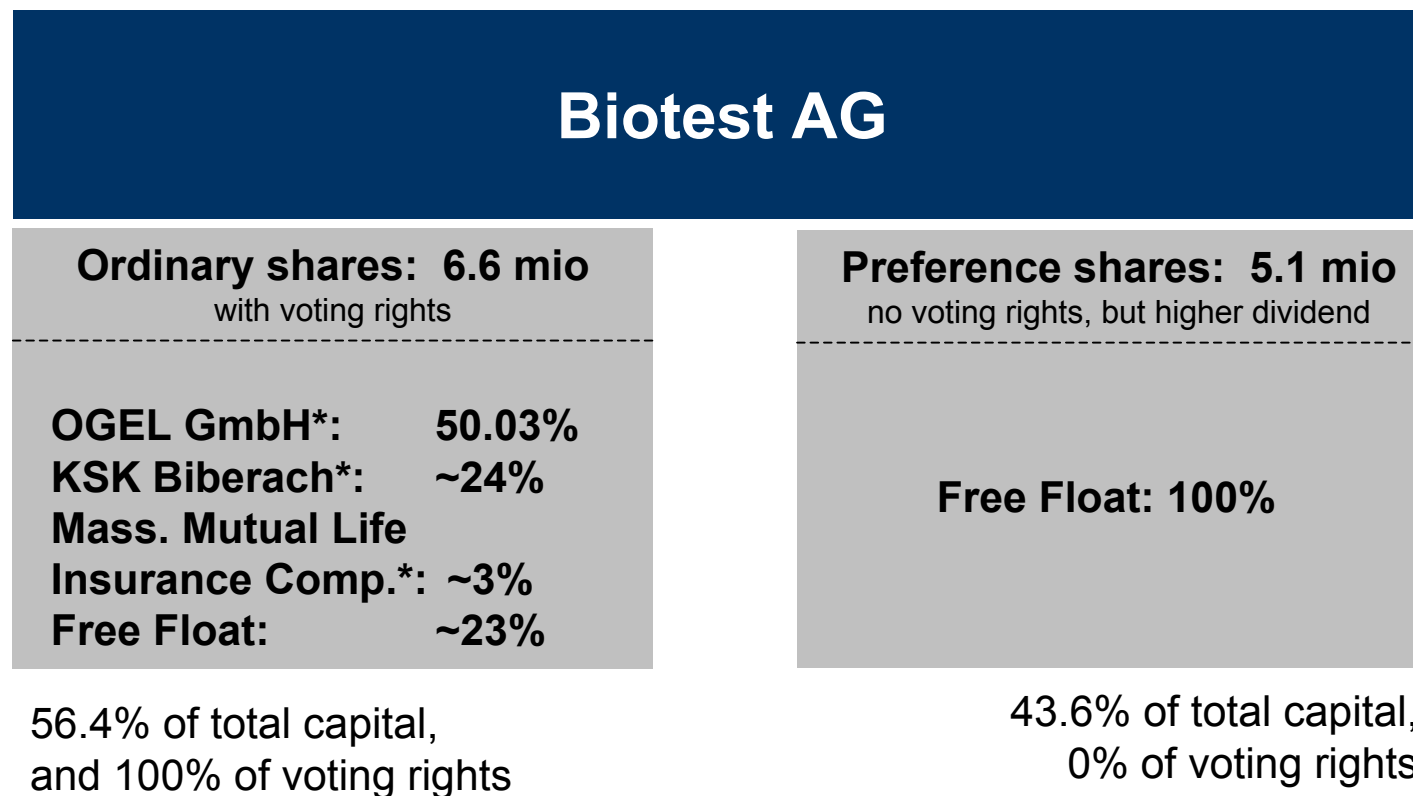
Both share classes recorded an all-time high in August 2008:

- €67.00 (ordinary shares), €64.00 (preference shares)

### Biotest shares and SDAX (as of year-end 2008 = 100)



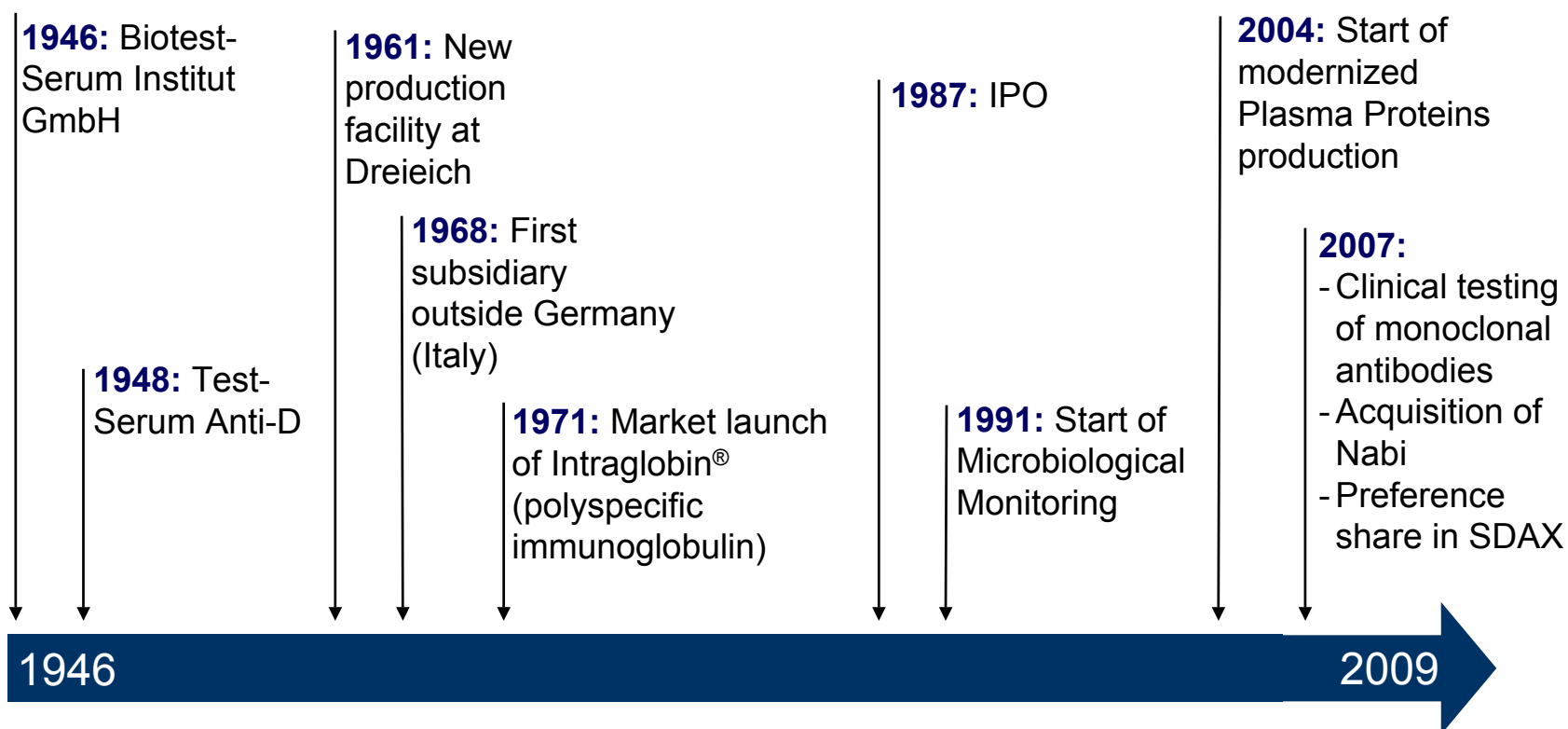
## Shareholder structure



\* as of August 2009



## Biotest: History and milestones achieved

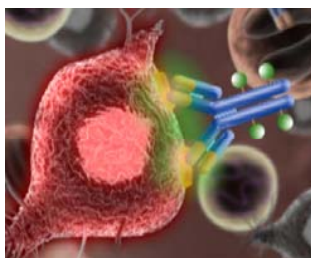




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## **Financials and highlights of H1 2009**

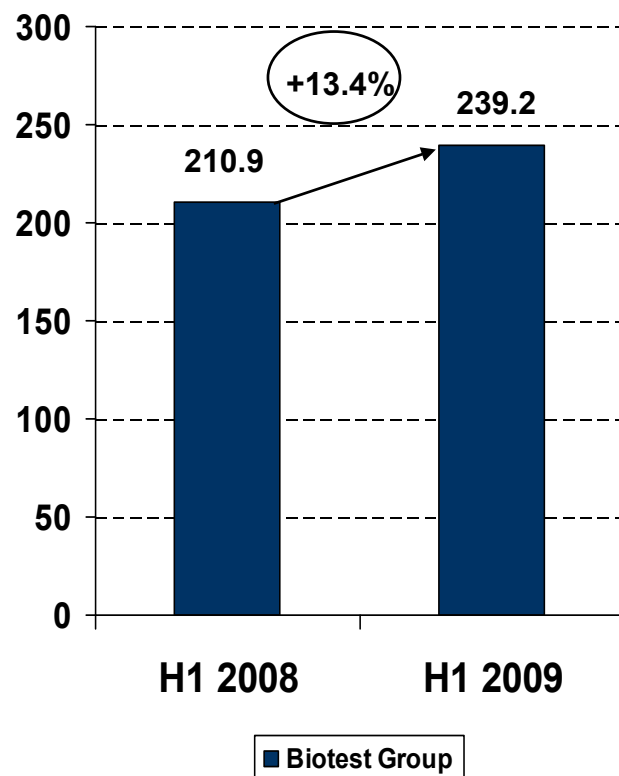
## H1 2009 - Highlights



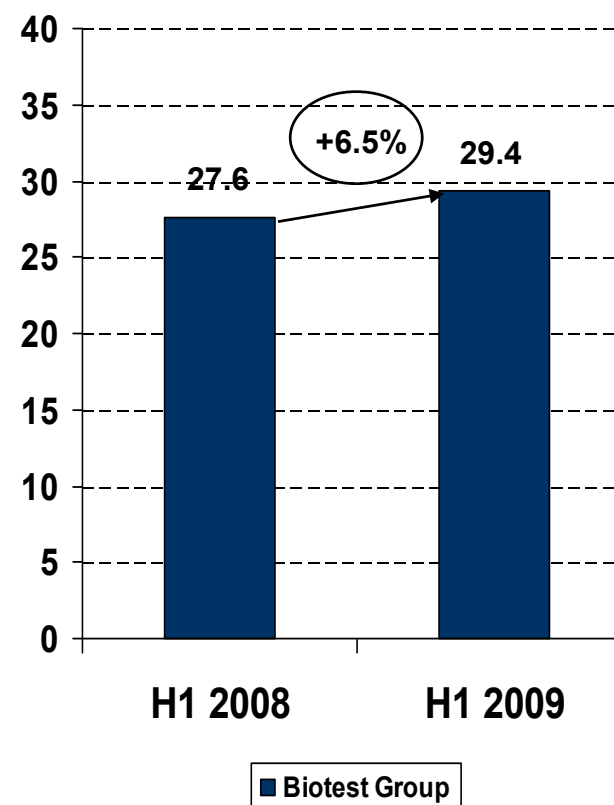
- Biotest Group Sales up by 13.4% in H1 2009 and EBIT increased by 6.5%
- Confirmation of 2009 Guidance: Sales +10% and EBIT at € 55m
- Medical Diagnostics: Exclusive negotiations with one party to sell the business area
- Production capacity expansion
- Biotherapeutics: further data demonstrating efficacy of BT-061 and phase I of BT-062 according to schedule
- Partnering process for BT-061 on track

## Sales and EBIT continue to increase

Sales (in € million)

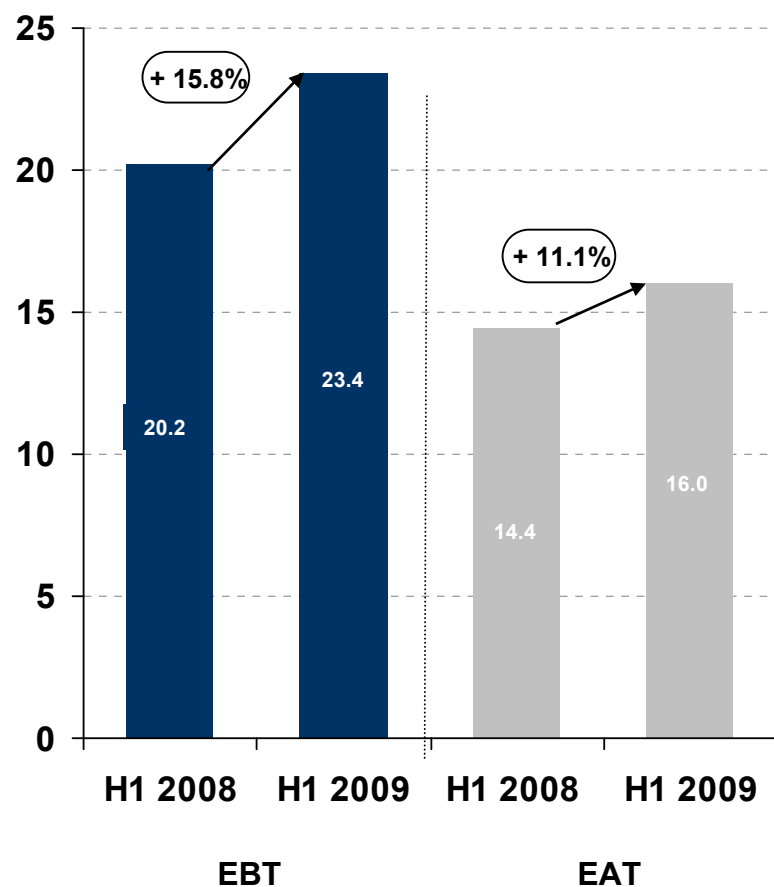


EBIT (in € million)



## Increase in profit in H1 2009

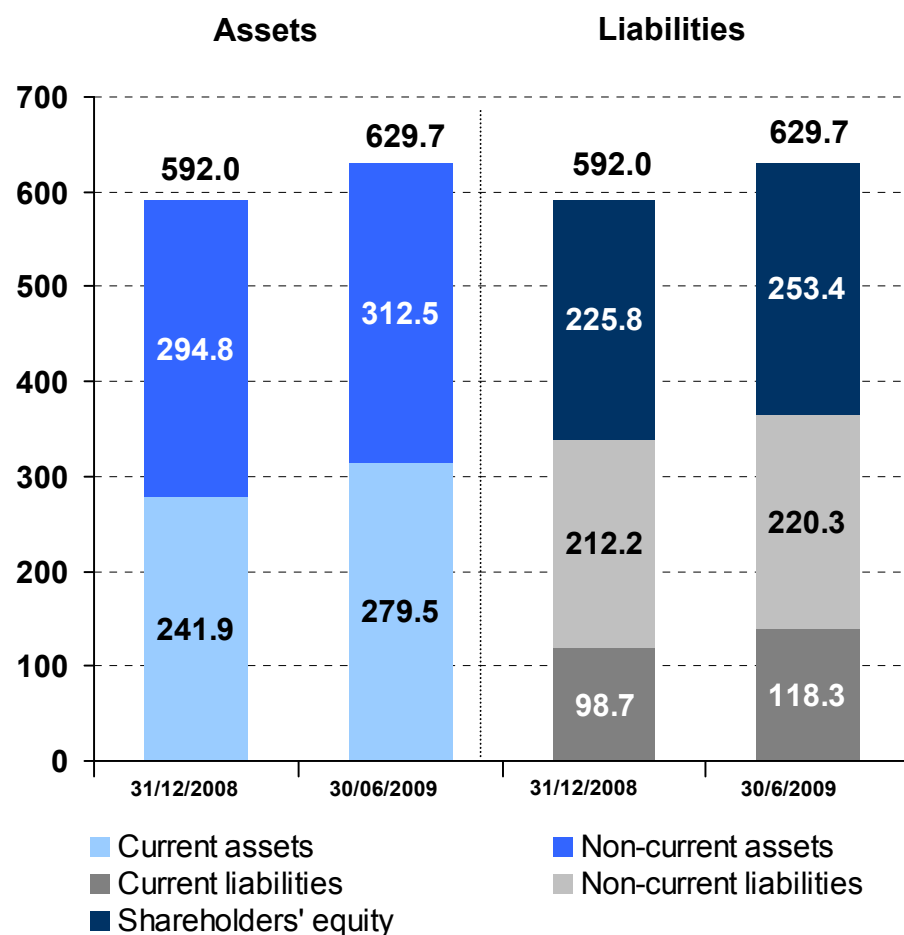
**EBT and EAT (in € million)**



- Rise in earnings before tax (EBT), due to more favourable financial result as a result of lower interest expenses
- Earnings after tax (EAT) at € 16 million
- Tax ratio: 31.3% (H1 2008 : 28.7%)

## Strong balance sheet

Balance sheet of the Biotest Group (in € million)



### Assets

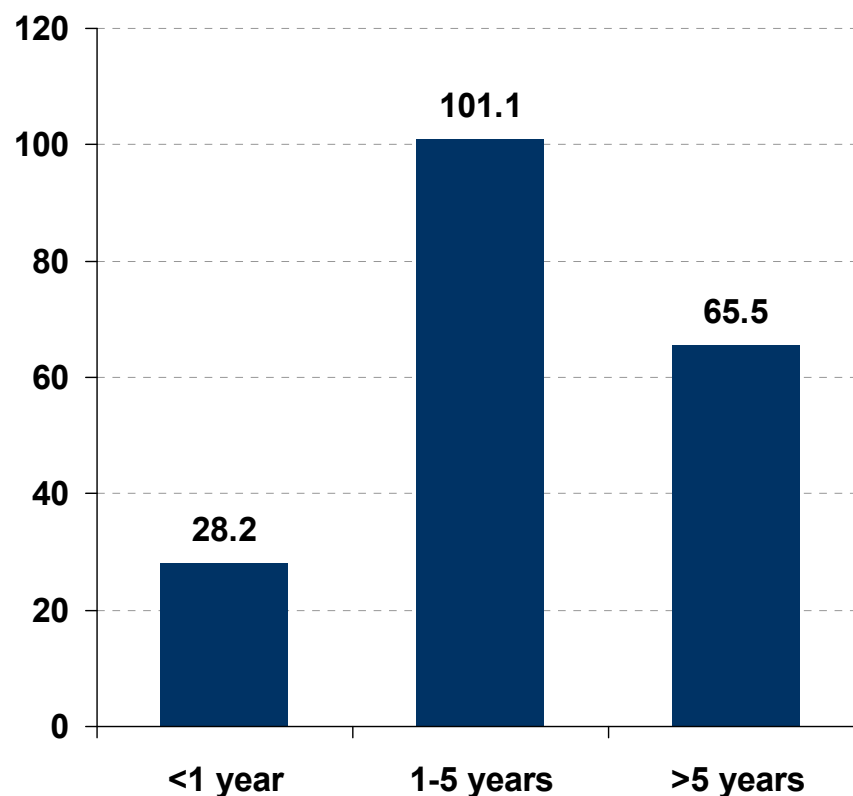
- Higher inventories driven by growth
- Higher Trade receivables due to higher sales volumes

### Liabilities

- Increase in current financial liabilities, primarily serving for pre-financing and interim financing of sales
- Equity ratio as of 30 June 2009: 42.0% ( 31 Dec. 2008: 42.8%)

## Long term debt financing secured

### Residual term of financial liabilities (31 December 2008, in € million)



- Financial liabilities as of 31 December 2008: €194.8 million (2007: €188.8 million)
- Extension of existing credit line (€40 million) in November 2008
- Total credit line expanded by €40 million in May 2009 (maturity of 2 years)
- Sufficient flexibility to support further growth



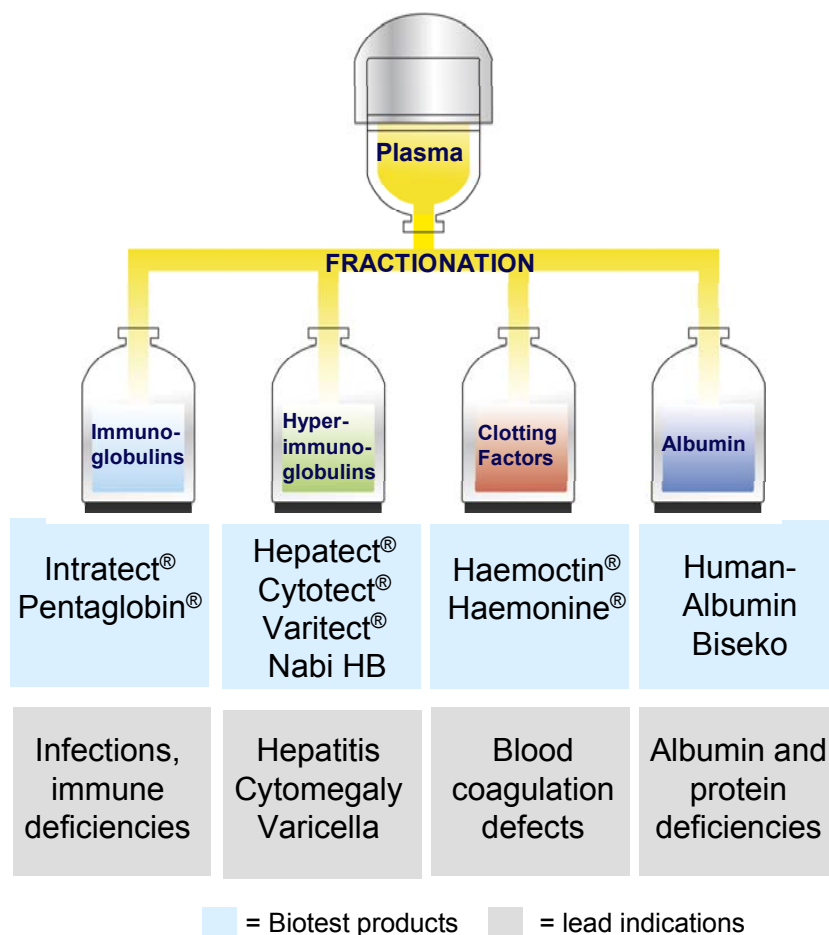
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## **Plasma Proteins**



## 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, CH: > 16%, in UK: > 8%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA
- Biotest covers full value creation chain: plasma sourcing, production, distribution  
 ⇒ vertical integration leads to rationalisation and higher productivity

## 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

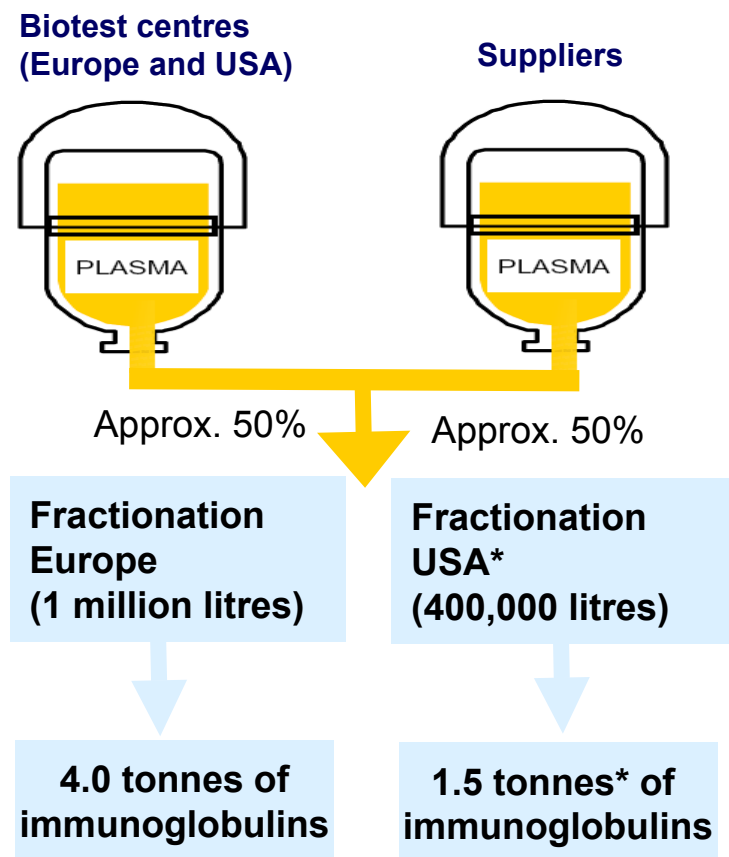
**Virus inactivation**



### 4. Filling and Packaging

## Plasma Proteins production – capacity doubled

### Biotest production network\*



\* In the final construction stages (2009/10)

### Fractionation:

- Plant in Dreieich: 700,000 litres p.a.
- Contract with C.A.F-D.C.F (Belgium): up to 300,000 litres p.a.
  - Facility included in regulatory files
  - 10 year contract
- Boca Raton: 400,000 litres p.a. (from 2010)

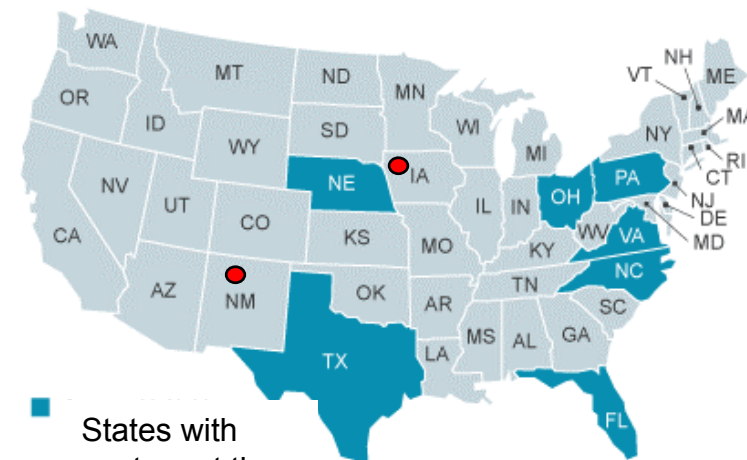
### Immunoglobulins:

- Capacity in Dreieich doubled
- Capacity expansion in Boca Raton (1.5 tonnes p.a. from 2010)

## Plasma collection – high level of own supply ensures independence and availability of raw material

- 4 new plasmapheresis centres in 2008
- 21 centres in total worldwide (10 in Europe, 11 in the USA)
- Level of own supply set to rise to over 45% by the end of 2009:
  - Less dependent on price fluctuations
  - Supply of hyperimmune plasma
- Production network Europe - USA

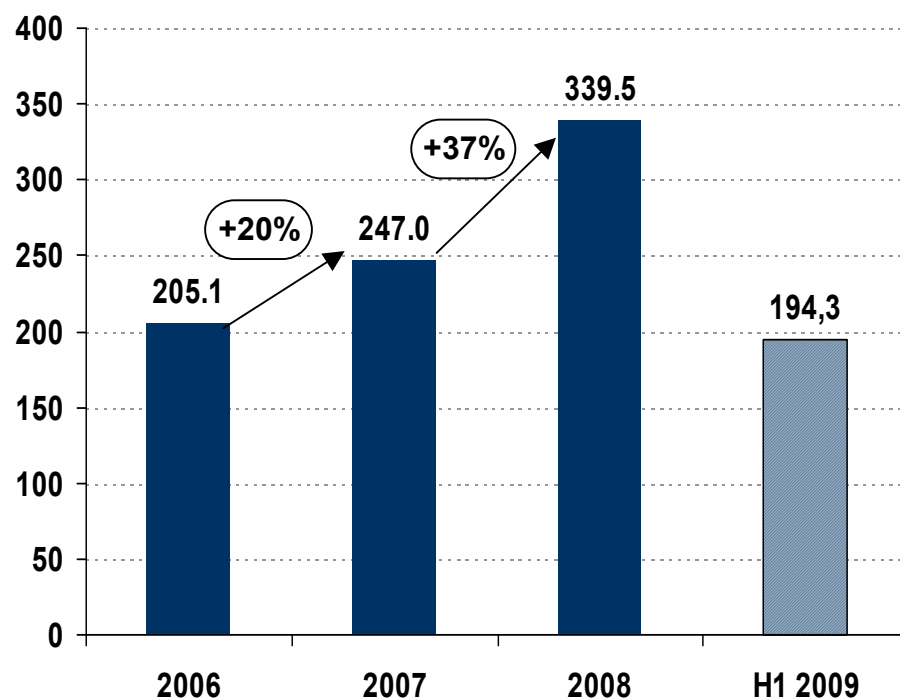
### BPC-run plasmapheresis centres in the USA



- States with centres at time of BPC acquisition (2007)
- New centres opened in the USA in 2008/2009: Santa Fe (NM), Iowa City (IA)

## Plasma Proteins: further growth in sales, but at a slower rate

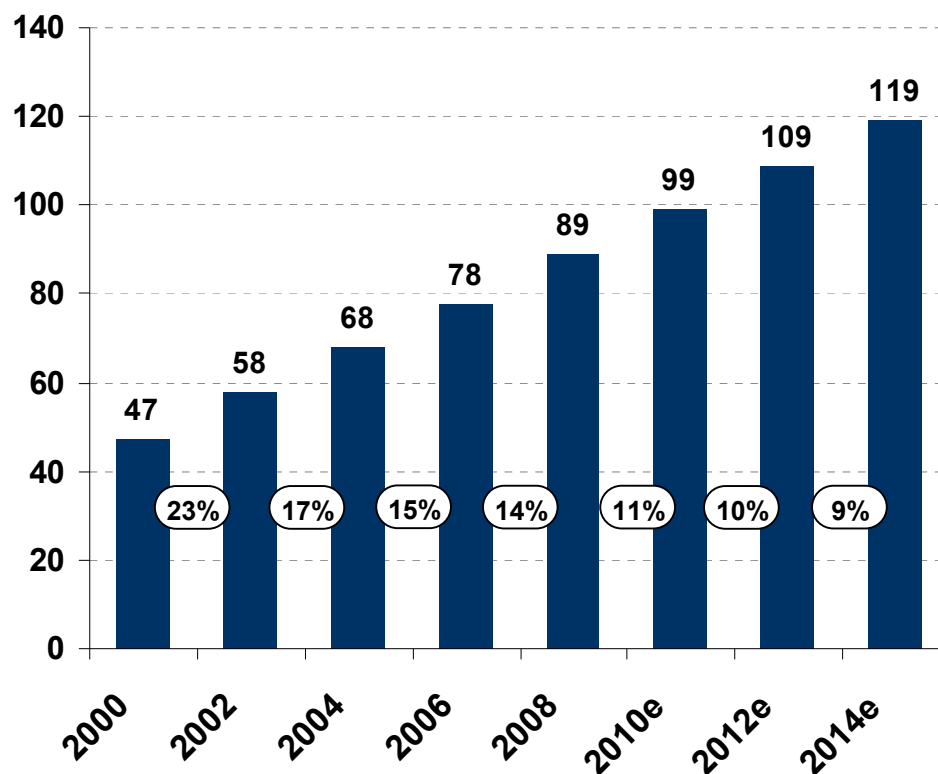
Plasma Proteins: sales volume (in € million)




- Sales in Plasma Proteins jumped by 37% in 2008 (incl. BPC for the first time)
- Contribution BPC in 2008: €64.1m
- In H1 2009 Plasma Protein sales increased by 14.5% to € 194.3 million

## Demand for Plasma Proteins is growing, but at a slower rate

Global IVIG market (in tonnes)



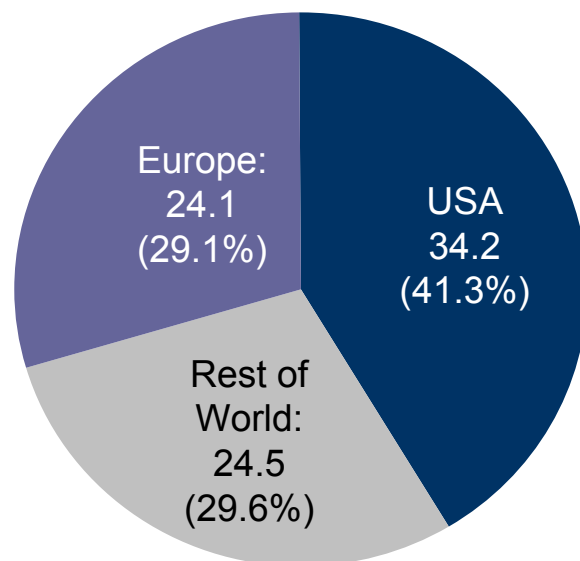
- New indications and higher dosages per capita drive demand for immunoglobulins
- Decrease of prices in major European markets and US

 = Growth (over a 2-year period)

Source: Biotest research, MRB, PPTA, Review of Australia's Plasma Fractionation Arrangements (Feb 2006)

## Immunoglobulins: approval of U.S.-IVIG bears significant upward potential

**IVIG world market 2007: volume (in tonnes) and regional distribution (in %)**

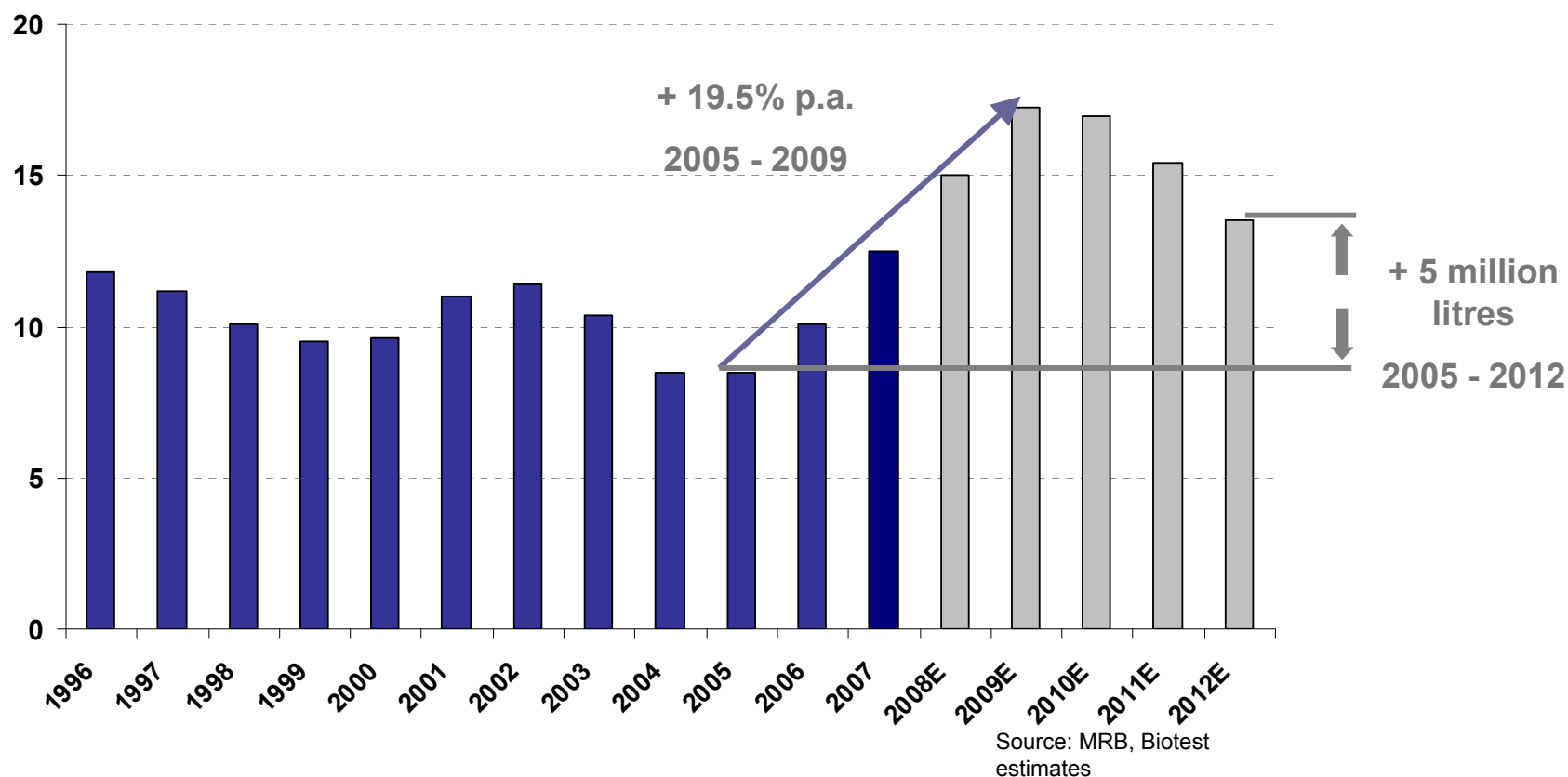


- Total volume IVIG world market as of 2008: ~ 90 tons
- USA by far the most important market for IVIG worldwide
- Registration of BPC's U.S.-IVIG (comparable to Intratect®) expected for H1 2011

Sources: MRB, APFA, UBS, Biotest Market Research

## Plasma: trend reversal expected in terms of collected volume

Total supply of donor plasma in the USA (in million litres)



**Our assessment: industry responds to expected price reductions.  
Capacity adjustments in line with growth in demand (6% to 8% p.a.).**



## Plasma Proteins: H1 2009 highlights



- Market entry in additional European countries after regulatory approval: Human Albumin, Hepatect<sup>®</sup>, Haemoctin<sup>®</sup>, Haemonine<sup>®</sup>
- Share of international sales up to 75%
- Tenders won for the delivery of coagulation factors
- R&D projects advanced
- Production capacity expanded

## Plasma Proteins: ongoing and new product development

### European approval expected in 2009 (centralised procedure):

Zutectra



Hepatitis B immunoglobulin for prophylactic treatment of reinfection following liver transplantation, administered subcutaneously – self-medication possible

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### Approval after 2010:

IVIG (USA):

Phase III completed by end of May 2009,  
Final evaluation available: good results with respect to safety and efficacy  
registration scheduled for H1 2011

IgM concentrate:

Clinical development Phase I was started in Q2 2009  
First part of Phase I finalized in Q3 2009  
Good tolerability observed

## Cytotect<sup>®</sup>: significant large-scale trial has started

**Indication: prevention of prenatal cytomegalovirus infection of the foetus in women who were infected by the virus for the first time.**



- Phase III trial to confirm existing positive results from a previous study
- High ethical relevance
- Comprehensive immunoscreening required (up to 20,000 tests)
- Following initial difficulties, trial is fully underway: more than 2,500 pregnant women have been screened
- Accelerated recruitment, new centers included in the study (e.g. England, Poland, Hungary, Austria)

## Intratect® – upside potential from additional indication

### Human immunoglobulin for intravenous use (IVIg)



- Chronic idiopathic pain syndrome (CIPS) (fibromyalgia) - Phase III trial completed
- Excellent clinical response in 30% of patients
- 1 - 2 % of the population in Europe and US are suffering from CIPS.
  - 5 % of them do not respond to conventional therapy (about 400,000 people)

## Outlook for Plasma Proteins: steady growth

- Internationalisation of business through new developments and the expansion of existing approvals
- Continued growth at a slower rate is expected
- Decrease of prices continues, but no price erosion





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## **Biotherapeutics**

## Biotherapeutics: investment in projects with potential

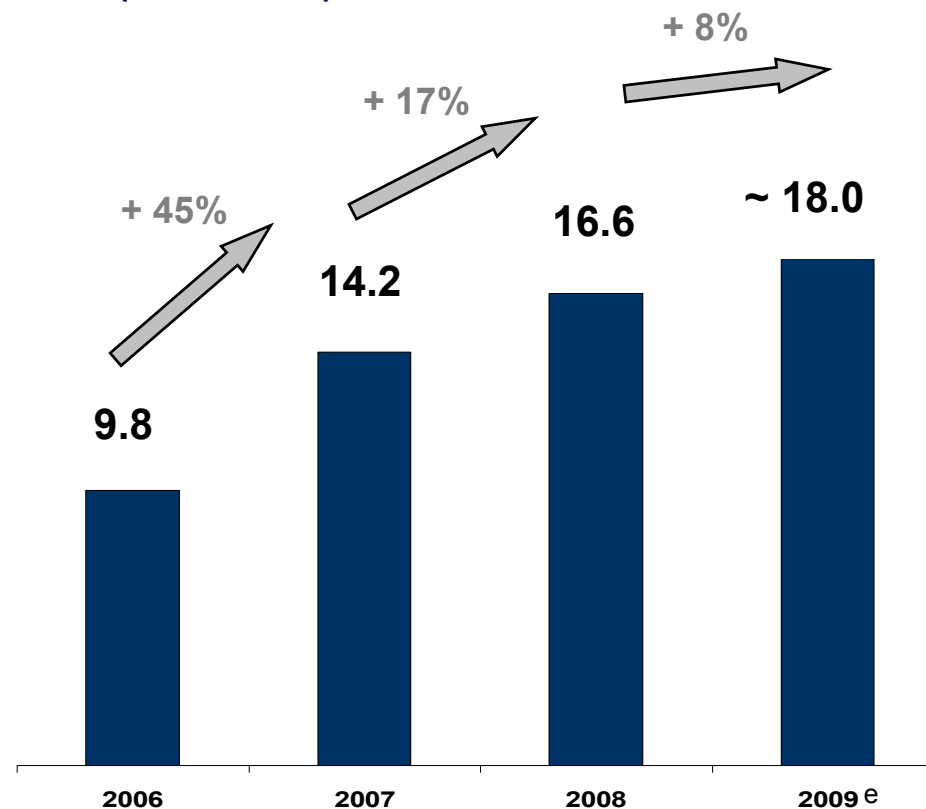
### Common features of Biotest's monoclonal antibodies

- High medical need
- Rapidly growing markets
- Blockbuster potential

### Lead indications

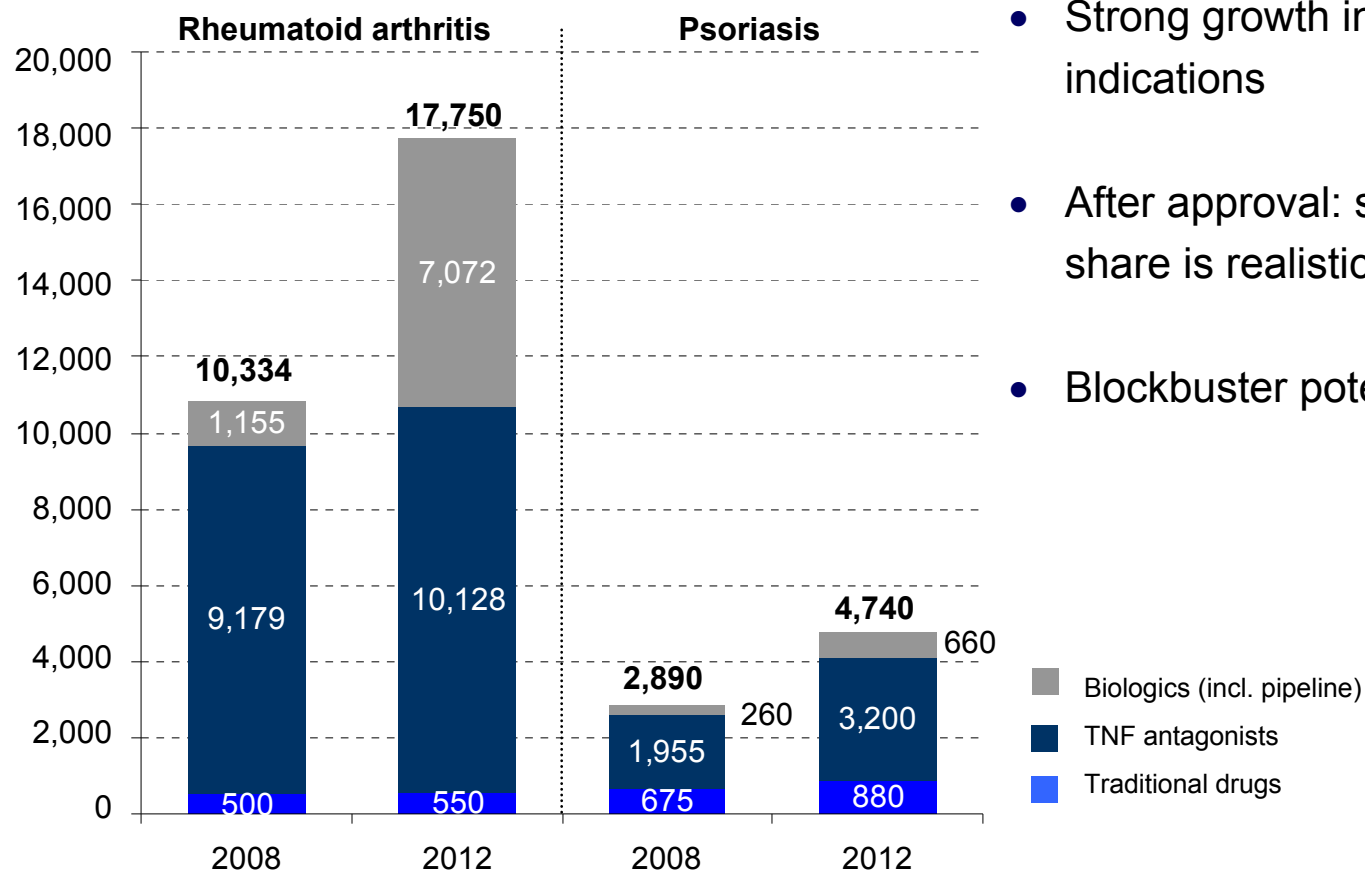
<b>BT-061</b>	Rheumatoid Arthritis, Psoriasis
<b>BT-062</b>	Multiple Myeloma
<b>BT-063</b>	Systemic Lupus Erythematosus and other autoimmune diseases

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



## Rheumatoid Arthritis and Psoriasis – a huge and growing market

### Market volume (in US\$ million)

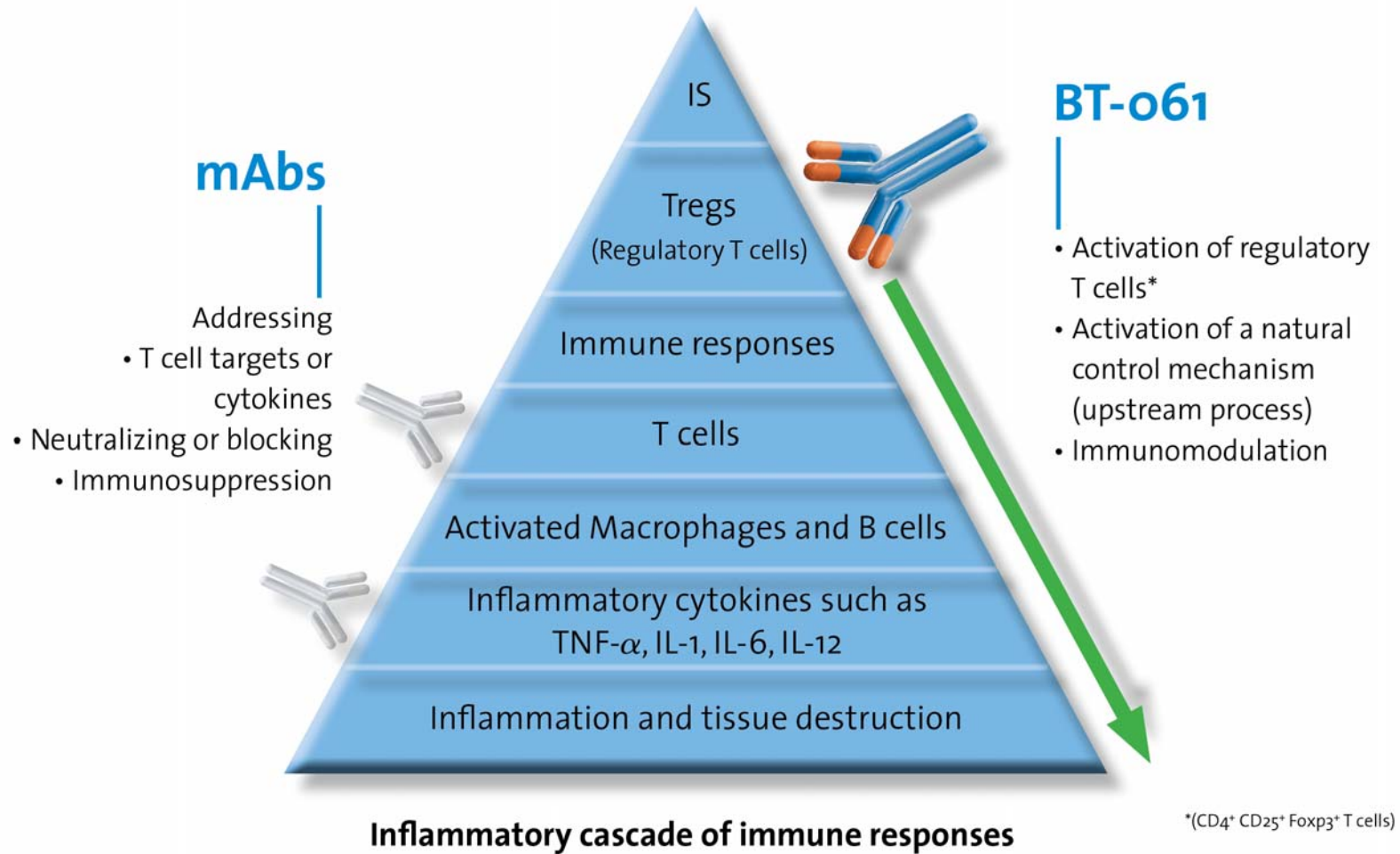


- Strong growth in both lead indications
- After approval: significant market share is realistic
- Blockbuster potential

(Source: Datamonitor, Commercial Insight Autoimmune Overview 2007; L.E.K, annual reports, Biotest studies)



## 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.**

## BT-061 – overview of clinical trials

### **Trial 961: (Phase I)**

Single dose, intravenously and subcutaneously,  
healthy subjects (tolerability), (57).

**Study completed**

### **Rheumatoid arthritis**

#### **Trial 962 (Phase IIa):**

Multi-dose, intravenously and  
subcutaneously, placebo-  
controlled, (96).

**Study ongoing**

#### **Trial 971 (Phase II):**

BT-061 with MTX\*, multi-dose,  
intravenously, placebo-  
controlled (110).

**Treatment of patients of first  
study group completed (N=70)**

### **Psoriasis**

#### **Trial 967 (Phase I/IIa):**

Single dose, intravenously and  
subcutaneously, placebo-  
controlled, (56).

**Study ongoing**

#### **Trial 973 (Phase II):**

Multi-dose, intravenously and  
subcutaneously, placebo-  
controlled\*\* (48).

**CTA submission Sept. 2009**

## Very encouraging interim results from clinical trials with BT-061

### Rheumatoid arthritis – Phase IIa\* (No. 962 + No. 971)

- **Marked clinical improvement** with the dosage groups used to date (s.c., i.v.) in up to **62.5% of patients. (Monotherapy)**
- **Combination** BT-061 with MTX (i.v.)
- **Clinical improvement** even higher compared to monotherapy (**up to 70%** of patients)

### Psoriasis – Phase I/IIa\* (No. 967)

- In therapeutically relevant dosages (intravenous) **marked clinical improvement in 75% of patients.**
- PASI improved by up to 88%
- Long-lasting effect even with low dosages

**More than 240 subjects** involved in all trials as of July '09, efficacy in both indications, general tolerability of BT-061 is good

\* Dose escalation trials: 75% of patients receive BT-061, 25% receive the placebo drug  
Interim results, blinded data

## Partnering for BT-061: process started successfully, positive response

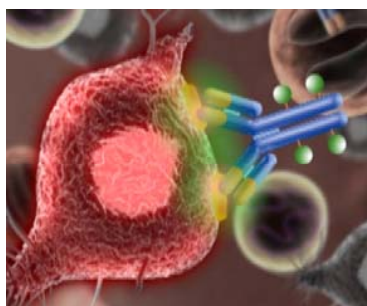
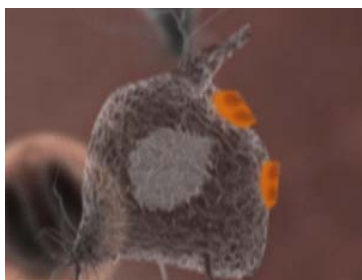


### **Biotest strategy:**

Co-development and  
co-marketing with “big  
pharma” from clinical  
Phase III onwards

- Start of partnering process successful
- Global pharmaceutical groups approached (“big pharma”)
- Predominantly positive response
- Negotiations started with selected companies
- Agreement expected by the end of 2009 / start of 2010

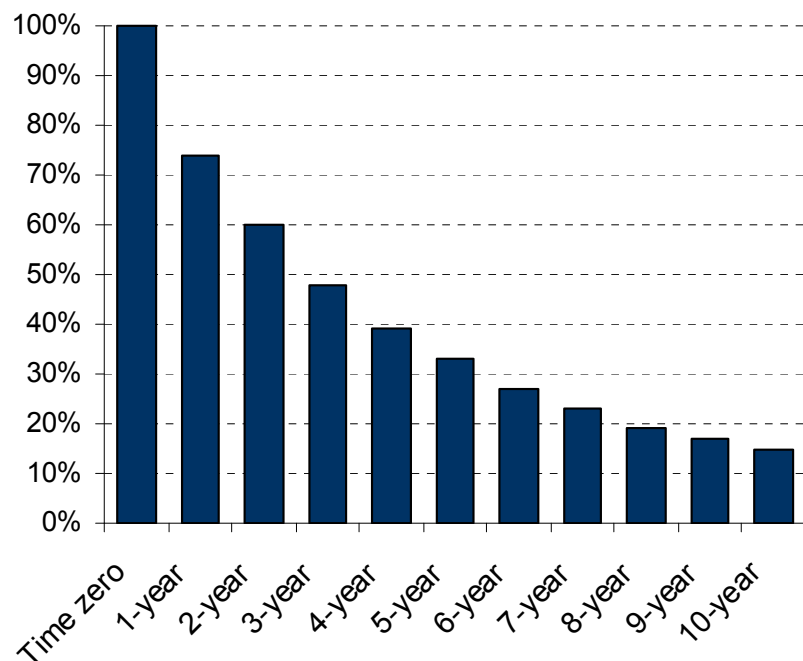
## BT-062 – good tolerability, first indications of efficacy



- BT-062: specific and highly effective immunotoxin: toxin part mediates high efficacy – antibody part mediates high specificity
- Phase I Study: Dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
- Clinical trials in 4 cancer centres in the US, open label, repeated single dose
- The agent is generally well tolerated
- Indications of efficacy already with low dosages:
  - **Aggressive progress of the disease halted in some patients for several months**
  - **Seventh dose level reached in current study**

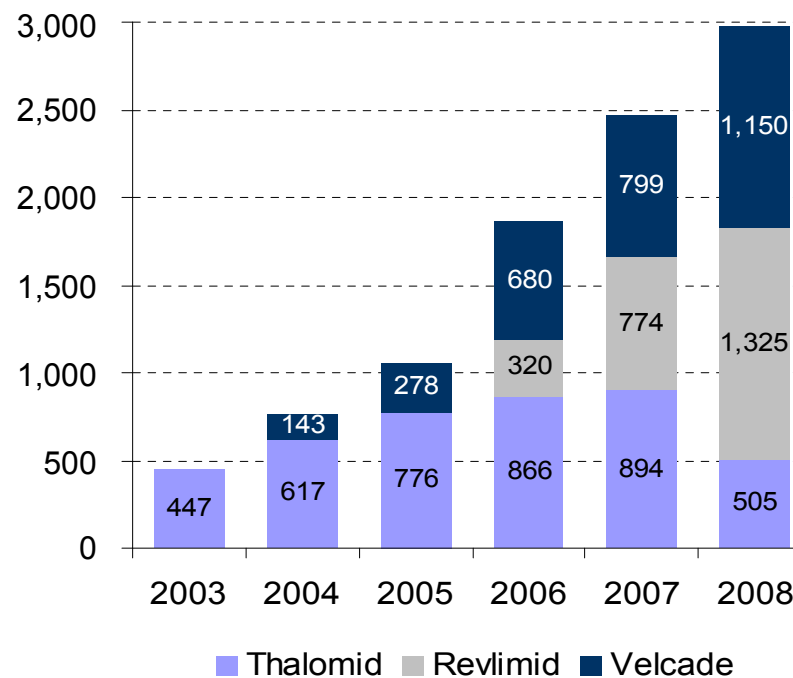
## Multiple Myeloma – unmet need and high market potential

### Survival rates for MM patients in the USA



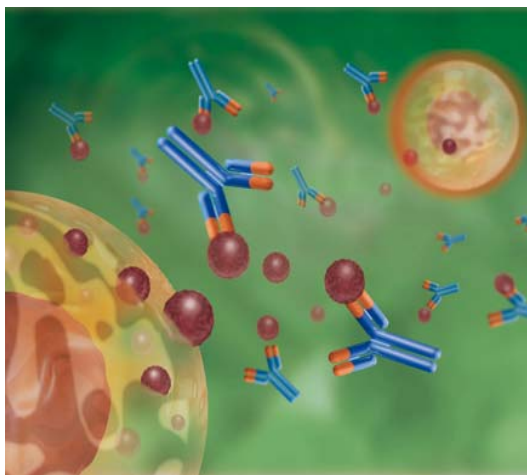
(Source: SEER Cancer Statistics Review, 1975 - 2004)

### Sales of novel targeted MM therapies (in US\$ million)



(Source: Company data and Biotest analysis 2009)

## BT-063 – Competitive advantages due to unique mode-of-action



### 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

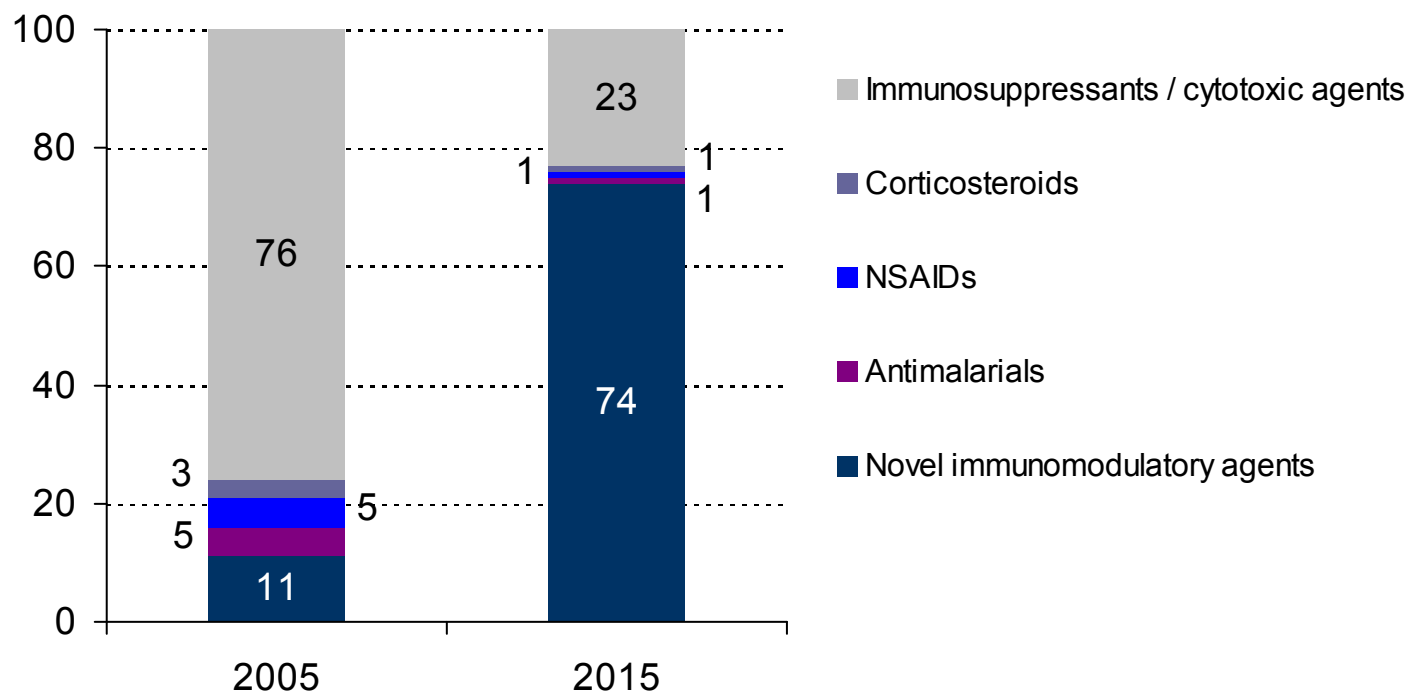
### Mode-of-action

- BT-063 positively modulates the immune system in this indication
- Few other biologics in development: mostly anti B cell antibodies
- Clinical data from pilot study with six patients very promising
- **CTA approval of clinical phase I trial expected in Sept. 2009**

## BT-063: expected SLE market development

- Market without specific or curative agents –
- Novel immunomodulatory agents will develop the SLE market

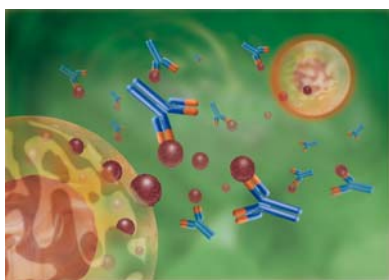
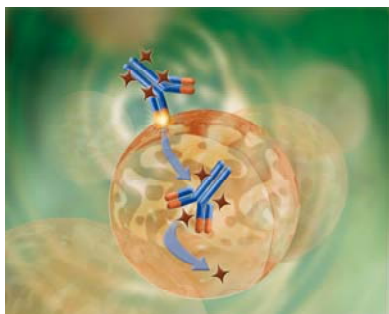
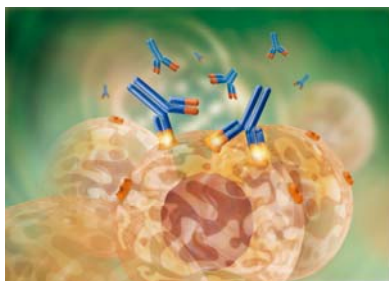
### Market share of SLE therapies (in %)



Source: Decision Resources, Inc., 2006



## Outlook Biotherapeutics: reach new development stage



- Significant progress with all projects
- BT-061: partnering process ongoing
- BT-063: CTA approval expected in Sept. 2009
- Set-up of own production of monoclonal antibodies progressing well at BPC

Projects require considerable effort and are associated with risks up to the final stage.

However, they offer major opportunities for steady revenue in the long term.



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

## **Microbiological Monitoring and Medical Diagnostics**

## Medical Diagnostics: reagents and system solutions

### Transfusion



Identification of blood groups  
Search for antibodies

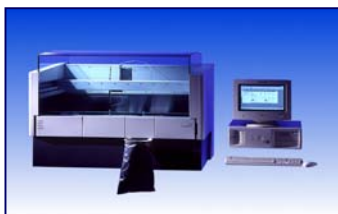
### Main products:

- TANGO® optimo
- Erytype
- Solidscreen
- Manual Test Reagents

### Competitive position:

- No. 4 worldwide
- Market share: 4% (Europe: 6-7%)
- Competitors:
  - Biorad
  - Immucor
  - Ortho
  - Diagast

### Transplantation



Typing of tissues

- HLA Serology
- HLA DNA Tests (ELPHA, SSP)
- HLA Antibody diagnostic

- No. 4 worldwide
- Market share: 8%
- Competitors:
  - One Lambda
  - Invitrogen
  - Tepnel

## Medical Diagnostics: improved business trend, but situation remains difficult



- Difficult market conditions in Europe, USA remains an attractive market
- Approval of manual reagents facilitates presence as full-service provider in the USA
- Sales increase in H1 2009 to € 24.3 million (+8.0%) – however, sales and profit development remain unsatisfactory
- Sale of the business to a strategic partner planned, negotiations under exclusivity are ongoing

## Microbiological Monitoring: Biotest leading supplier



### Reagents and system solutions for:

- Hygiene Monitoring
- Detection of germs and particles

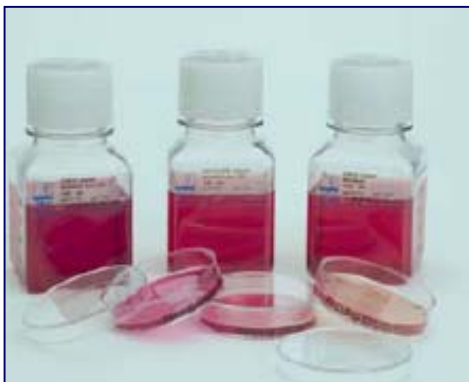
### Main Products:

- Microbiological air samples (RCS)
- Air Particle Counters (APC)
- Surface germ indicators (OKI)
- heipha culture media

### Market Position:

- Among top 5 worldwide
- Market share 8-10%

## Microbiological Monitoring continues to perform well



- Sales increase in H1 2009: €20.6 million (+9.0%);
- Complex and high quality standards require high quality products
- Pooling R&D activities at the Eppelheim site
- R&D: focus on solutions for the paperless laboratory

## 2009 outlook – Strong first half year, further growth expected



- **Solid growth in H1 2009:**
  - Sales +13.4% vs. H1 /2008, growth in all segments
  - EBIT +6.5%
  
- Economic crisis has had no significant impact to date – however, increased vigilance is necessary
  
- **Reconfirmed Targets for 2009:**
  - Sales +10%
  - EBIT at previous year's level (€55 million)

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## Creating Value. Living Values.



### **Biotest – sustained company value**

- Successful operations
- Growth opportunities
- Pipeline with strong potential
- Sound financing
- Highly qualified and committed employees



## Disclaimer

This document contains forward-looking statements on overall economic developments as well as on the business, earnings, financial and asset situation of Biotest AG and its subsidiaries. These statements are based on current plans, estimates, forecasts and expectations of the company and thus are subject to risks and elements of uncertainty that could result in deviation of actual developments from expected developments.

The forward-looking statements are only valid at the time of publication. Biotest does not intend to update the forward-looking statements and assumes no obligation to do so.

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

## Contact and Financial Calendar 2009/ 2010

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### **Financial Calendar 2009/ 2010**

05 November 2009 Quarterly Report for  
Q3 2009

05 November 2009 Analysts Conference

## 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-Syndrom, and Kawasaki Syndrom

### Properties:

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

### Clinical trial:

- Phase III trial in chronic idiopathic pain syndrom completed
- Laboratory parameters are currently evaluated to identify predictive clusters that are linked to positive outcome

## 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®

**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)
- Post exposure prophylaxis after exposure to HBV, e.g. needle stick injuries
- HBV prophylaxis in newborns from HBV carrier mothers

### Properties:

- Ready-for-use solution
- Sugar-free, isotonic low-salt solution
- Natural function and activity of specific immunoglobulins is preserved

## Cytotect®

**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:**

- Ready-for-use solution
- Sugar-free, isotonic low-salt solution
- Orphan Drug Designation for prevention and treatment of congenital CMV-infections (Europe, U.S., CH)

### **Clinical trial:**

- Phase III study to prevent CMV infection in children of mothers who acquired a primary CMV infection during pregnancy
- Ongoing process to optimise recruitment and study procedures

## Haemoctin® / Haemonine®

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



### Therapeutic indications:

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

### 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.**



### **Therapeutic indications (after approval):**

- Prophylaxis of HBV re-infection after liver transplantation

### **Properties:**

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

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

### **Clinical trial:**

- Phase III study completed and submitted for a centralised European authorisation procedure
- Approval expected end of 2009