

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



## **Management Presentation**

**Biotest AG**  
**November 2009**

## Biotest at a glance

### Figures Q1-Q3 2009:

<b>Sales</b>	€ 361.9 m	(+12.0%)
Thereof Plasma Proteins	€ 294.3 m	(+12.8%)
<b>EBIT</b>	€ 45.2 m	(+3.0%)

### 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



Purchase agreement signed with Bio-Rad

## Biotest – key figures

- Headquarters in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 10 countries worldwide
- Employees (FTE)\*: 2,135  
    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



Headquarters, Dreieich

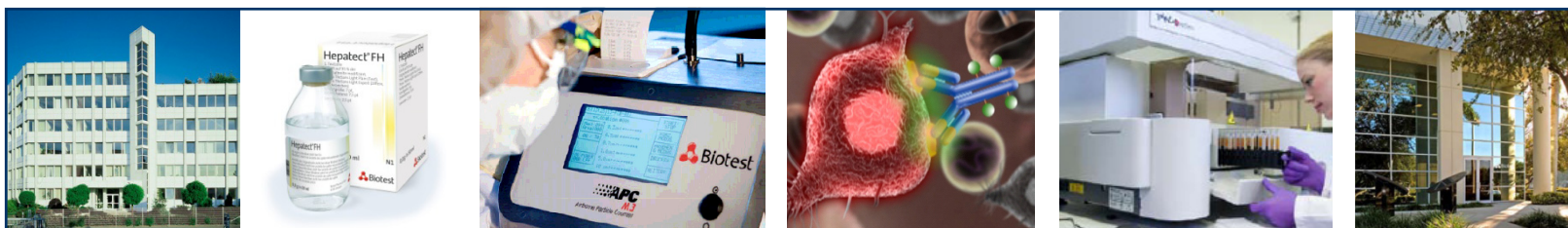
\*: as of 30 Sept. 2009

## Biotest strategy

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

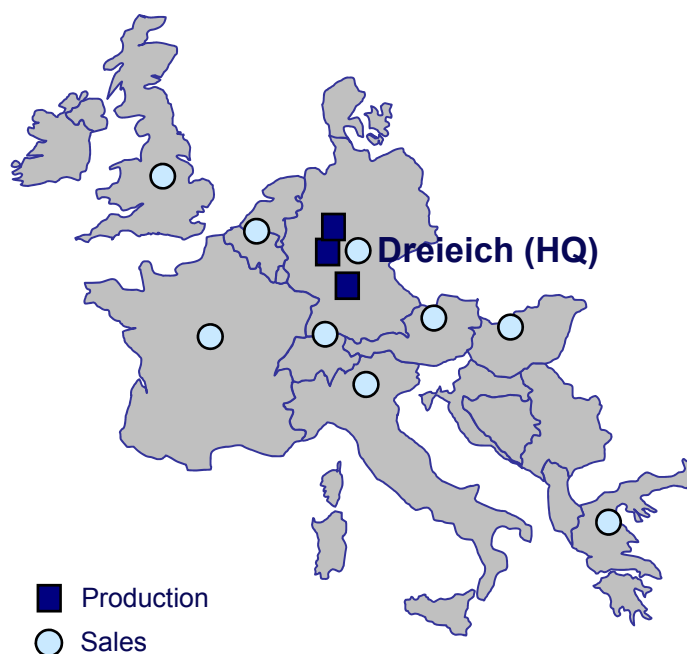


Sustained profitable growth



## Biotest Group overview

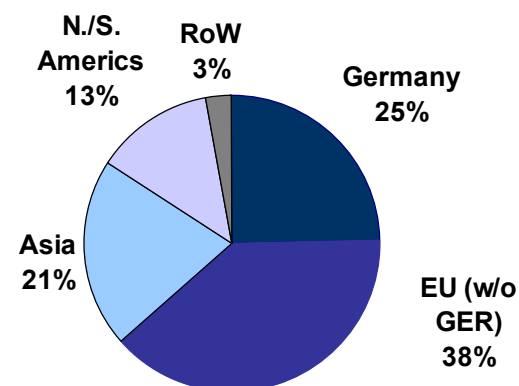
### European production and distribution sites



### Additional sites overseas:

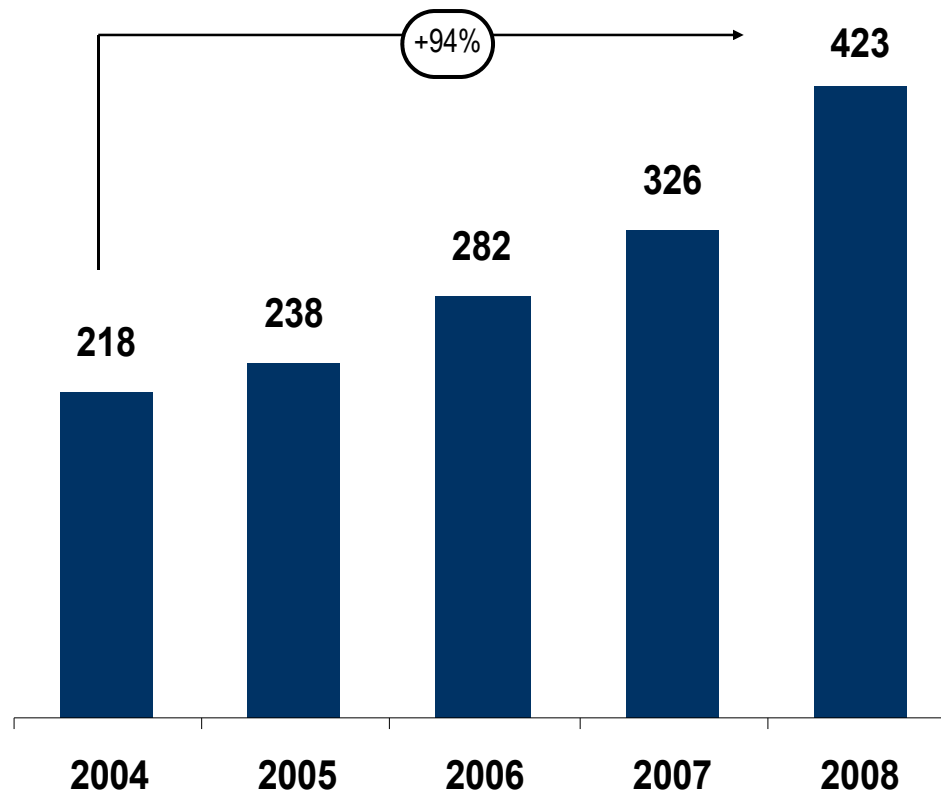
- USA: Florida (■ ○), New Jersey (○)
- Japan: Tokyo (○)
- Distribution also via 138 distributors in 76 countries

### Sales by region (Q1-Q3 2009):



## About Biotest – strong track record

Sales of Biotest Group (in € million)

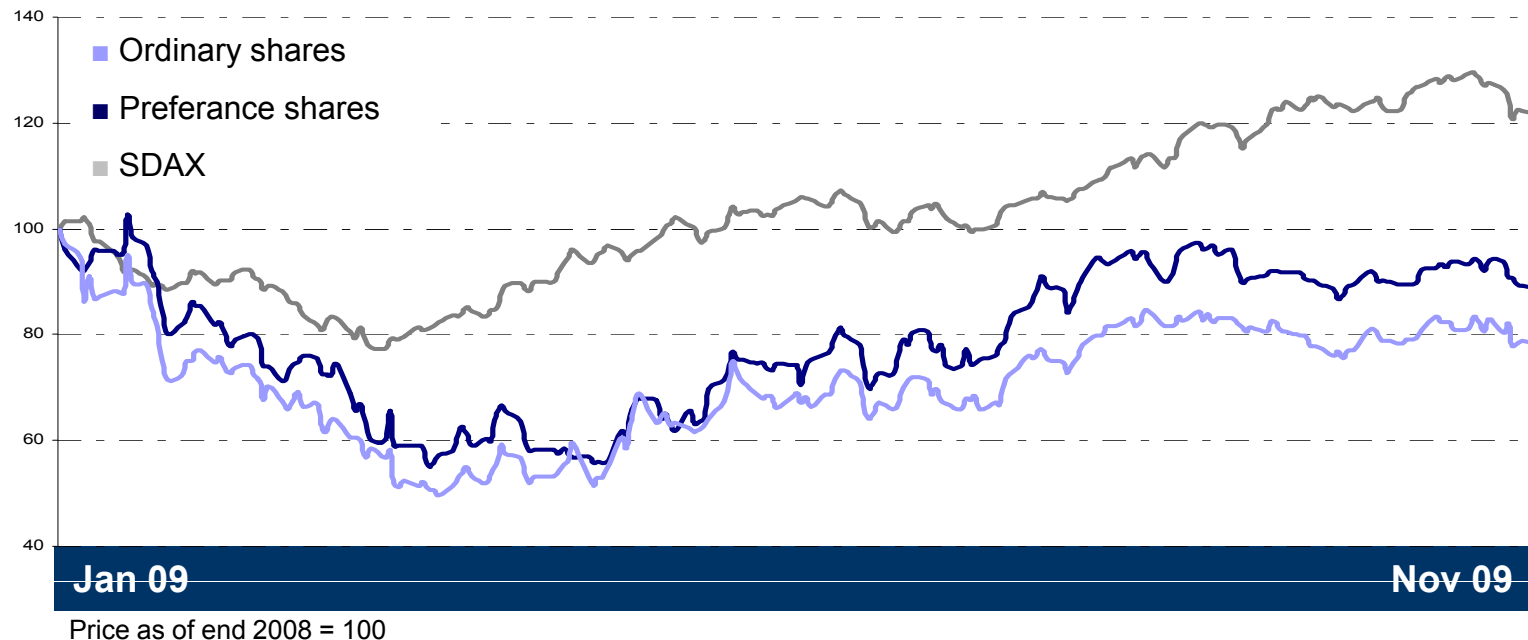


- Strong revenue growth, particularly in Plasma Proteins business
- Plasma Proteins account for 80% of Group's sales in 2008
- EBIT increase by 199% from 2004 to 2008

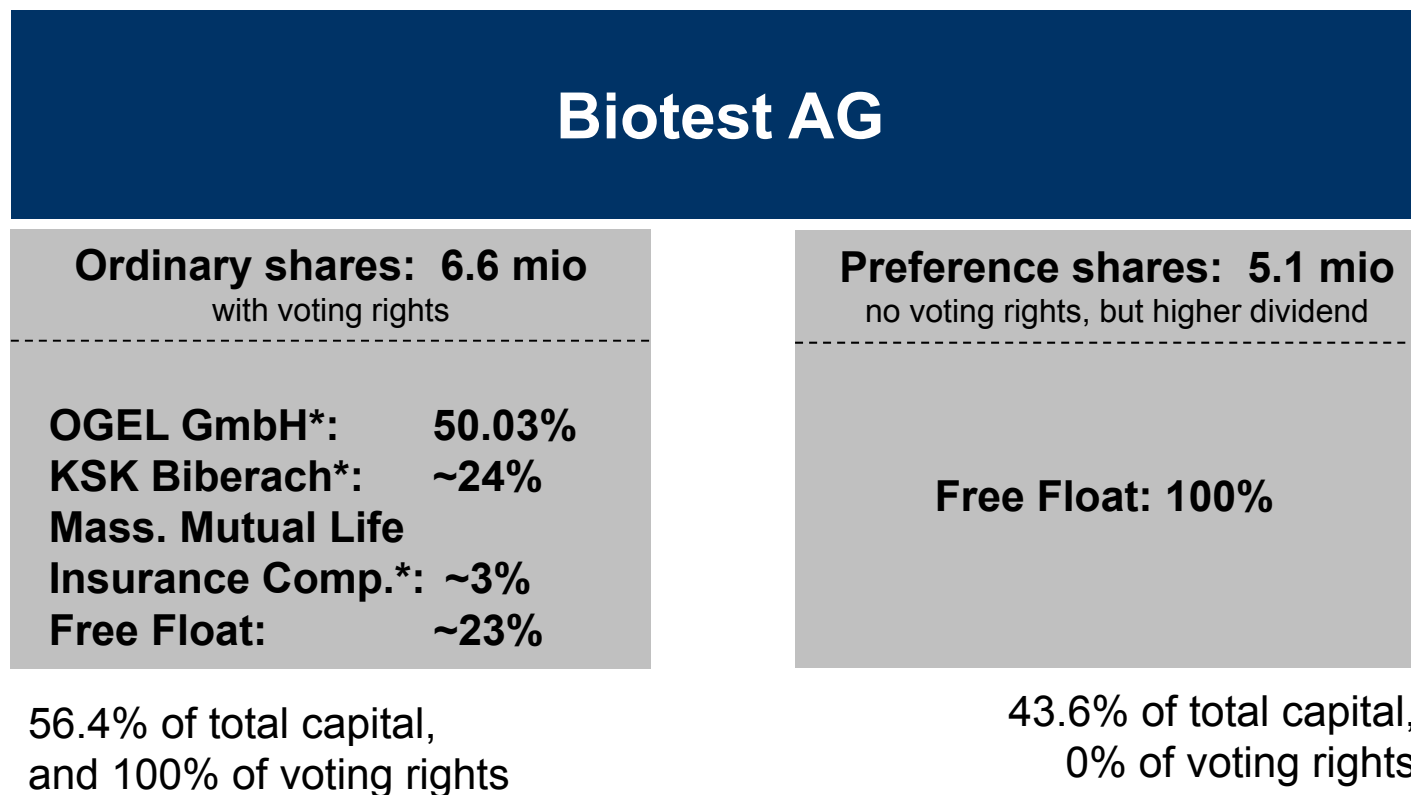
## Biotest shares: positive development in 2009

- Decline of share price after majority shareholder terminates discussions about shares' sale
- Share price increase triggered by positive news flow

### Biotest shares and SDAX in 2009 (index)



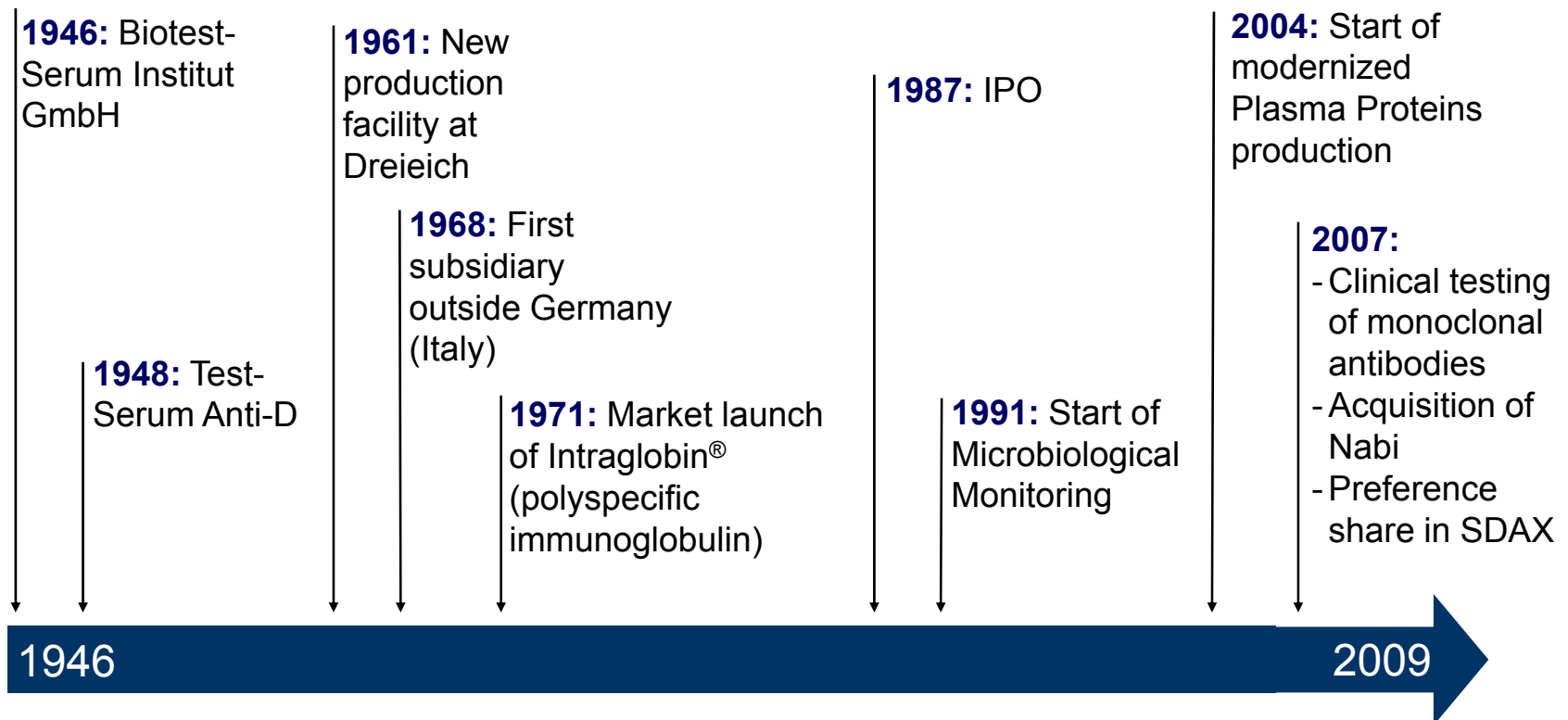
## Shareholder structure



\* as of November 2009



## Biotest: History and milestones achieved

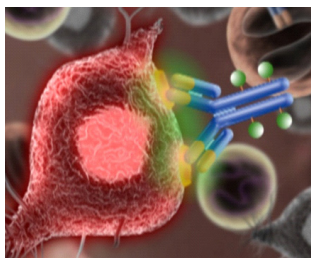




**Biotest Group: Creating Value. Living Values.**

## **Financials and highlights of Q1-Q3 2009**

## Q1-Q3 2009 / Highlights Q3



- Biotest Group Sales up by 12.0% and EBIT increased by 3.0%
- Confirmation of 2009 Guidance: Sales +10% and EBIT at € 55m
- Medical Diagnostics: Signing of purchase agreement with Bio-Rad Laboratories, Inc.
- Zutectra received positive CHMP\* opinion for marketing approval in EU
- Biotherapeutics: further data demonstrating efficacy of BT-061
- Clinical Phase III of IVIG (US) successfully completed
- Commissioning of technical plant ongoing in Boca Raton

\*: Committee for Medicinal Products for Human Use (CHMP);  
The positive opinion is based on data available to the EMEA,  
as part of the centralised approval procedure.

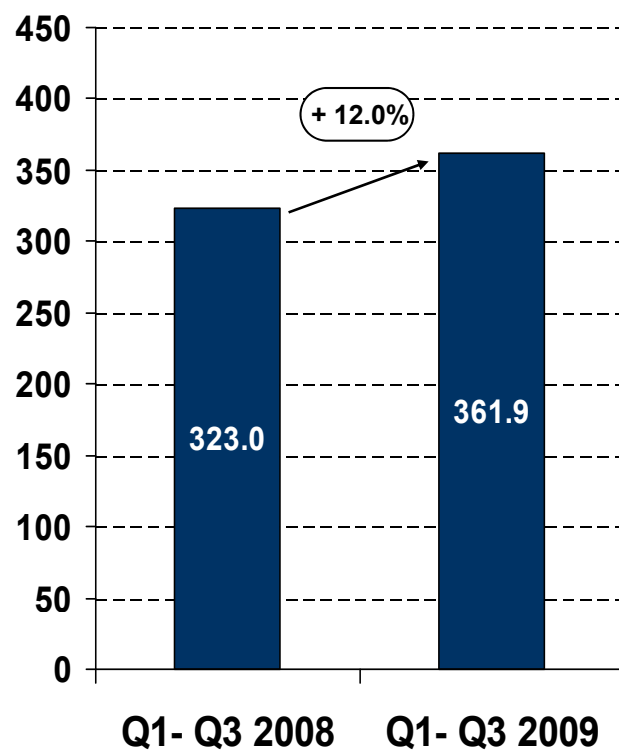
---

## **Biotest to sell Medical Diagnostic business to Bio-Rad**

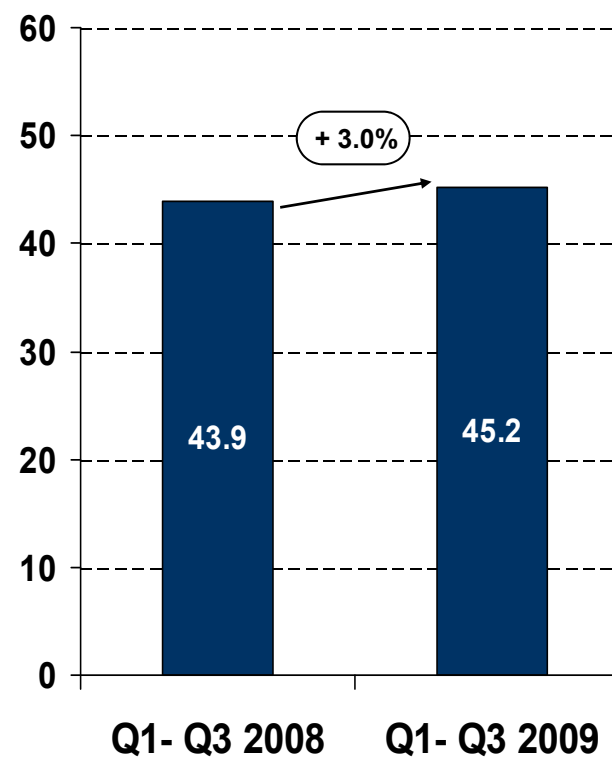
- Contract signed to sell a major part of the Medical Diagnostics segment to Bio-Rad Laboratories Inc. (Hercules, CA/ US)
- Transaction subject to closing conditions, incl. merger approval and is expected to close in first quarter 2010
- Bio-Rad will acquire all shares of Biotest Medical Diagnostics GmbH (Dreieich) and Biotest Diagnostics Corporation (Rockaway/ US), as well as the transfusion and transplantation diagnostics business in Biotest Group's international subsidiaries under an asset deal; H1 revenues of activities to be sold approx. € 21 million
- Purchase price: € 45 million
- Transfer of assets and certain liabilities, except shareholder loans granted to BMD and BDC of approx. € 16 million

## Sales continue to increase, EBIT increase at lower rate

Sales (in € million)



EBIT (in € million)



## Plasma Proteins business drives EBIT

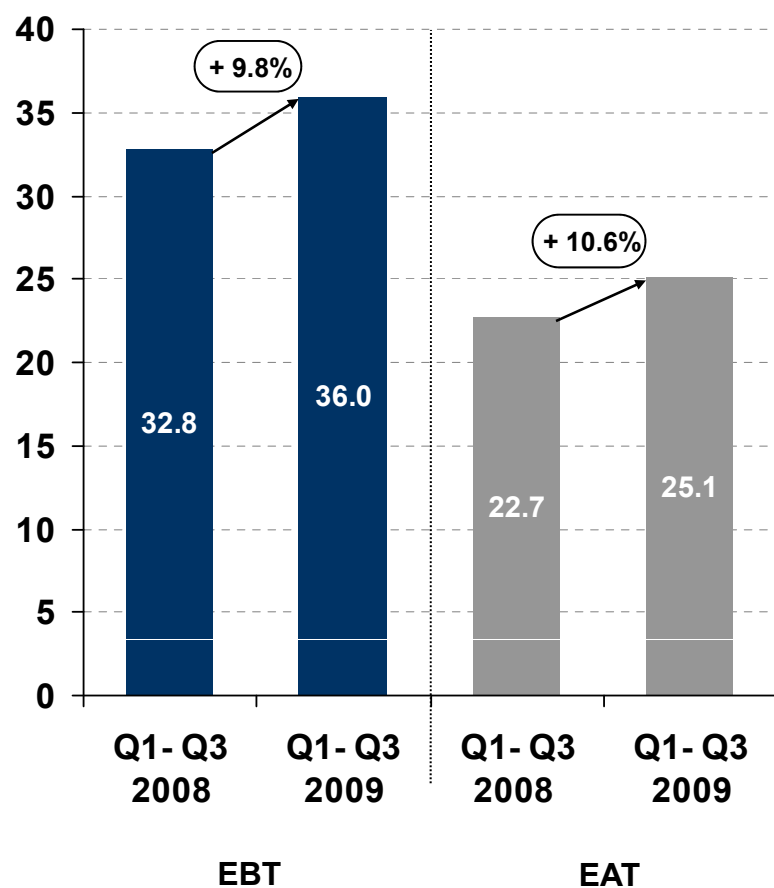
### EBIT by segments (in € million)

	Q1-Q3 2009	Q1-Q3 2008
Plasma Proteins	<b>63.7</b>	60.1
Biotherapeutics	<b>-13.2</b>	-10.1
Microbiological Monitoring	<b>3.7</b>	3.9
Medical Diagnostics	<b>-1.4</b>	-2.5
Corporate/ Reconciliation	<b>-7.6</b>	-7.5

- EBIT of Plasma Proteins segment increased by 6.0 %
- Biotherapeutics EBIT influenced by level of maturity of clinical studies
- EBIT improvement of Medical Diagnostics due to increased sales in the US

## Increase in profit in Q1-Q3 2009

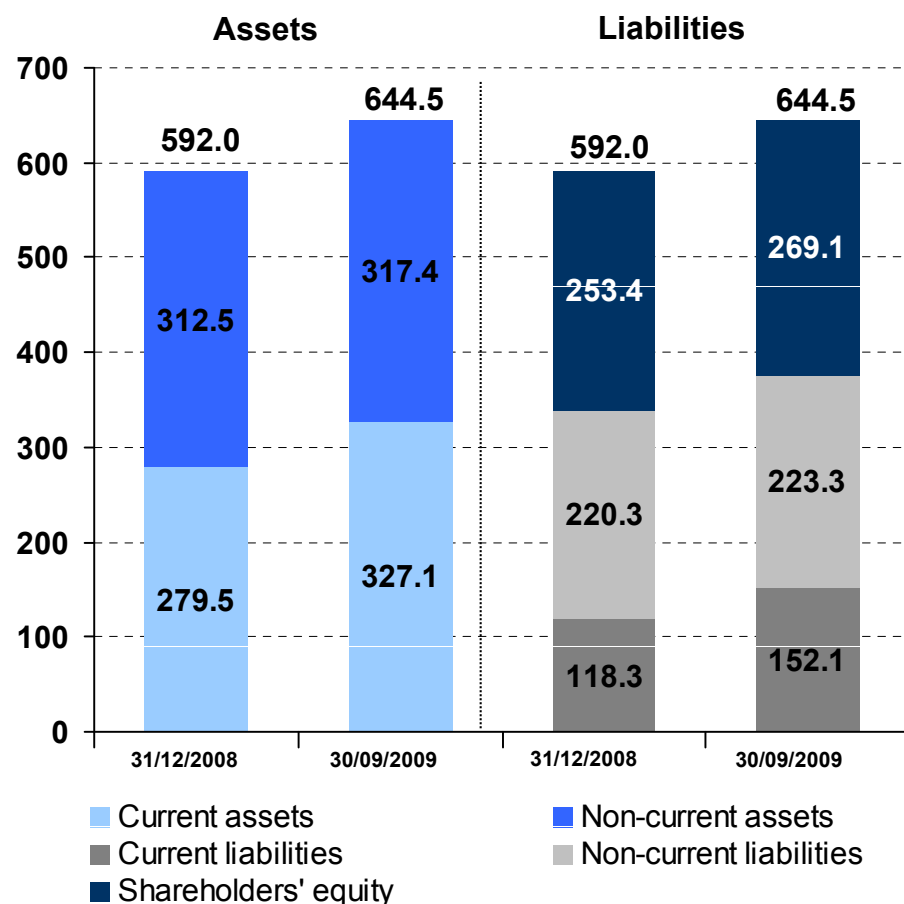
### EBT and EAT (in € million)



- Rise in earnings before tax (EBT), due to more favourable financial result as a result of lower interest expenses
- Earnings after tax (EAT) at € 25.1 million
- Tax ratio: 30.3% (Q1-Q3 2008 : 30.8%)

## Strong balance sheet

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



### Assets

- Higher inventories driven by growth and products which could not be marketed as planned
- Higher Trade receivables due to higher sales volumes mainly in the plasma proteins segment

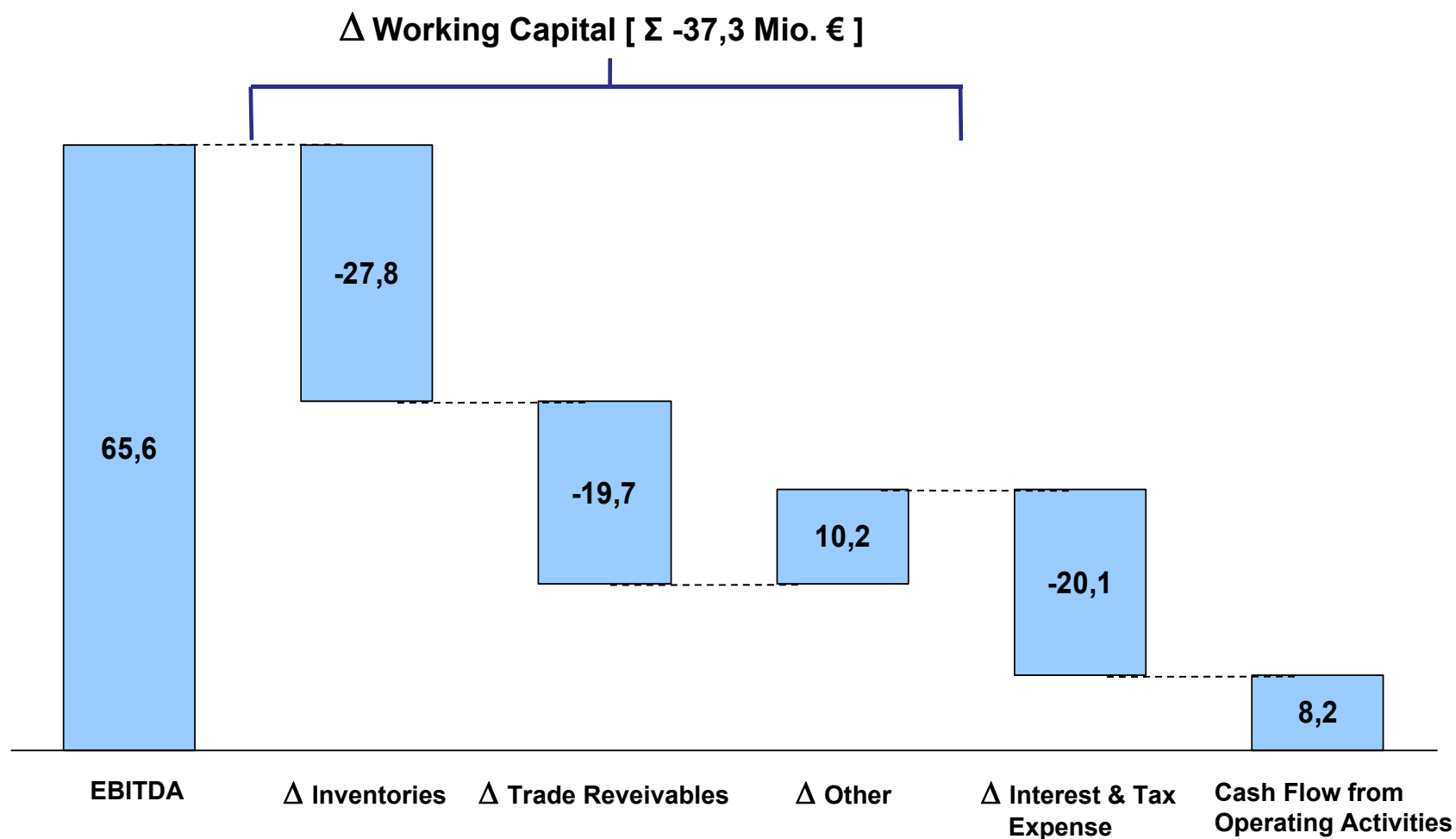
### Liabilities

- Increase in current financial liabilities, primarily corresponding to working capital development
- Equity ratio as of 30 Sept. 2009: 41.8% ( 31 Dec. 2008: 42.8%)



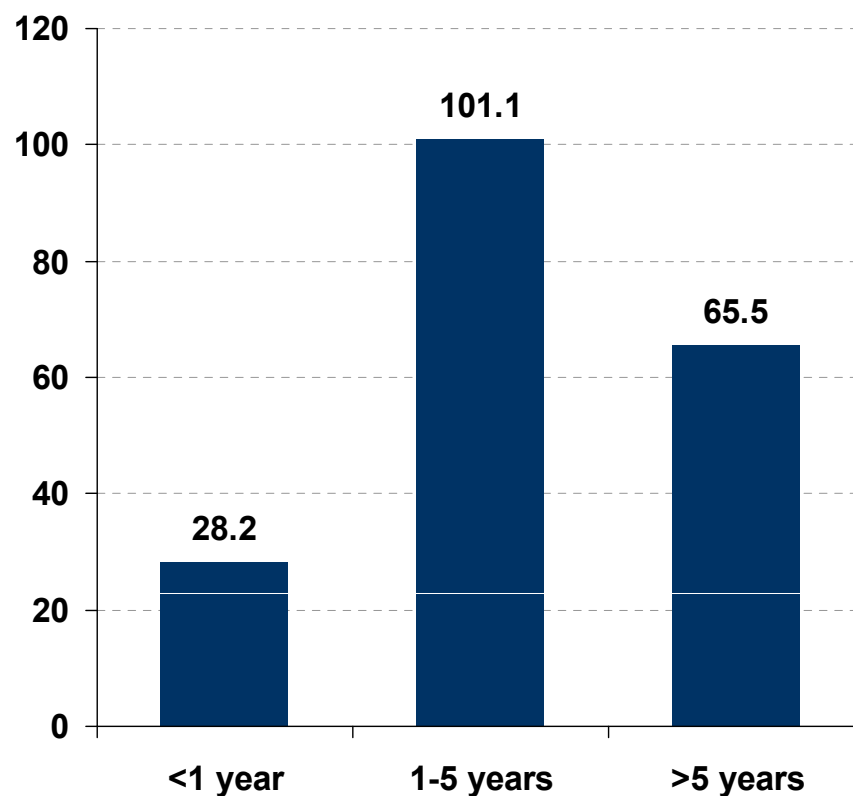
## Cash Flow from Operating Activities in € million

Q1 – Q3 : January – September 2009



## 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

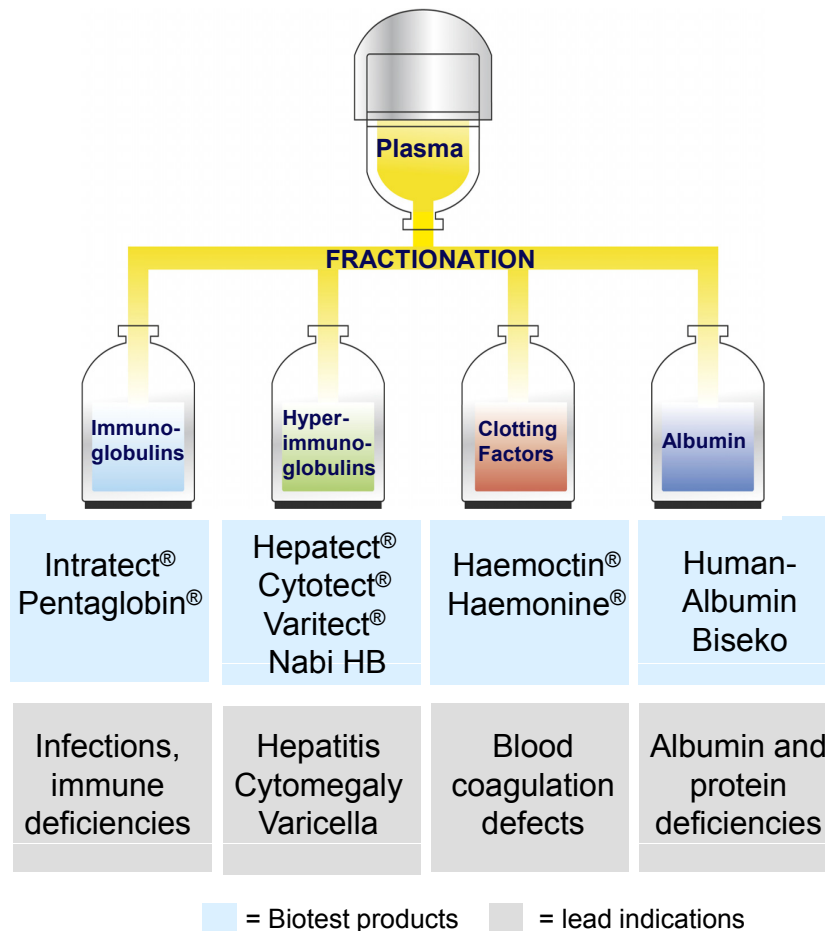


**Biotest Group: Creating Value. Living Values.**

## **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: > 13%, in UK: > 9%
- 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

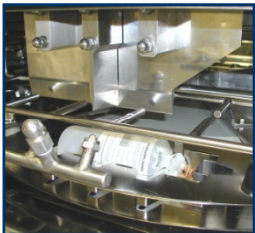


### 1. Plasma Sourcing

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

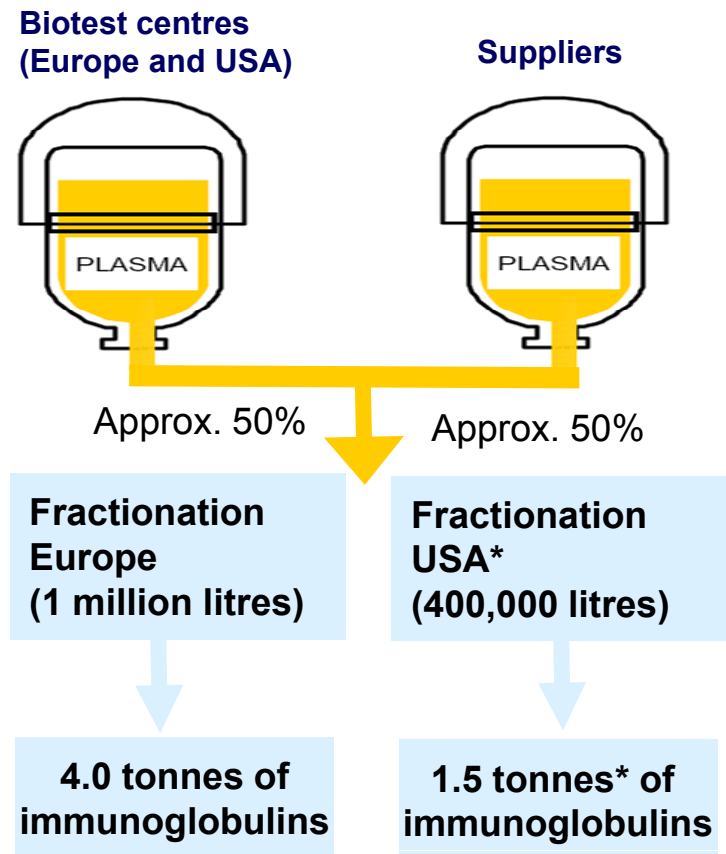
**Virus inactivation**



### 4. Filling and Packaging

## Plasma Proteins production – capacity doubled

### Biotest production network\*



\* In the final construction stages (2010/11)

### 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 H1/ 2011)

### Immunoglobulins:

- Capacity in Dreieich doubled
- Capacity expansion in Boca Raton (1.5 tonnes p.a. from H1/2011)

## Status Projekt IVIG and Boca Raton (USA)

- **IVIG clinical Phase III**

- Clinical phase III study completed
- Finalization of clinical study report in Dec. 2009



- **Enlargement of production facility**

- Construction work part 1 nearly finalised; commissioning of facility has started
- Completion of production facility (part 1) in Q4 2009
- Final completion of utility systems and warehouse (part 2) in H1 2010
- Final capacity:           400.000 l fractionation  
                                  1.5 t immunoglobulin purification

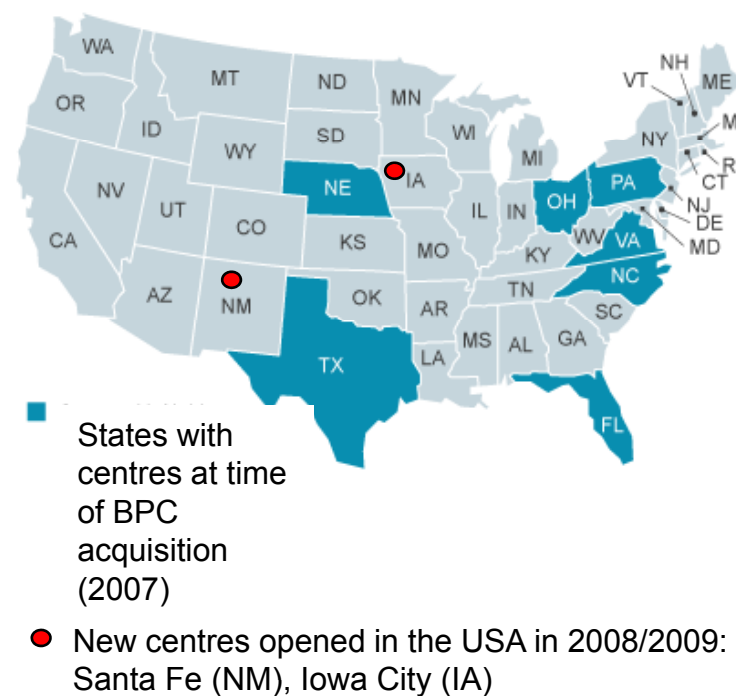
- **Registration of IVIG**

- Submission of BLA to FDA in mid 2010
- Expected approval in H1 2011

## 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

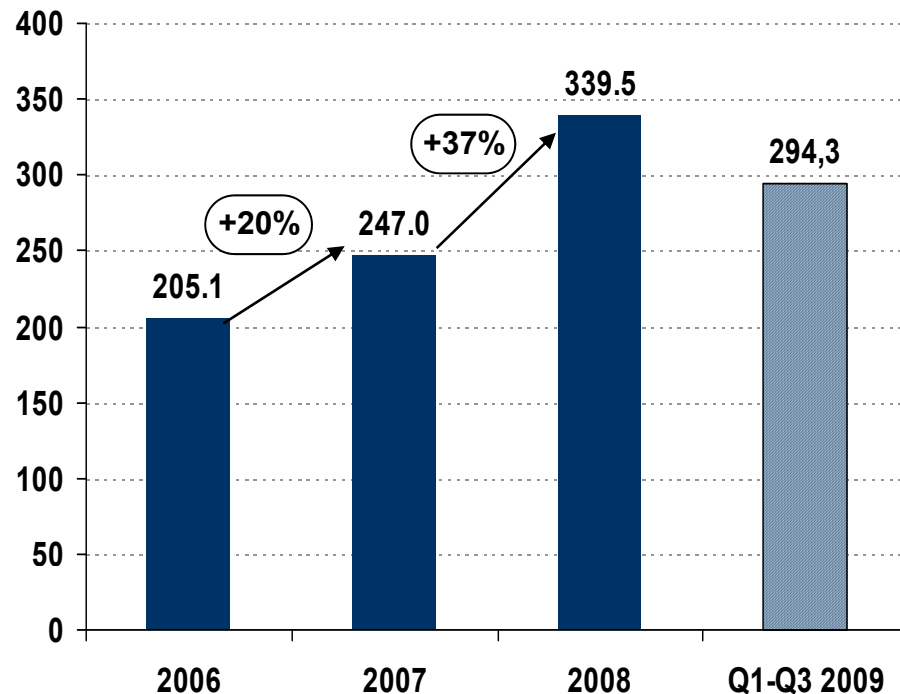
**BPC-run plasmapheresis centres in the USA**





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

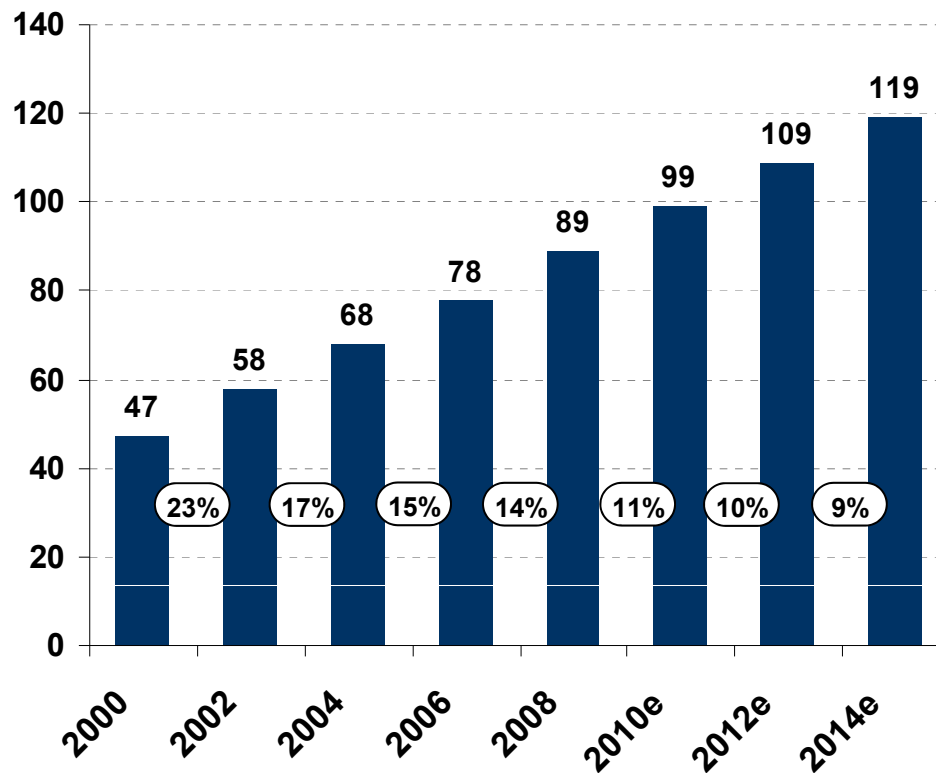
Plasma Proteins: sales volume (in € million)




- Sales in Plasma Proteins jumped by 37% in 2008 (incl. BPC for the first time)
- Contribution BPC in 2008: €64.1m
- In Q1-Q3 2009 Plasma Protein sales increased by 12.8% to € 294.3 million

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

Global IVIG market (in tonnes)



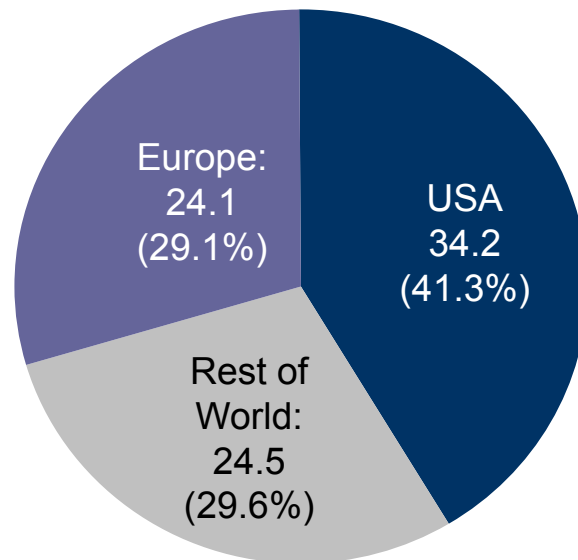
- New indications and higher dosages per capita drive demand for immunoglobulins
- Decrease of prices in major European markets and US

 = 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

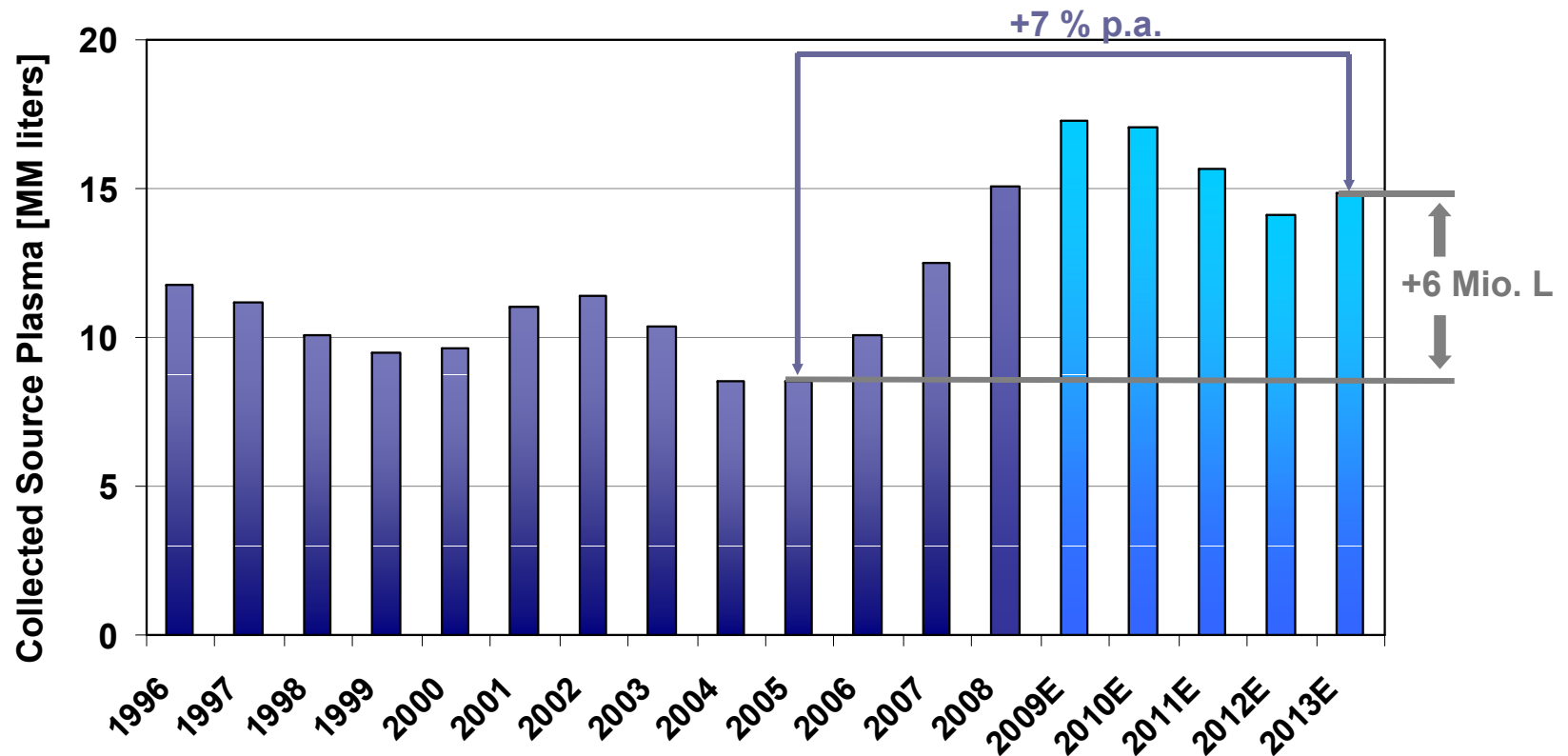
**IVIG world market 2007: volume (in tonnes) and regional distribution (in %)**



- 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

## US source plasma collection forecast, 1996 - 2013



➔ **Plasma collections will increase by 6 MM liters compared to last minimum**

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

## Plasma sourcing trends in the US

### Plasma Centers in US

	2005	2007	2009
April	290	330	<b>401*</b>
May	291	332	400
June	290	334	<b>391</b>

### Collected Plasma in US (litres mio.)

	2005	2007	2009
April	0.68	0.99	<b>1.58*</b>
May	0.67	1.02	1.53
June	0.67	1.02	1.54

\*: Highest number since 2003

### Reaction of plasma industry:

- Closing of first plasma collection centers in the US
- Reduction of opening hours in centers
- Lower compensation paid to donors
- Reduction of plasma collection volumes

Source: PPTA

## Plasma market analysis

- We expect, that plasma sourcing activities will be reduced over time
- This will lead to reduction of inventories
- It is our assumption, that the plasma market environment will stabilise within the next 1-2 years, and therewith also the pricing situation



## Plasma Proteins: Q1- Q3 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 77%
- 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

---

### Approval after 2010:

IVIG (USA):

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

IgM concentrate:

Clinical development Phase I was started in Q2 2009  
Recruitment and treatment of healthy volunteers completed  
Good tolerability observed



## Biotest received positive opinion for Zutectra®

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

**First subcutaneous injectable HBIG for self-administration by the patient**



### **Therapeutic indication:**

- Prophylaxis of HBV re-infection after liver transplantation

### **Properties:**

- Subcutaneous injectable HBIG in a pre-filled syringe = ready-for-use
- High specific activity of 500 IU/ml

### **Clinical Results:**

- Effective anti-HBs-serum levels achieved in all patients in the registration trial with weekly Zutectra® application, no infection

### **Timelines:**

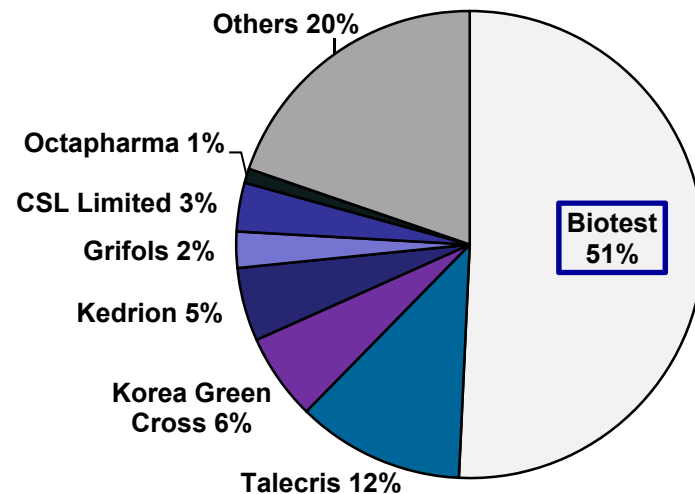
- Positive CHMP\* opinion, Sept. 2009
- EU Commission approval scheduled for December 2009
- Launch in major EU countries in 2010

\*Committee for Medicinal Products for Human Use



## 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

## Two ideal therapies designed for acute and maintenance treatment

..... with proven efficacy and safety



<b>Hepatect® CP</b>	<b>Zutectra®</b>
<p>... will be the gold standard for high dose intravenous application needed in the peri-operative phase after transplantation</p> <p>...additional indications e.g. for post exposure prophylaxis and HBV prophylaxis in newborns</p>	<p>... was especially designed to simplify current treatment and to offer patients more flexibility in their everyday life</p> <ul style="list-style-type: none"> <li>• easy self administration</li> <li>• time and cost saving for physicians and patients</li> <li>• well tolerated and painless injection (only 1ml)</li> <li>• sugar-free</li> </ul>

---

## **IgM Concentrate**

IgM Concentrate is successor product of Pentaglobin®

**Lead indication:** Sepsis

**Current Status:** Phase I Study

- 24 healthy volunteers (18 - 45 years)
- Single dose: n = 18 (incl. Placebo); multiple dose: n = 6
- Recruitment and treatment of healthy volunteers completed
- No major safety issues, no occurrence of SAEs\*

**Phase II preparation activities ongoing:**

- Development of synopsis and study protocol (indication, endpoints, sample size)
- Preparation of PEI and FDA-Advice in Q1 2010

\*: SAE = Serious adverse event

## Summary Plasma Proteins: Biotest made significant progress in implementation of its corporate strategy

- Biotest will grow the Plasma Proteins segment
- Presence in the U.S. market extended
- Regulatory approval for IVIG expected H1 2011  
Market potential for this product in USA estimated to be > \$ 100 m
- Strong R&D pipeline: New products and new clinical indications





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

## **Biotherapeutics**

## Biotherapeutics: investment in projects with potential

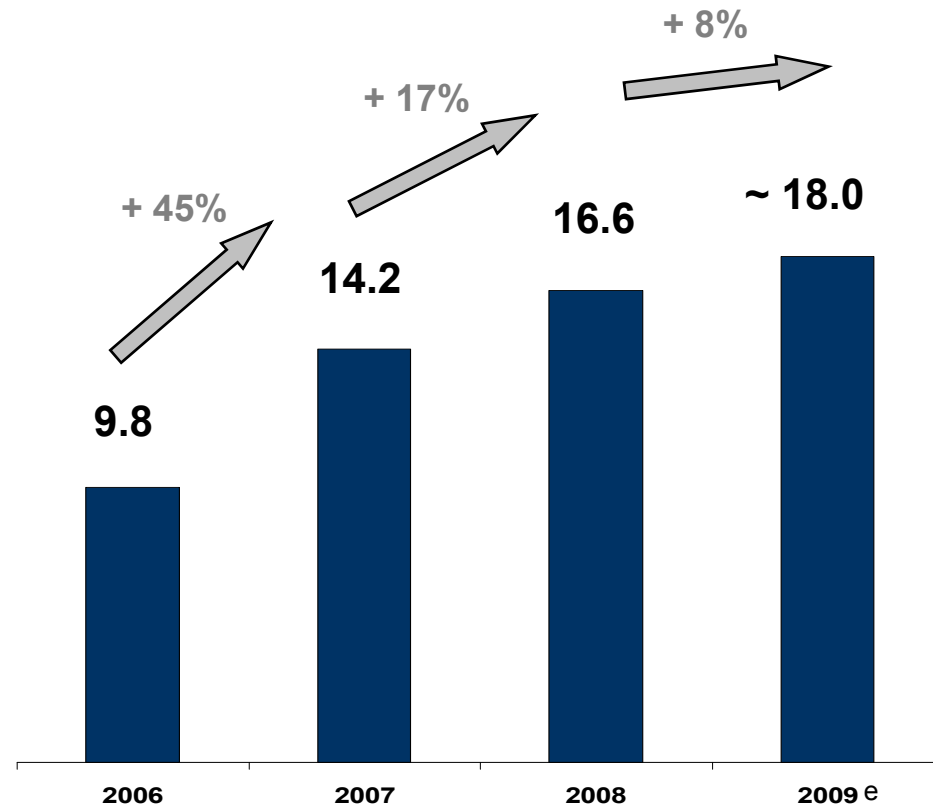
### Common features of Biotest's monoclonal antibodies

- High medical need
- Rapidly growing markets
- Blockbuster potential

### Lead indications

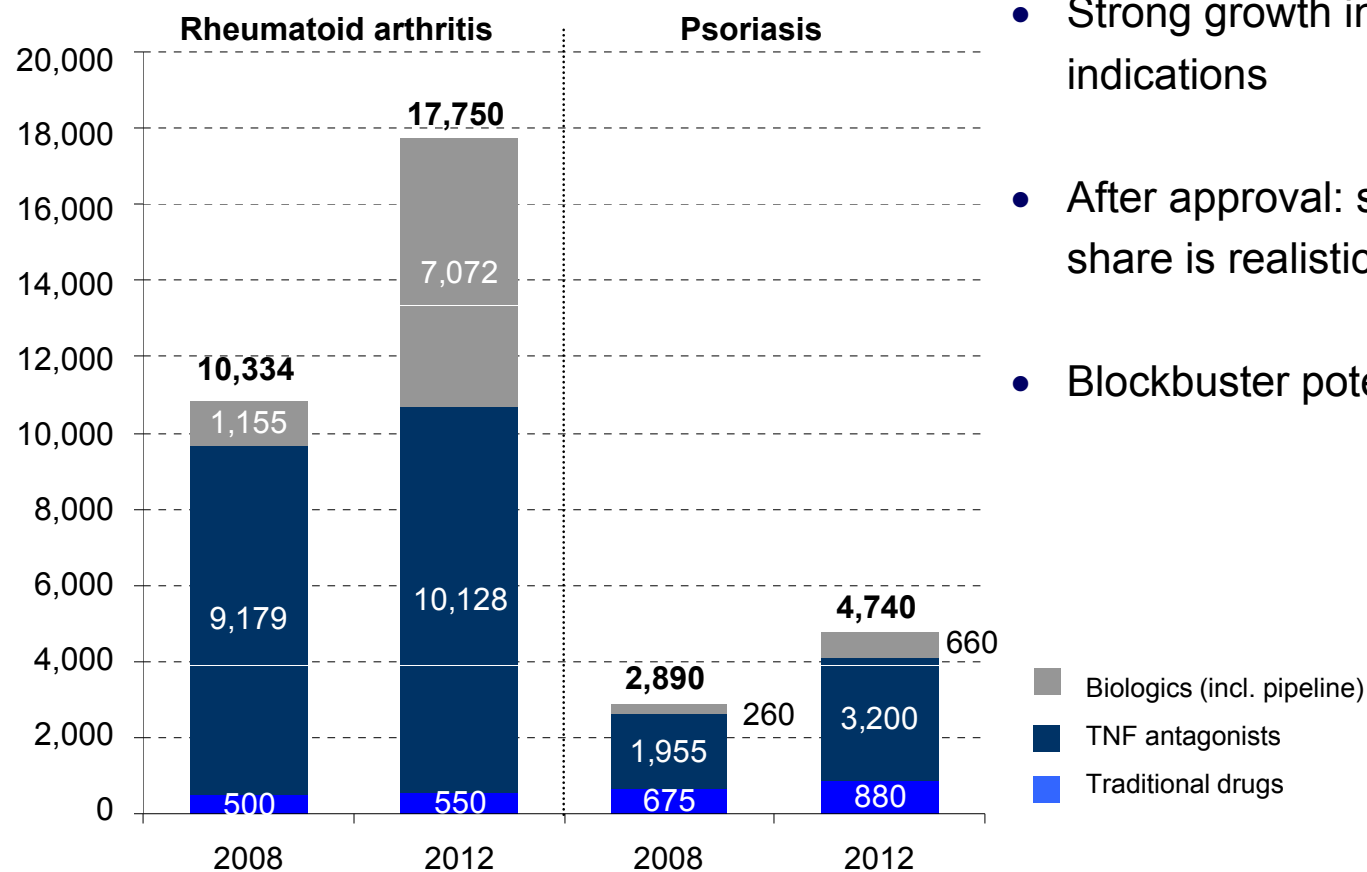
<b>BT-061</b>	Rheumatoid Arthritis, Psoriasis
<b>BT-062</b>	Multiple Myeloma
<b>BT-063</b>	Systemic Lupus Erythematosus and other autoimmune diseases

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



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

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

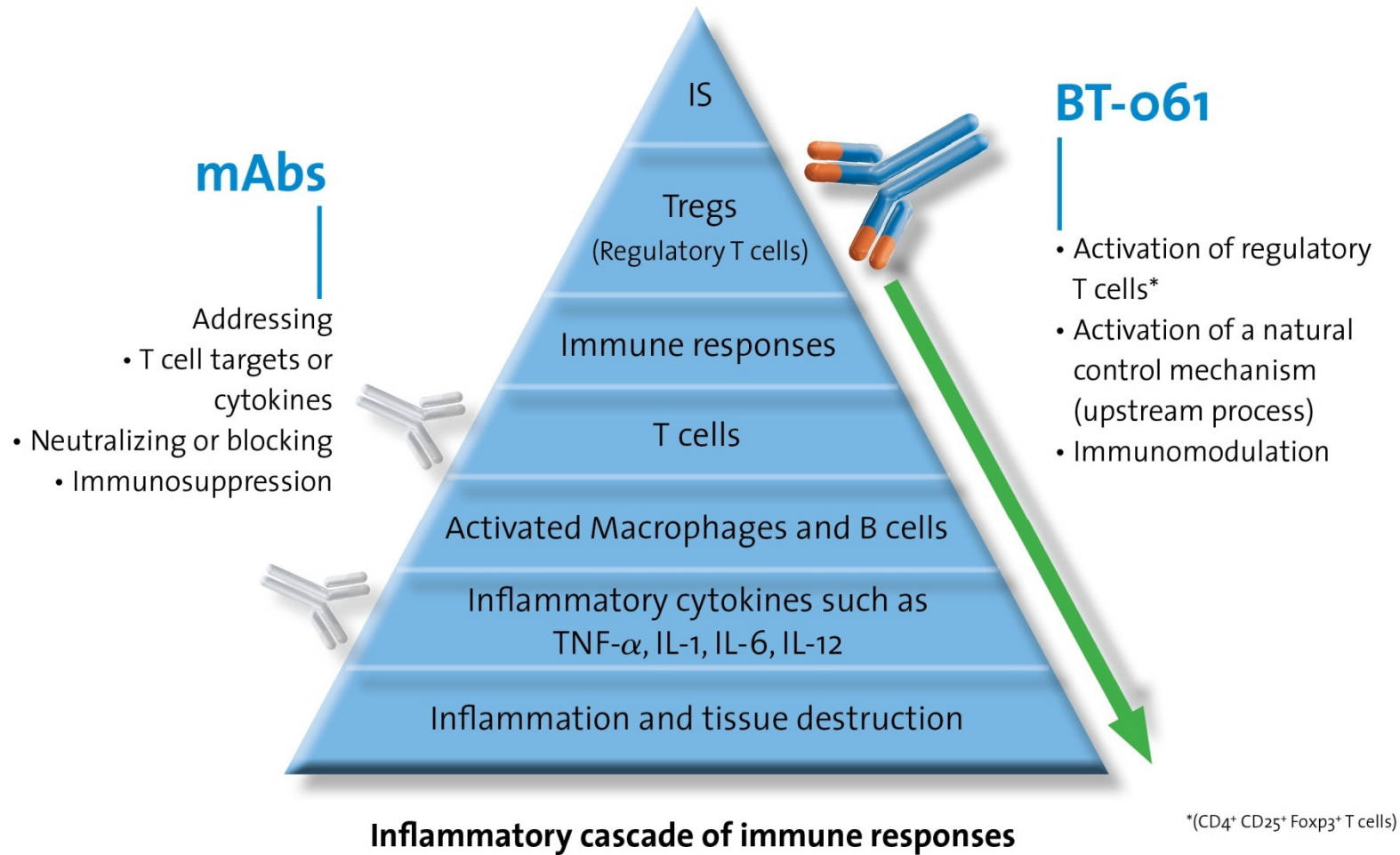


- Strong growth in both lead indications
- After approval: significant market share is realistic
- Blockbuster potential

(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.**

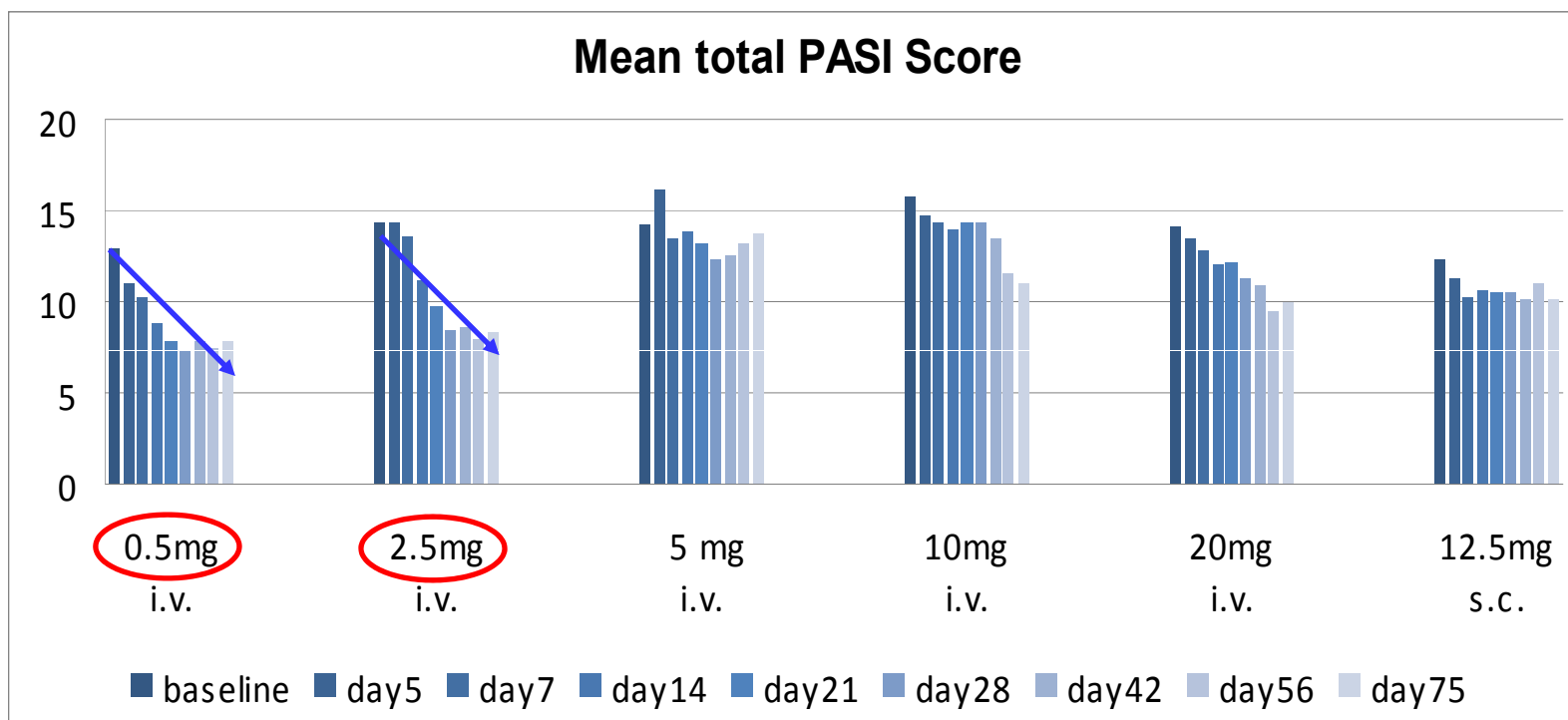
## Clinical development BT-061

### Overview

Study no.	Indication	Design	Subjects planned	Status
961	Healthy volunteers	single dose <i>iv and sc up to 180 mg</i>	57 ✓	Study completed
967	Phase I/IIa: Psoriasis	single dose, placebo controlled <i>iv and sc up to 25 mg</i>	56 ✓	Recruitment completed
973	Phase II: Psoriasis	multiple dose, placebo-controlled	48	Submitted September 09
962	Phase IIa: Rheumatoid Arthritis	multiple dose, placebo controlled	96	Recruitment ongoing
971	Phase II: Rheumatoid Arthritis	BT-061+ MTX multiple dose, placebo controlled	110	Recruitment ongoing

## Study 967 single dose Psoriasis:

Blinded PASI course for all dosing groups\* including placebo patients



➡ **0.5 mg and 2.5 mg single iv dose with a pronounced and long lasting PASI response up to 75 days after single dose application**

PASI = Psoriasis Area and Severity Index)

**\*evaluation of 25 mg sc dose level ongoing**

---

## Monotherapy Rheumatoid Arthritis: Status of Study 962

- Broad dose finding iv and sc
- Most effective dose **iv**: 2 mg
- **Sc**: comparable efficacy at 50 mg
- Higher sc doses currently under evaluation in ongoing study

## Study 971 MTX-Combination Rheumatoid Arthritis: ACR response after multiple applications (Part I)\*

Weekly application for 8 weeks ACR <u>at week 9</u>	0.5 mg BT-061 iv + MTX (n=8)	2 mg BT-061 iv + MTX (n=24)	Placebo iv + MTX (n=8)
ACR 20	5/8 (62.5%)	18/24 (75%)	4/8 (50%)
ACR 50	1/8 (12.5%)	10/24 (41.7%)	2/8 (25%)
ACR 70	1/8 (12.5%)	4/24 (16.7%)	0/8 (0%)

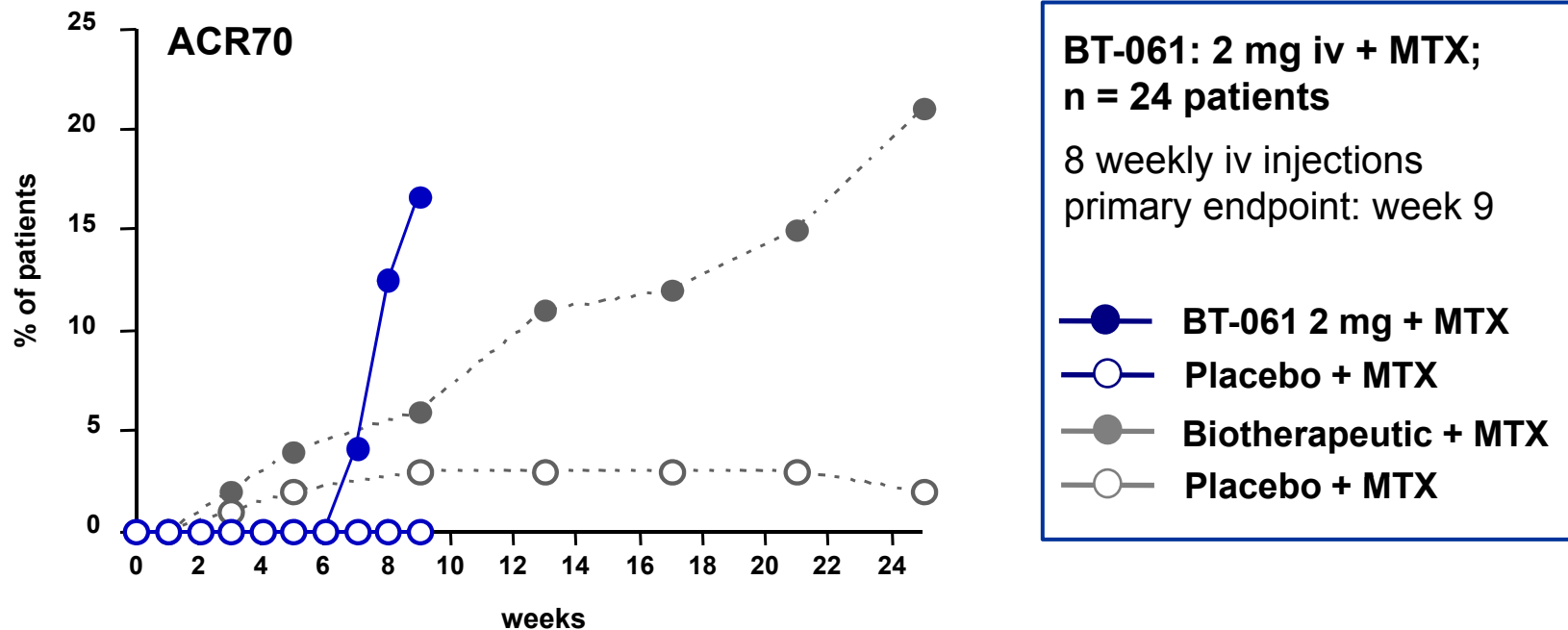
➔ **In part II 40 patients with 50 mg sc  
treatment will be included**

\*Data cut off: September 2009,  
Unblinded Data from Interim Analysis (n=40)

## Study 971 MTX-Combination Rheumatoid Arthritis:

Kinetic of ACR70 response (%) of BT-061

Compared to other biotherapeutic<sup>1</sup> (TNF- $\alpha$  antagonist, no direct comparison<sup>2</sup>)



➡ Improvement up to ACR 70% in 17% of patients after iv application of 2 mg BT-061 + MTX

➡ Data of 50 mg sc dose level (Part II of Phase II trial) are not yet available

<sup>1</sup>Source: Keystone, 2004

<sup>2</sup>Please note: data from independent trials are not directly comparable as patient characteristics, route of administration, dose levels and treatment frequency are different

---

## **BT-061: summary clinical results**

### **Psoriasis :**

- Pronounced and long-lasting reduction of PASI scores observed in single dose psoriasis study at very low doses (0.5 mg iv, 2.5 mg iv)

### **Rheumatoid Arthritis:**

- Competitive ACR20, 50, 70 responses at 2 mg iv and 50 mg sc
- Higher response rates anticipated by further dose optimization and prolongation of treatment period
- Still sharp increase of ACR responses at week 9: further improvement expected with continued treatment
- Typical plateaus of ACR response observed for biologics not reached yet\*

---

\*expected plateaus: ACR20 after 3 months; ACR50 after 4 months; ACR70 after 6 months

PASI = Psoriasis Area and Severity Index)

---

## **BT-061: clinical development**

### Next steps

#### **Rheumatoid Arthritis:**

- Ongoing Phase II combination trial (+ MTX):
  - treatment of additional patients with 50 mg sc in combination with MTX
- New Phase II clinical trial planned:
  - inclusion of more patients (200-300) in relevant dose levels
  - extension of treatment period up to 3 month

 **broadening efficacy and safety data base**

#### **Psoriasis:**

- Phase II clinical trial (48 patients) submitted:
  - first patient expected to be included in December 2009
  - finalization of dose-finding (focus on sc administration)
  - repeated weekly dosing and extension of treatment period up to 8 weeks

 **higher response rates expected**



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

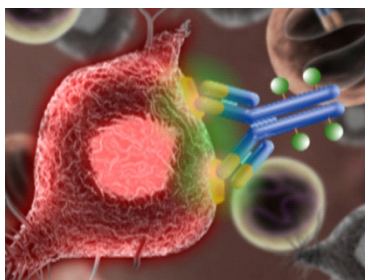
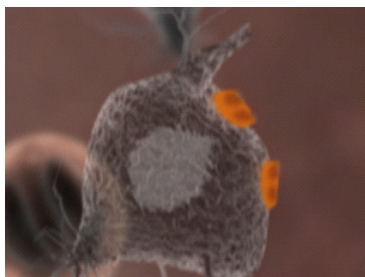


### **Biotest strategy:**

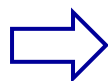
**Co-development and co-marketing with “big pharma” from clinical Phase III onwards**

- Start of partnering process successful
- Global pharmaceutical groups approached (“big pharma”)
- Predominantly positive response
- Close interactions with selected companies
- Further data will be submitted (Q4/2009)
- Request of non-binding offer
- Agreement expected in H1/2010

## 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
- Indications of efficacy already with low dosages:
  - **Disease progression halted in some patients for several months**
  - **Seventh dose level completed (maximal tolerated dose identified)**
  - **publication of first data on scientific congress<sup>1</sup>**

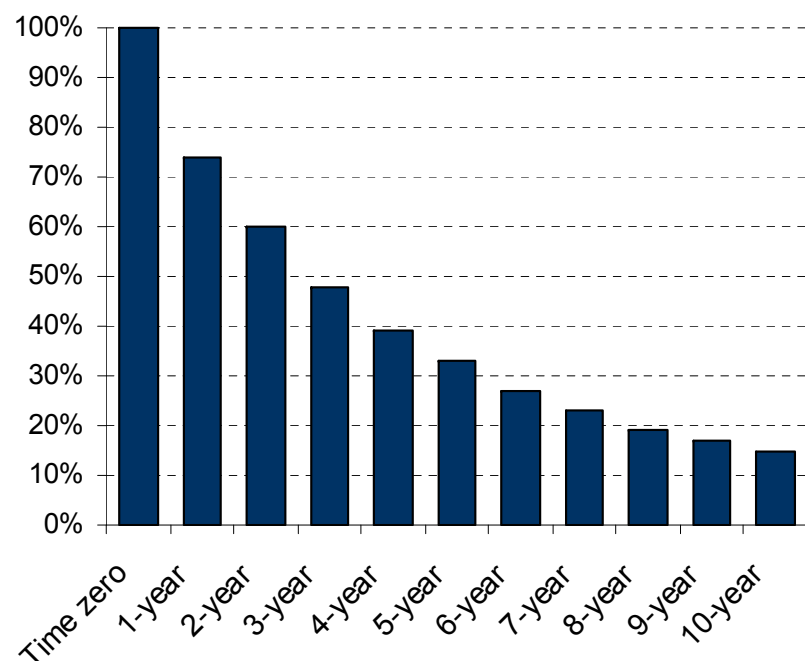


Based on positive results from Phase I trial, a US- based multidose trial (Phase I/IIa) has been submitted in October 2009

<sup>1</sup>American Society of Haematology, Dec. 2009

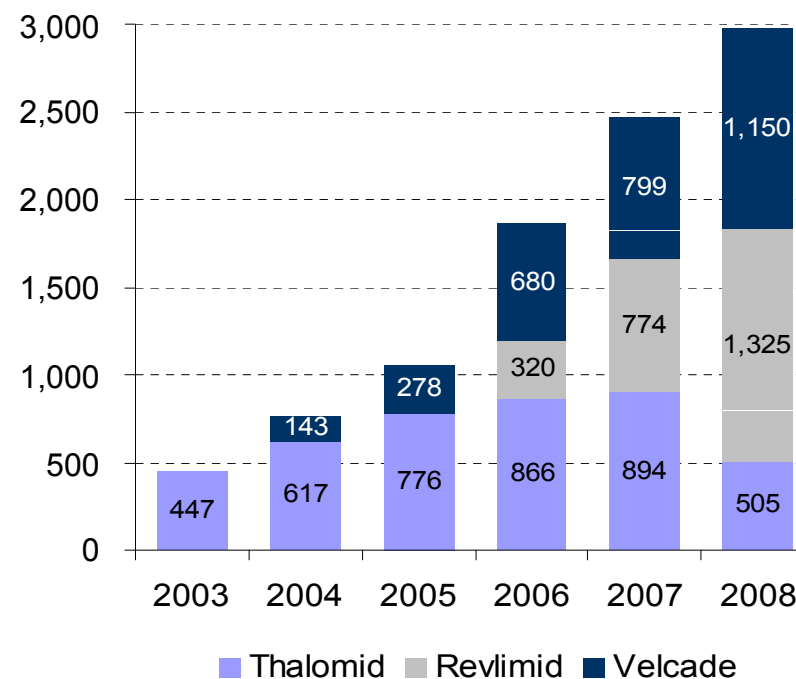
## Multiple Myeloma – unmet need and high market potential

### Survival rates for MM patients in the USA



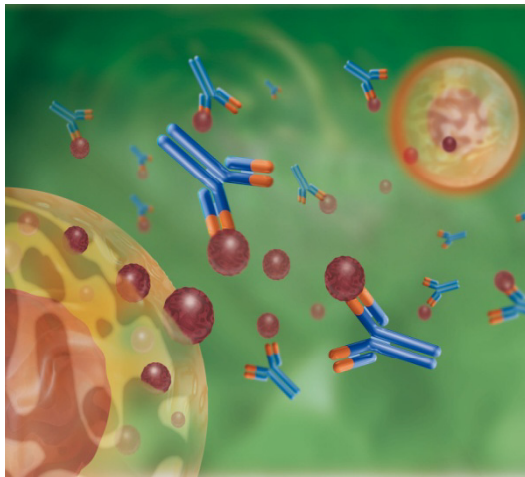
(Source: SEER Cancer Statistics Review, 1975 - 2004)

### 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

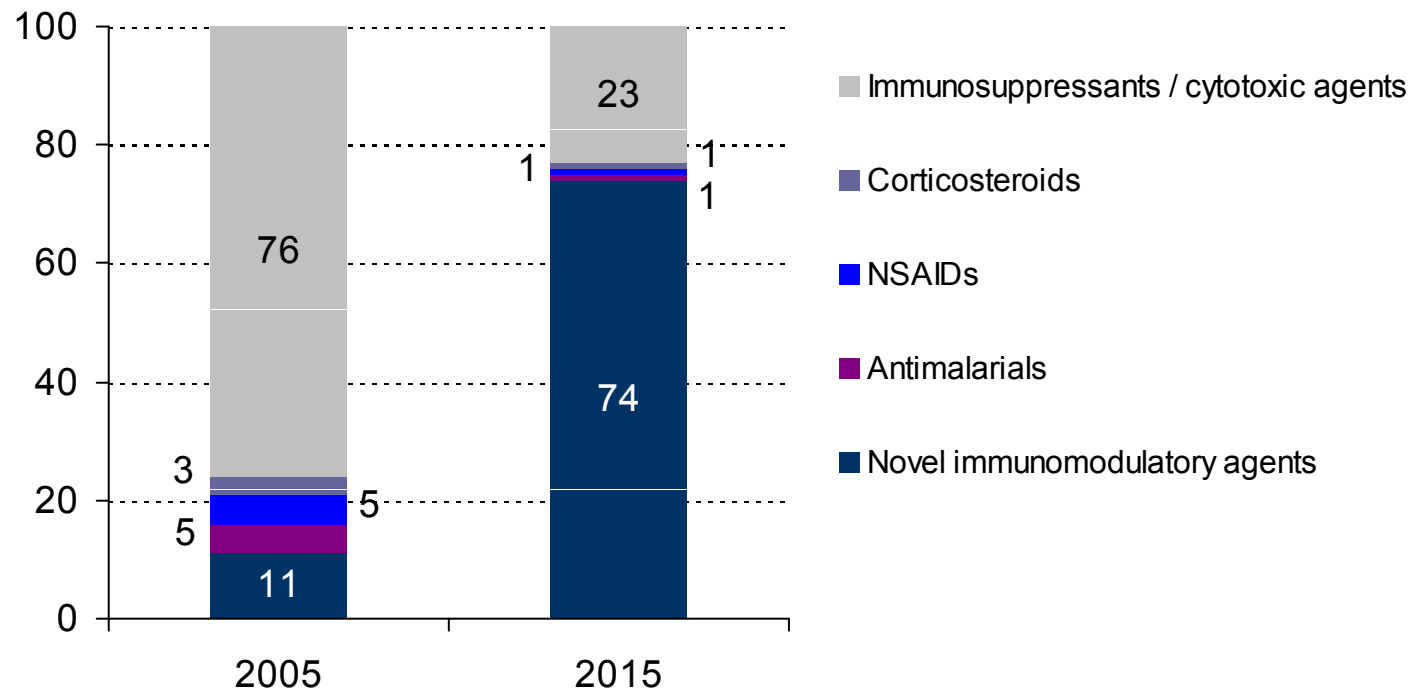
### Clinical development

- Phase I trial has started in healthy volunteers in October 2009

## BT-063: expected SLE market development

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

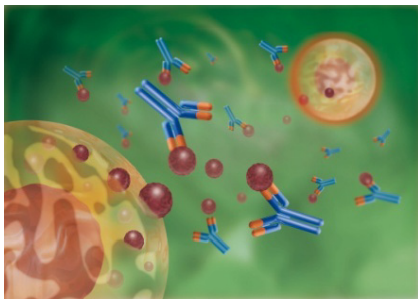
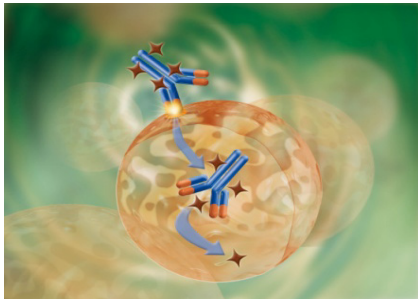
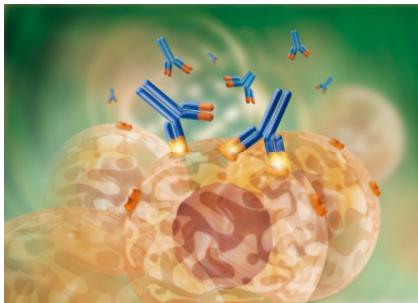
### Market share of SLE therapies (in %)



Source: Decision Resources, Inc., 2006

## Outlook Biotherapeutics: reach new development stage

### Significant progress with all projects



#### **BT-061:**

- clear proof-of-concept in RA and Psoriasis
- last patient of Phase I / IIa clinical trial in Psoriasis recruited
- additional Phase II trial in Psoriasis will start in Dec. 2009
- new Phase II trial in RA with 200-300 pts will be submitted in H1/2010
- partnering process ongoing

#### **BT-062:**

- first indications of efficacy from dose-escalating study
- multidose trial submitted in October 2009

#### **BT-063:**

- Phase I trial started in September 2009
- first healthy volunteers treated

#### **Production:**

- Set-up of own manufacturing of monoclonal antibodies progressing well at BPC



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

## **Microbiological Monitoring and Medical Diagnostics**

## 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 Q1-Q3 2009: €31.3 million (+9.1%);
- 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

## Medical Diagnostics: reagents and system solutions

### Transfusion



Identification of blood groups  
Search for antibodies

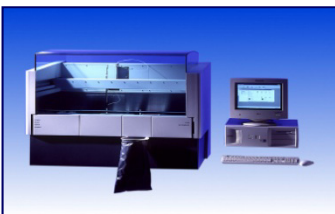
#### Main products:

- 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
  - Telpnel

## 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 Q1-Q3 2009 to € 36.3 million (+9.0%) – however, sales and profit development remain unsatisfactory
- Purchase Agreement signed with Bio-Rad; Closing of the transaction is expected in Q1/2010

## **Outlook 2009**

### **Our goals for the year 2009:**

- Increase in sales of about 10 %, EBIT on last year's level at 55 € m
- EBIT 2009 on level of 2008 due increased pricing pressure in plasma protein segment, potential exchange rate impact and unabsorbed facility costs resulting from expansion of production capacity
- Economic crisis has had no significant impact to date – however, increased vigilance is necessary

---

## 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 2010

### Investor Relations Biotest AG:

Dr. Monika Buttkerleit  
Head of Investor Relations

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

### Financial Calendar 2010

19 March 2010	FY 2009 Results Analyst Conference
6 May 2010	Annual General Meeting
11 May 2010	Q1 Results
12 August 2010	H1 Results
8 November 2010	Q1-Q3 Results 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