

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



**UniCredit Group - German Investment Conference 2009** 

**Dr. Michael Ramroth** 

22 September, 2009



### H1 2009 - Highlights





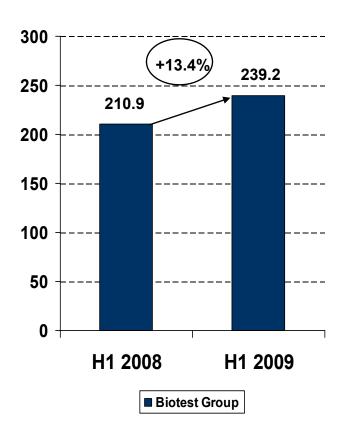


- Biotest Group Sales up by 13.4% in H1 2009 and EBIT increased by 6.5%
- Confirmation of 2009 Guidance:
   Sales +10% and EBIT at € 55m
- Medical Diagnostics: Exclusive negotiations with one party to sell the business area
- Production capacity expansion
- Biotherapeutics: further data demonstrating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

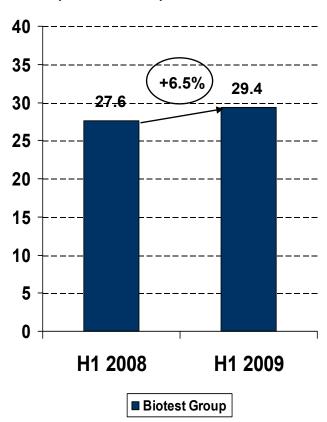


### Sales and EBIT continue to increase

#### Sales (in € million)



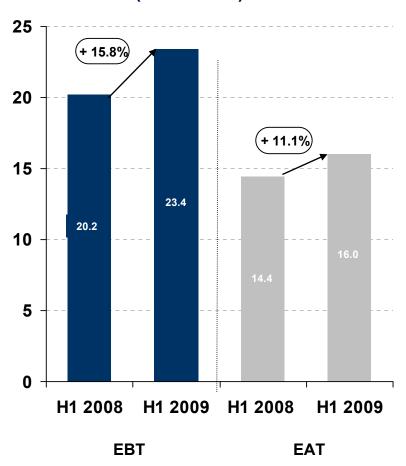
#### **EBIT** (in € million)





### **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%)





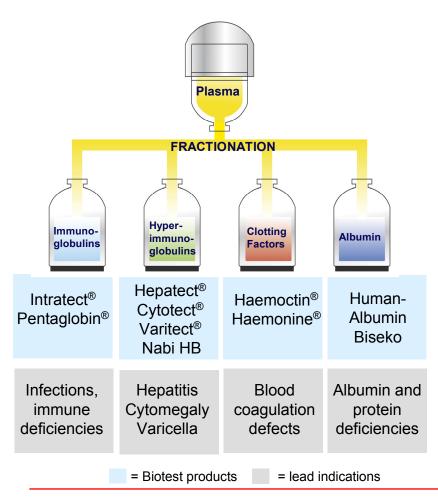
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## **Plasma Proteins**



### Plasma Proteins business at a glance

#### **Biotest Plasma Protein products**

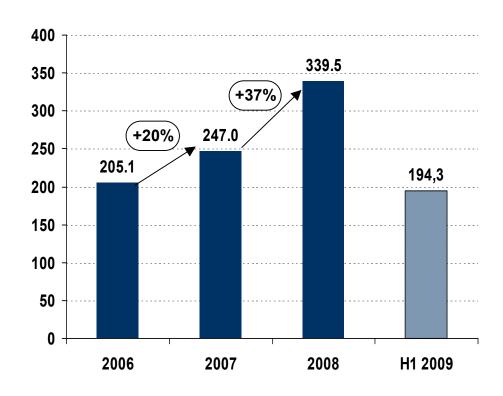


- Global market share: 3%
- Market share in relevant markets (GER, AUT, CH, GRE, UK): 14%
- Intratect<sup>®</sup> market share in GER, AUT, CH: > 16%, in UK: > 8%
- World market leader with Cytotect<sup>®</sup> and Varitect<sup>®</sup>
- Leading position with Hepatect<sup>®</sup> in Europe and Nabi HB<sup>TM</sup> in USA
- Biotest covers full value creation chain:
   plasma sourcing, production, distribution
   vertical integration leads to
   rationalisation and higher productivity



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

#### Plasma Proteins: sales volume (in € million)

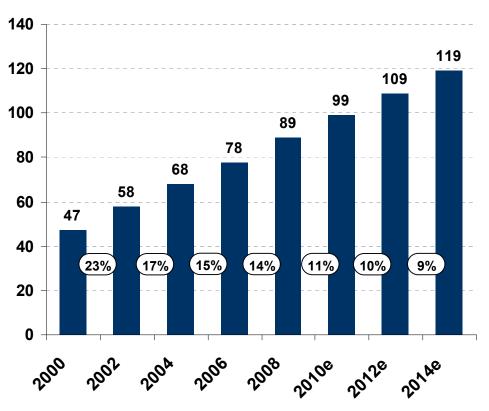


- Sales in Plasma Proteins jumped by 37% in 2008 (incl. BPC for the first time)
- Contribution BPC: €64.1m
- In H1 2009 Plasma Protein sales increased by 14.5% to
   € 194.3 million



# 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

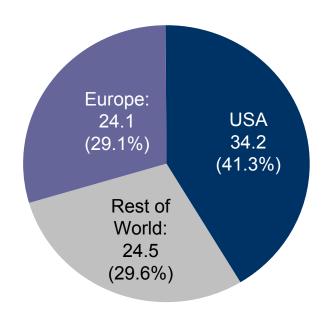
= Growth (over a 2-year period)

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 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

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®: 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
- Drecrease of prices continues, but no price erosion















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

## **Biotherapeutics**



## Biotherapeutics: investment in projects with potential

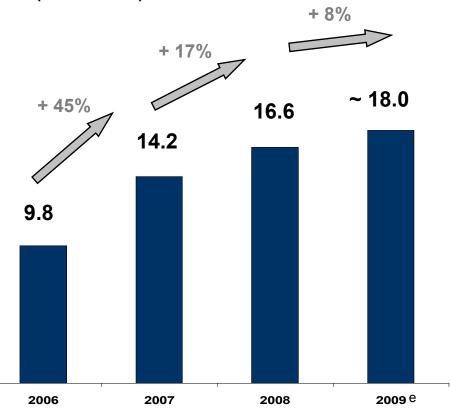
## Common features of Biotest's monoclonal antibodies

- High medical need
- Rapidly growing markets
- Blockbuster potential

#### Lead indications

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

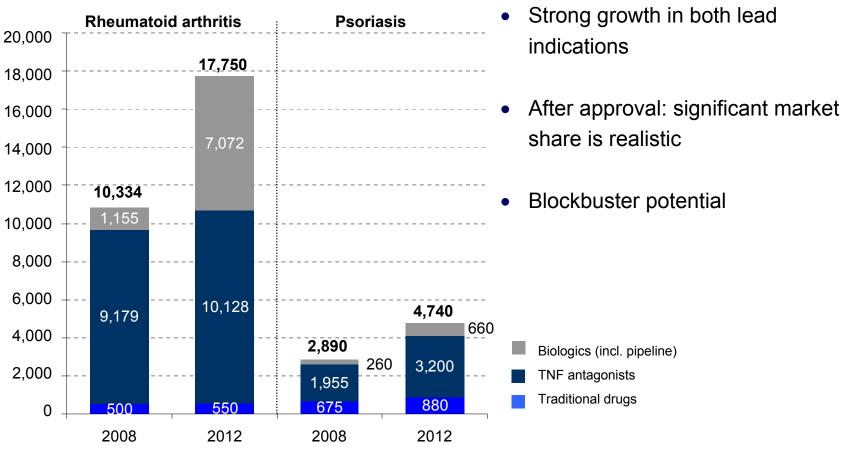
## R&D expense – Biotherapeutics (in € million)





# Rheumatoid Arthritis and Psoriasis – a huge and growing market

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



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



#### 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

<sup>\*</sup> 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:** 

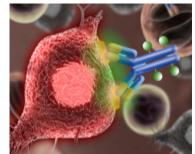
Co-development and co-marketing with "big pharma" from clinical Phase III onwards

- 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





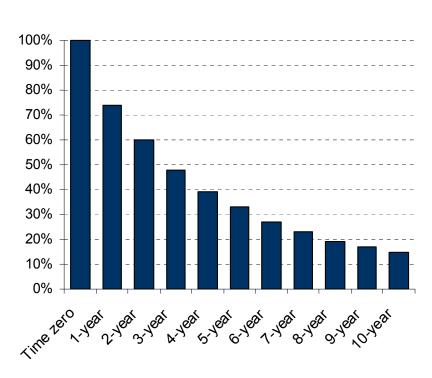


- BT-062: specific and highly effective immunotoxin: toxin part mediates high efficacy – antibody part mediates high specificity
- Phase I Study: Dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
- Clinical trials in 4 cancer centres in the US, open lable, repeated 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



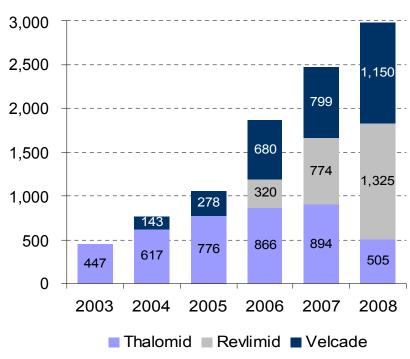
### Multiple Myeloma – unmet need and high market potential

#### Survival rates for MM patients in the USA



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

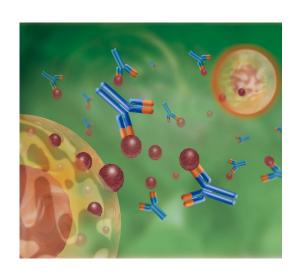
## Sales of novel targeted MM therapies (in US\$ million)



(Source: Company data and Biotest analysis 2009)



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



#### BT-063 lead indication

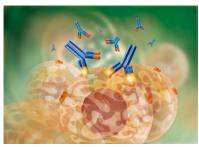
- Systemic Lupus Erythematosus (SLE)
- High medical need: SLE incurable today, no new approval since ~ 40 years
- 2.5 million patients are suffering from SLE worldwide today

#### 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



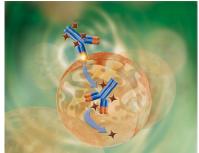
### Outlook Biotherapeutics: reach new development stage



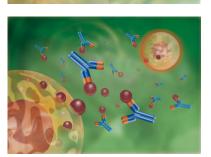




BT-061: partnering process ongoing



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.



# 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)



#### **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