

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



**Analyst Conference – Q1-Q3 2009**  
**Frankfurt/Main, November 5, 2009**

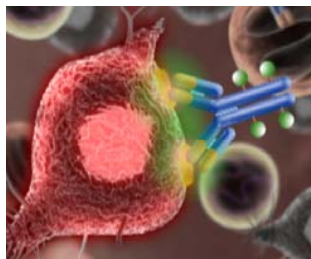
## **Disclaimer**

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

## 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.

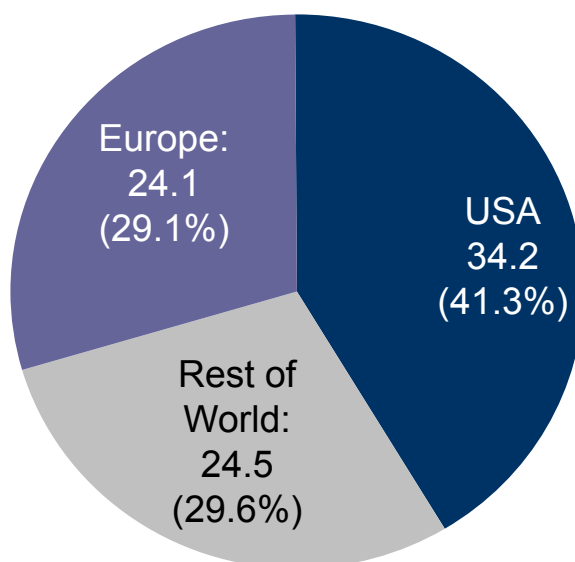


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## **Plasma Proteins**

## Current market environment and pricing situation for polyspecific immunoglobulins

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



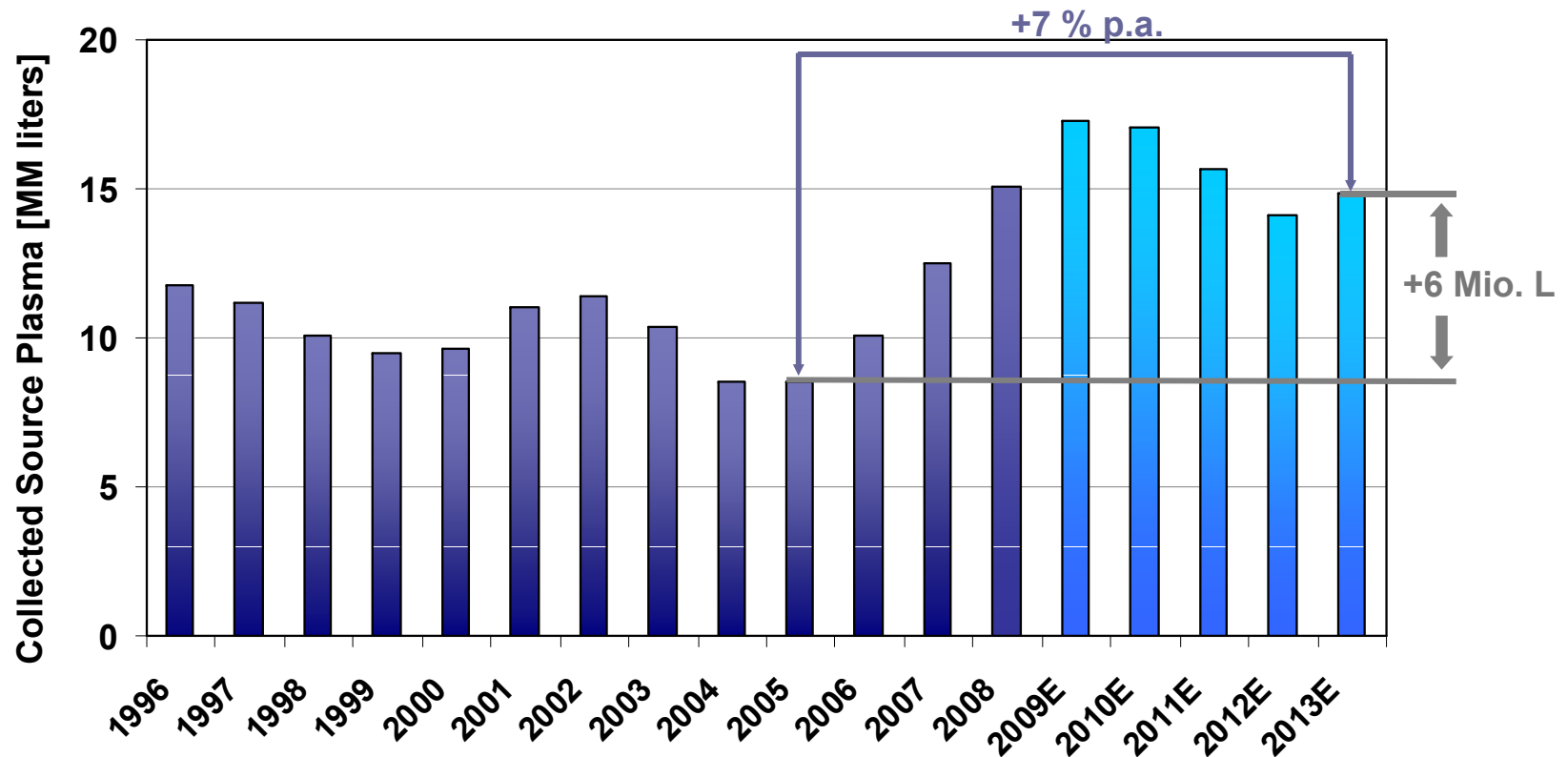
- Total volume IVIG world market as of 2008: ~ 90 tons
- USA by far the most important market for IVIG worldwide

### Current Market trends

	<b>US</b>	<b>EU</b>	<b>RoW</b>
Volume Growth	5-6%	2-4%	4-5%
Price:	~ 67 \$/g	~ 35-45 €/g	~31-45 €/g

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





## 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

## 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:**

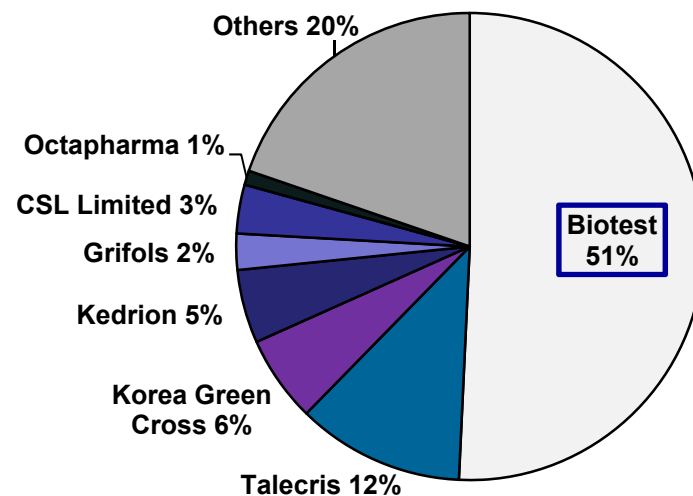
- Positive CHMP\* opinion, Sept. 2009
- EU Commission approval scheduled for December 2009
- Launch in major EU countries in 2010

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

## 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>

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## **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

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## **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



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## **Biotherapeutics**

## Clinical development BT-061

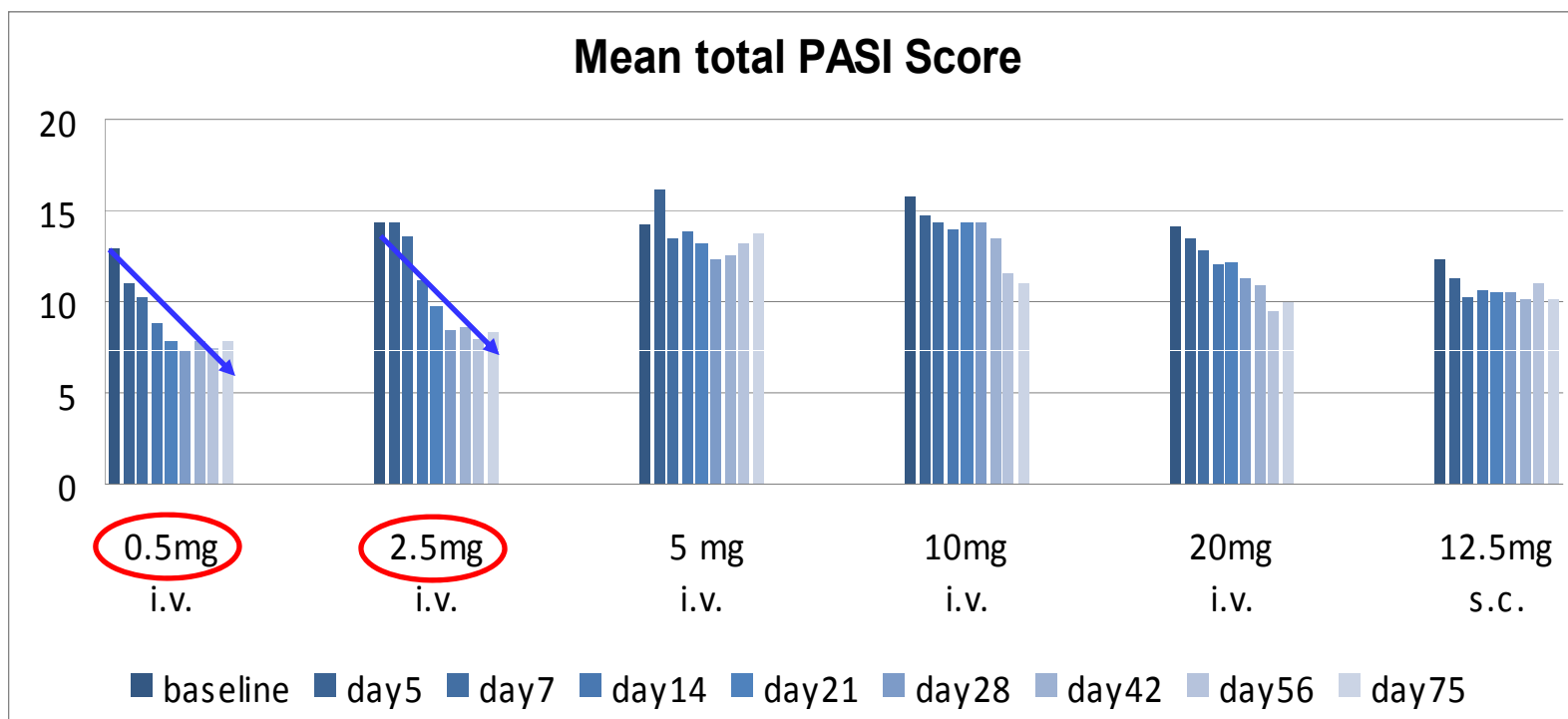
### Overview

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**

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## 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%)

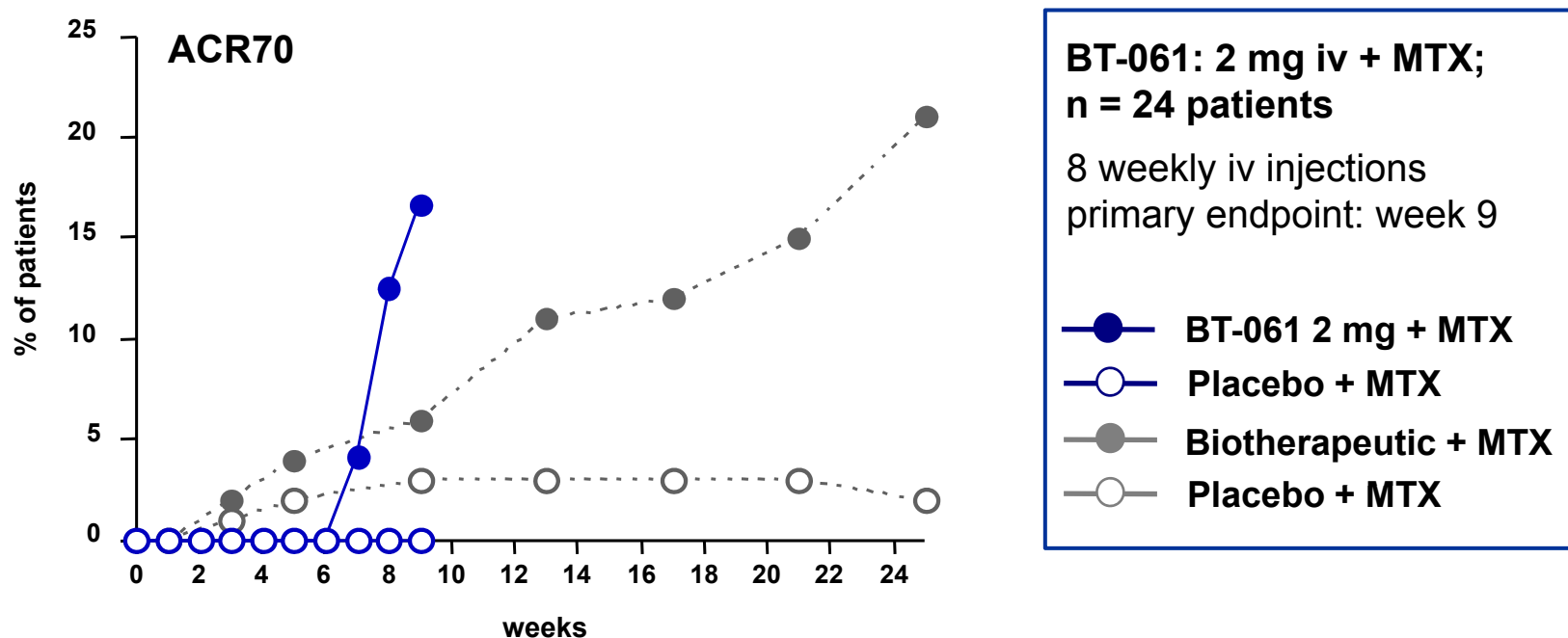
➔ **In part II 40 patients with 50 mg sc  
treatment will be included**

\*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

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## **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\*

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

PASI = Psoriasis Area and Severity Index)

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## **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

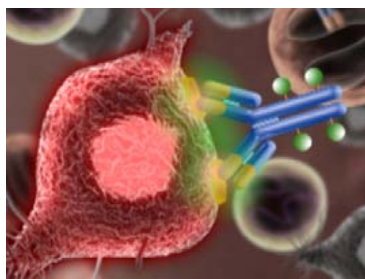
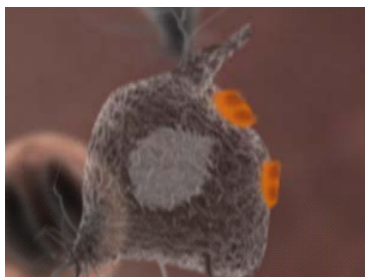


### **Biotest strategy:**

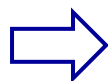
**Co-development and co-marketing with “big pharma” from clinical Phase III onwards**

- 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>**

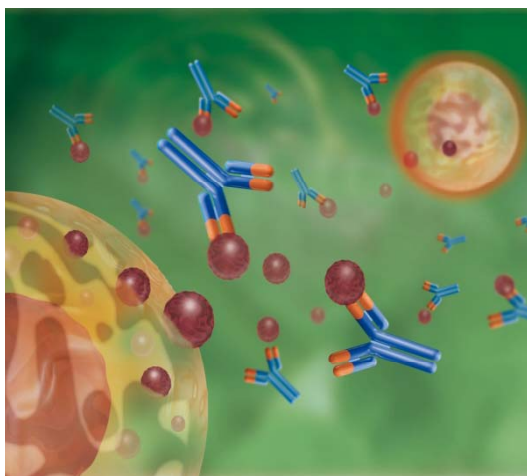


Based on positive results from Phase I/IIa trial, a US- based multidose trial (Phase II) has been submitted in October 2009

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

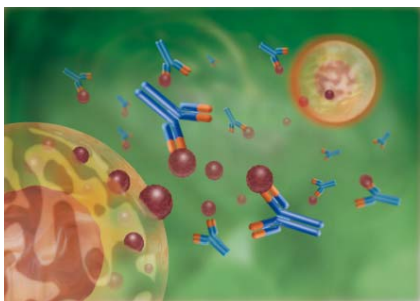
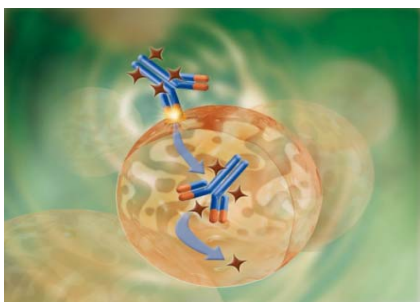
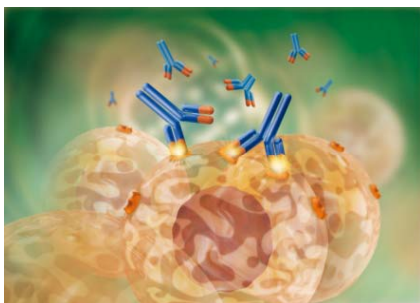
- BT-063 positively modulates the immune system in this indication
- Few other biologics in development: mostly anti B cell antibodies

### Clinical development

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

## 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



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Financials Q1-Q3 2009**

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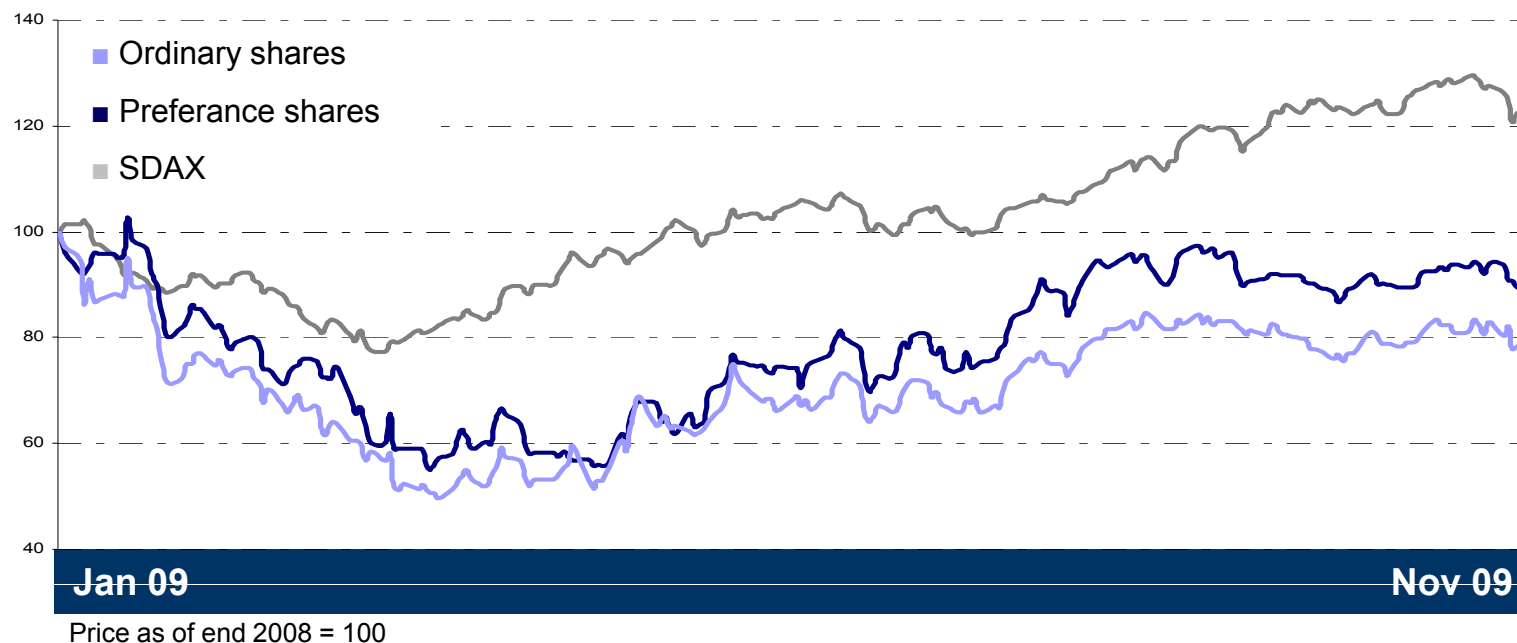
## **Biotest to sell Medical Diagnostic business to Bio-Rad**

- 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

## Biotest shares: positive development in 2009

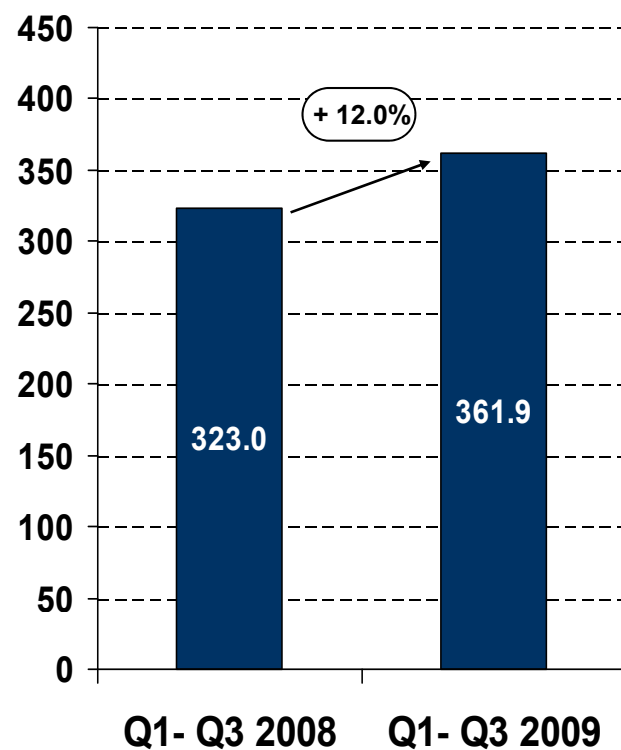
- Decline of share price after majority shareholder terminates discussions about shares's sale
- Share price increase triggered by positive news flow

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

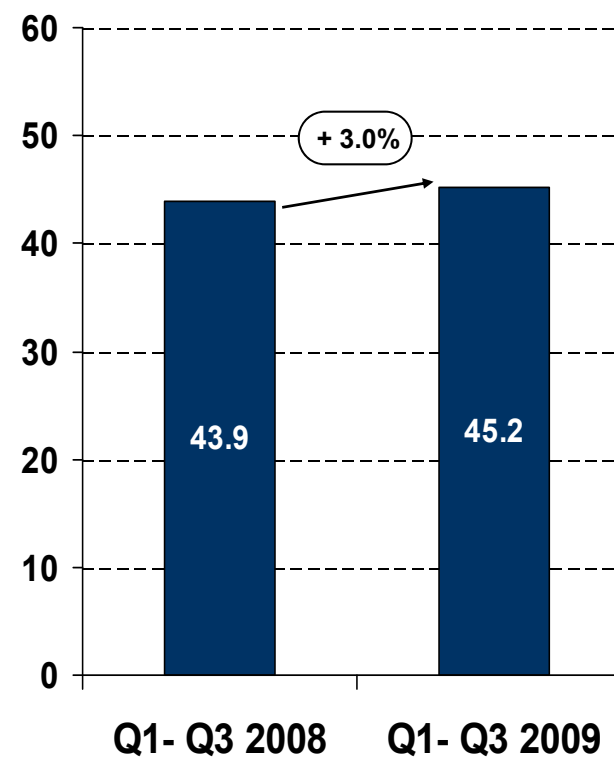


## Sales continue to increase, EBIT increase at lower rate

Sales (in € million)



EBIT (in € million)



## Plasma Proteins business drives EBIT

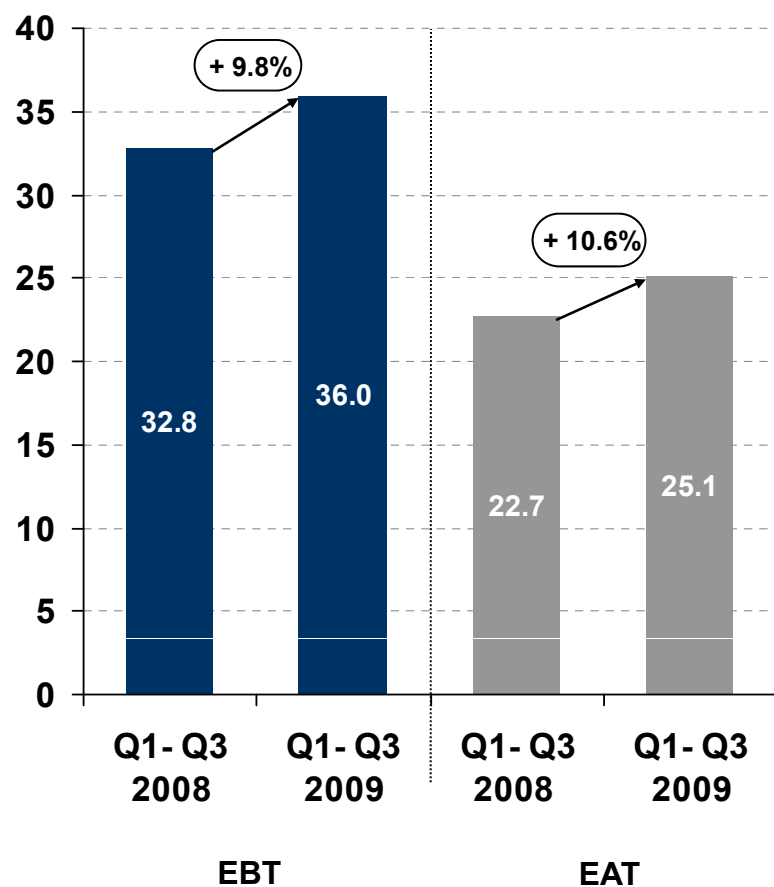
### EBIT by segments (in € million)

	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)

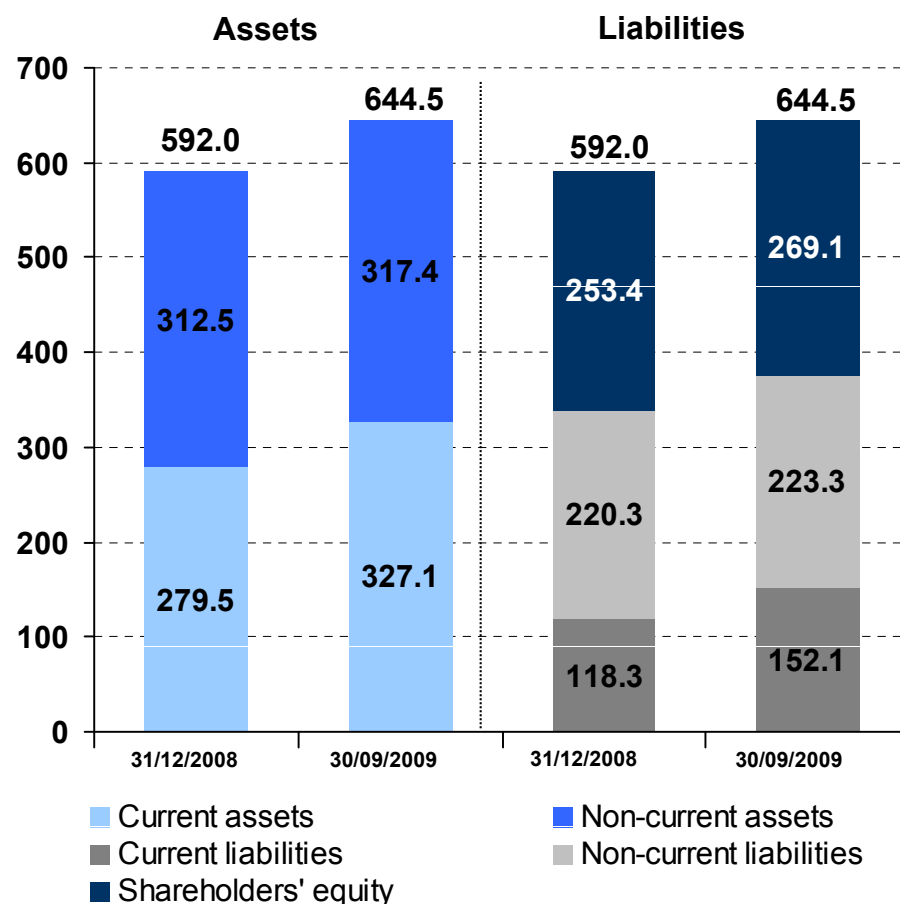


- Rise in earnings before tax (EBT), due to more favourable financial result as a result of lower interest expenses
- Earnings after tax (EAT) at € 25.1 million
- Tax ratio: 30.3% (Q1-Q3 2008 : 30.8%)



## Strong balance sheet

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



### Assets

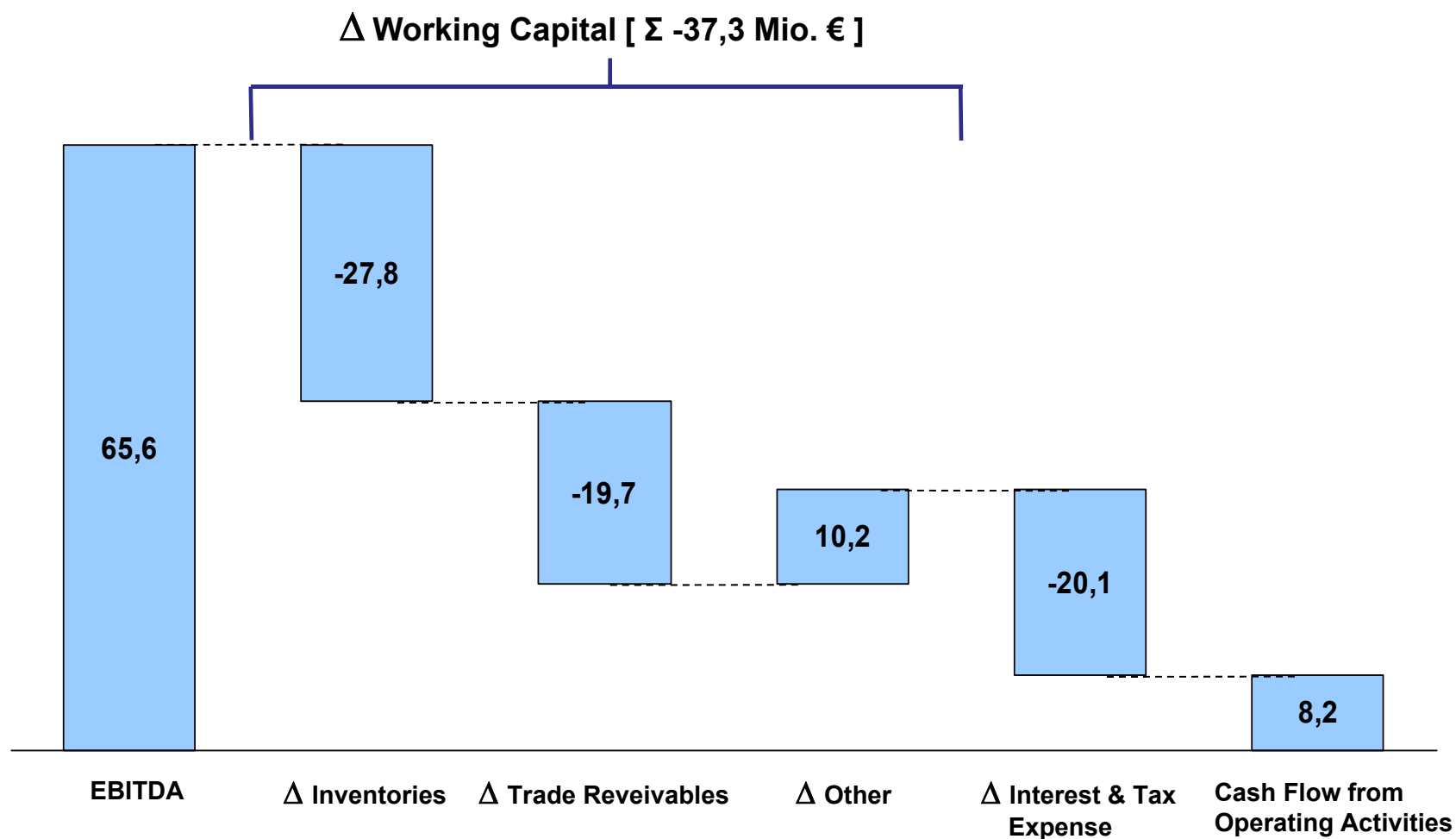
- Higher inventories driven by growth and products which could not be marketed as planned
- Higher Trade receivables due to higher sales volumes mainly in the plasma proteins segment

### 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



## **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

**Thank you for your attention!**



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## Contact and Financial Calendar 2010

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### 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