Biotest

From Nature for Life

Management Presentation

Biotest AG

Stockholm

September 2008

Biotest: Overview

Biotest AG	(01-06/2008)
Sales	€ 211 m
EBIT	€ 27.6 m
Employees	1,850

Pharma

Plasma Proteins

- Immunoglobulins
- Hyper-Immunoglobulins
- Clotting Factors
- Albumin

Biotherapeutics

- Monoclonal Antibodies (mAb)

Diagnostics

Immunology

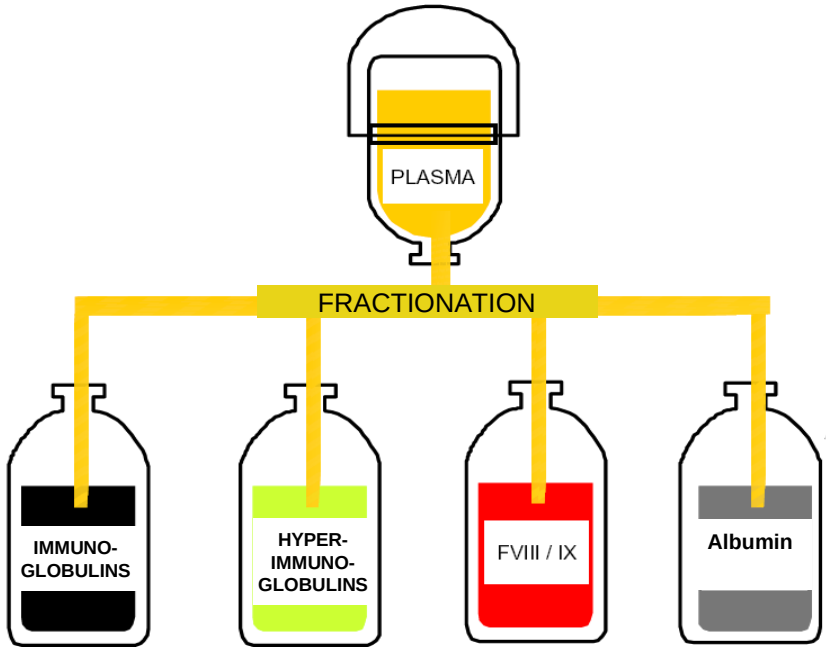
- Transfusion
- Transplantation
- Infectious Disease

Microbiology

- Hygiene Monitoring

Biotest Pharma: Plasma Proteins

- Global market share: 3 %
- Market share in relevant markets: 10 %
- Major competitors: Baxter, CSL Behring, Talecris, Octapharma, Grifols
- Intratect® market share in Germany, Austria and Switzerland > 25 %; UK > 15%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB in USA
- Albumin: commodity



Intratect® Pentaglobin®	Hepatect® Cytotect® Varitect® Nabi HB	Haemoctin® Haemonine®	Human-Albumin Biseko
Infections, immune deficiencies	Hepatitis Cytomegaly Varicella	Blood coagulation defects	Albumin and protein deficiencies

Passive Immunisation during Pregnancy for Congenital Cytomegalovirus Infection

(Nigro G. et al, N Engl J Med 2005; 353: 1350-62)

Prevention:	Cytotect	Control
Children with CMV infection after primary infection of the mother	**6 out of 37 (16%)**	**19 out of 47 (40%)**

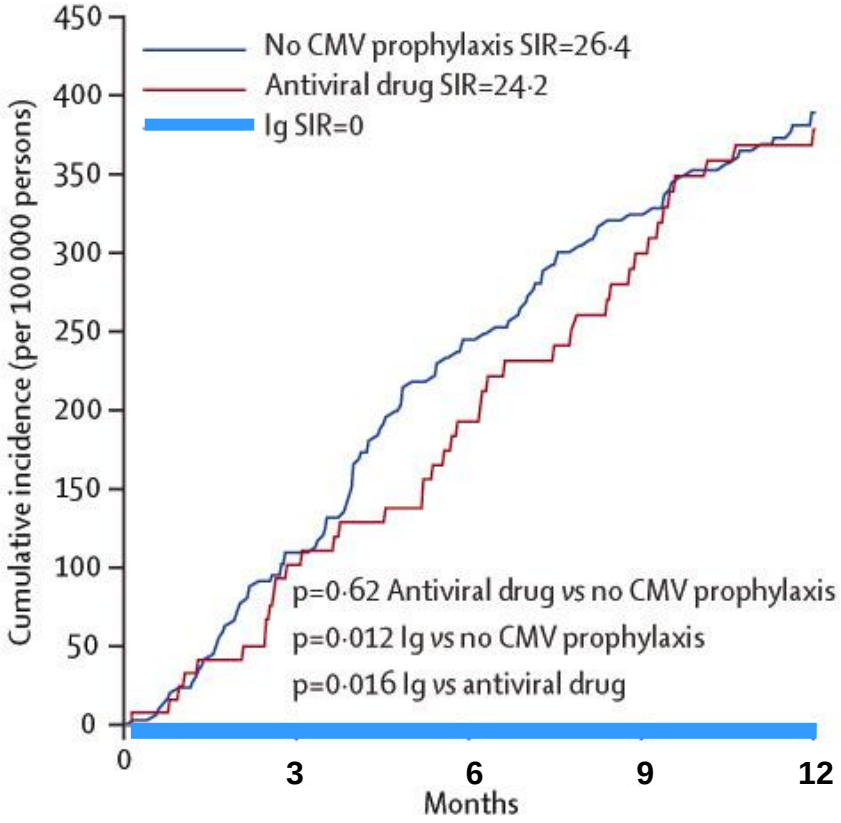
The transmission rate of 40 in the control group Corresponds with published data.
With Cytotect the rate was lowered to 16%.

Therapy:	Cytotect	Control
Children with CMV-induced damages after proven connatal infection	**1 out of 31 (3%)**	**7 out of 14 (50%)**

15 fetuses of the Cytotect group showed symptoms in ultrasound. With Cytotect therapy the symptoms disappeared in all but one cases.

Effect of cytomegalovirus prophylaxis with immunoglobulin or with antiviral drugs on post-transplant non-Hodgkin lymphoma.

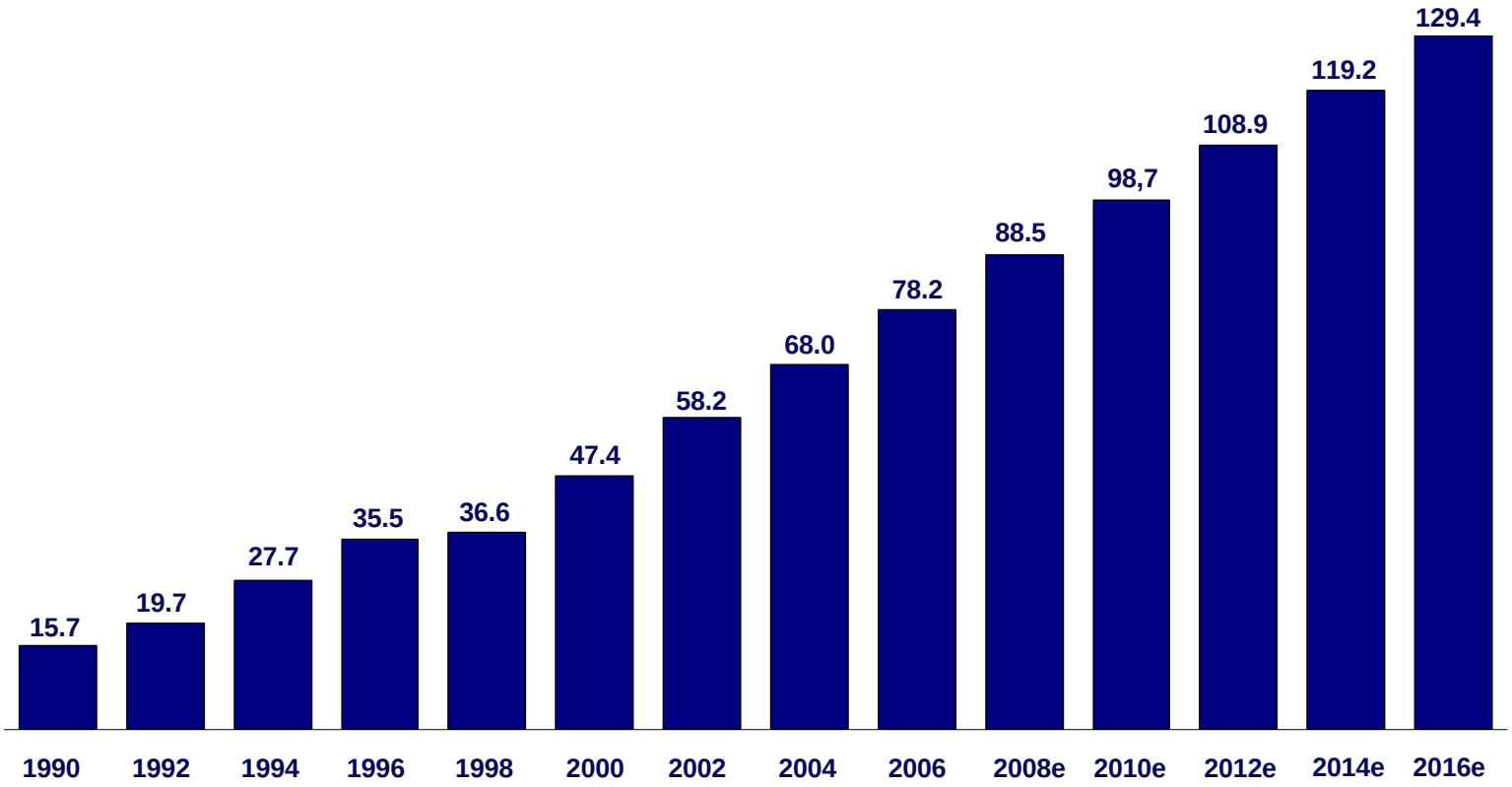
Opelz et al., Lancet Oncology 2007; 8: 212-218



- After prophylaxis with CMV immunoglobulins no non-Hodgkin lymphomas occur (40% Cytotect®) in the first year following trans-plantation.
- The protective effect of immuno-globulins is not measurable in later periods. Most lymphomas develop within the first year after transplantation.

Immunoglobulins: Increasing demand worldwide

IVIG [tons]



Source: Review of Australia's PFA 2007

Biotest Pharmaceuticals Corporation (BPC): Our US market entry

- Acquisition of Plasmaprotein business of Nabi Biopharmaceuticals Inc.:
- Asset-Deal ($185 m USD)
- Closing: December 2007
- Transfer of Assets into Biotest Pharmaceuticals Corp.

BPC – Investment rationales:

- **Immediate strong presence in the US market**
- **Global leader in hepatitis B hyperimmunoglobulin market**
- **Additional capacity (plasmapheresis, production)**
- **Experienced and driven team of experts**
- **Positive contribution to sales + EBIT from the very start**
- **Promising R&D pipeline with huge market potential**

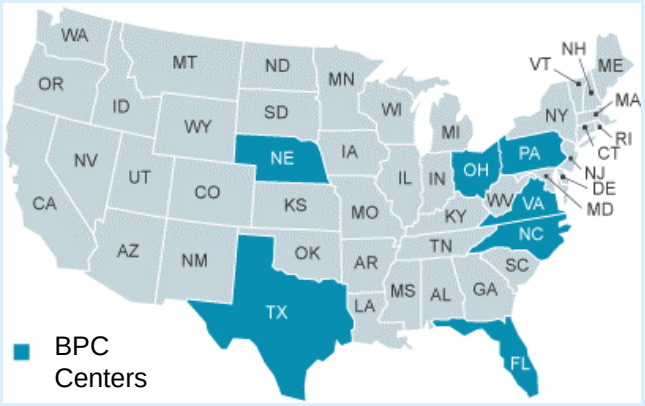
Important Assets of Biotest Pharmaceuticals Inc. (BPC, Florida)

Plasma protein production plant

- Built in 2002, certified by FDA
- Fractionation capacity 400,000 litres (after limited capex)
- Maximum output 1.5 tons IVIG
- Includes labs, QC, storage capacity

Plasma collection centers

- Nine centers in seven US states
- Certified by FDA and EMEA
- Collection volume ~ 400,000 litres
- 1 new center opened in July 08, 3 more to come in 2008/09

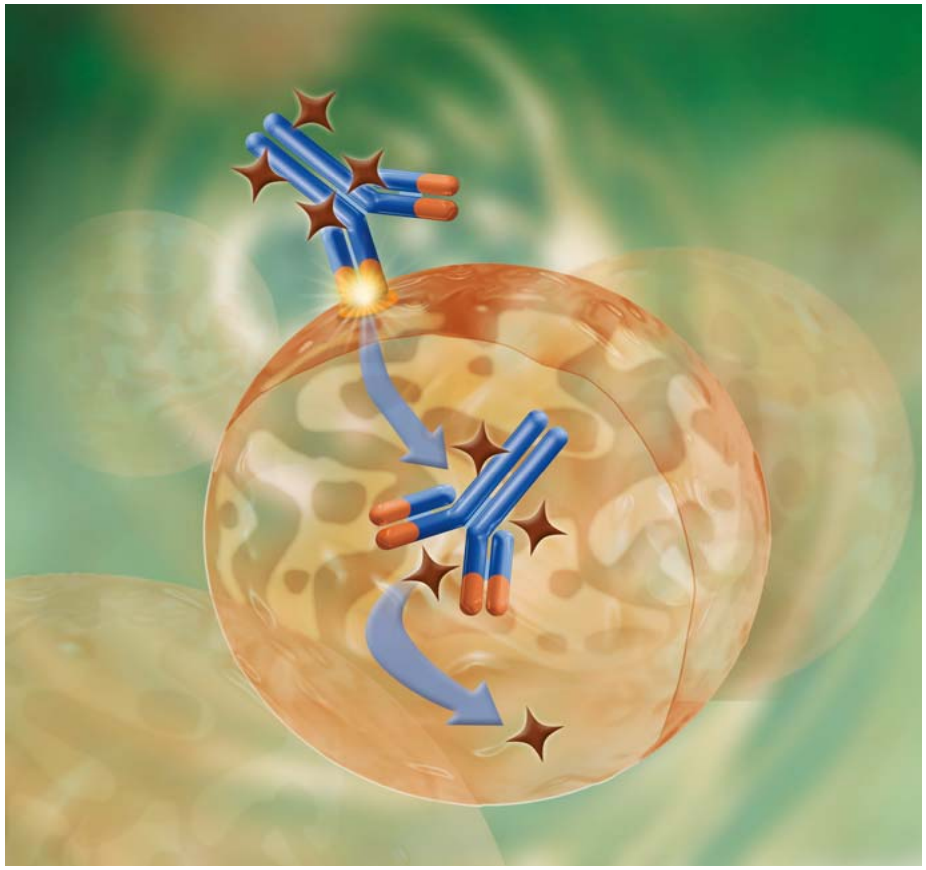


Biotest Pharma - Plasma Proteins: Strategy

- Building US presence with Biotest Pharmaceuticals Corp. (BPC)
- FDA approval for polyspecific IVIG in the US in 2010 -
  FDA approval for Civacir in the US in 2013
- Plasma sourced from own pherese centers > 50%
- Increase of fractionating capacity (with partners and BPC)
  to 1.4m litres
- Increase of production capacity for immunoglobulins (Dreieich and BPC)
  > 5,5 tons
- European-wide approvals of all Biotest plasma proteins

⇨ **Strenghtening our position as no. 6 of all global players**

Biotest Pharma: Biotherapeutics



Biotest Biotherapeutics: Focused Research

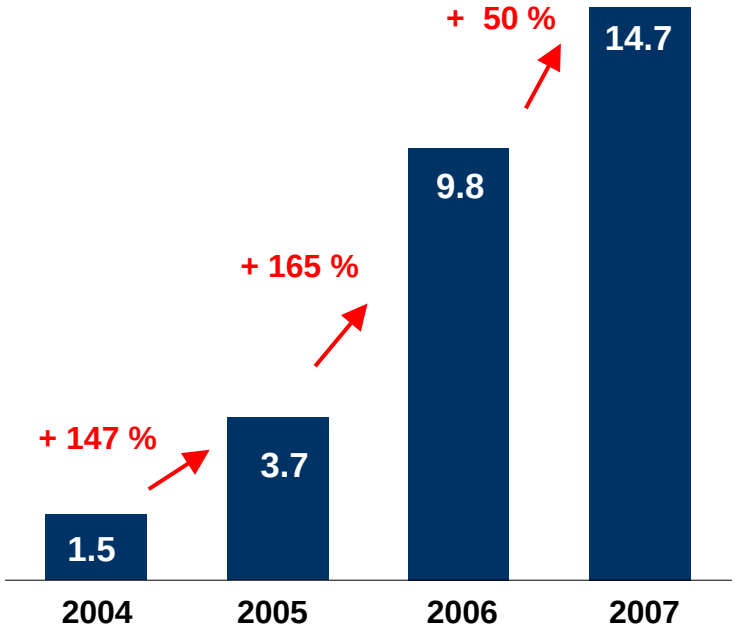
Three monoclonal antibody (MAB) projects:

- High medical need
- Fast growing markets
- Blockbuster potential

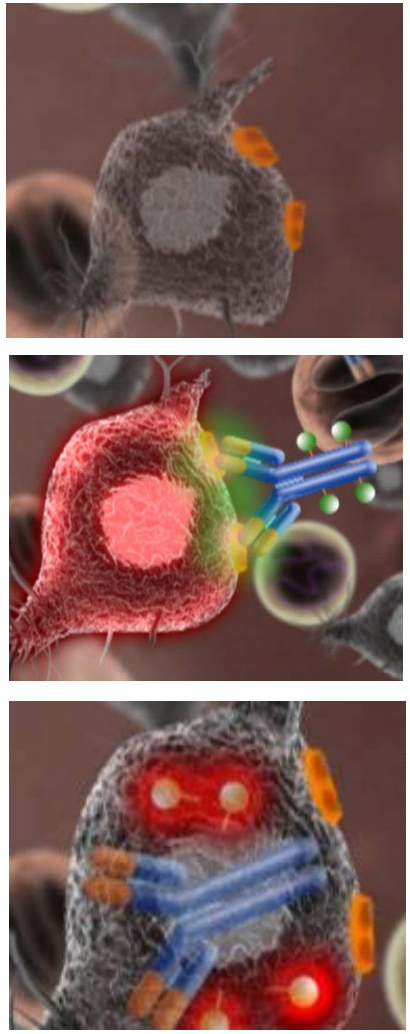
Biotest MABs and major indications:

BT-061	Rheumatoid Arthritis Psoriasis
BT-062	Multiple Myeloma
BT-063	Systemic Lupus Erythematodes and other Autoimmune Diseases

Expenditures for Biotherapeutics [m €]



Monoclonal antibodies: Investments offering considerable potential



BT-061: Rheumatoid arthritis (RA), psoriasis

- High medical need: approx. a quarter of patients do not respond, or not sufficiently, to approved therapies
- Approx. 6 million patients suffer from rheumatoid arthritis
- Volume of biotechnological RA drugs in 2007: US$8.8 billion, forecast for 2010: US$12 billion

BT-062: Multiple myeloma (MM)

- High medical need: there is no known cure for multiple myeloma to date; survival rate is 10 years from diagnosis in around 5% of cases
- Volume of MM therapeutics in 2007: US$2.5 billion, with strong market growth

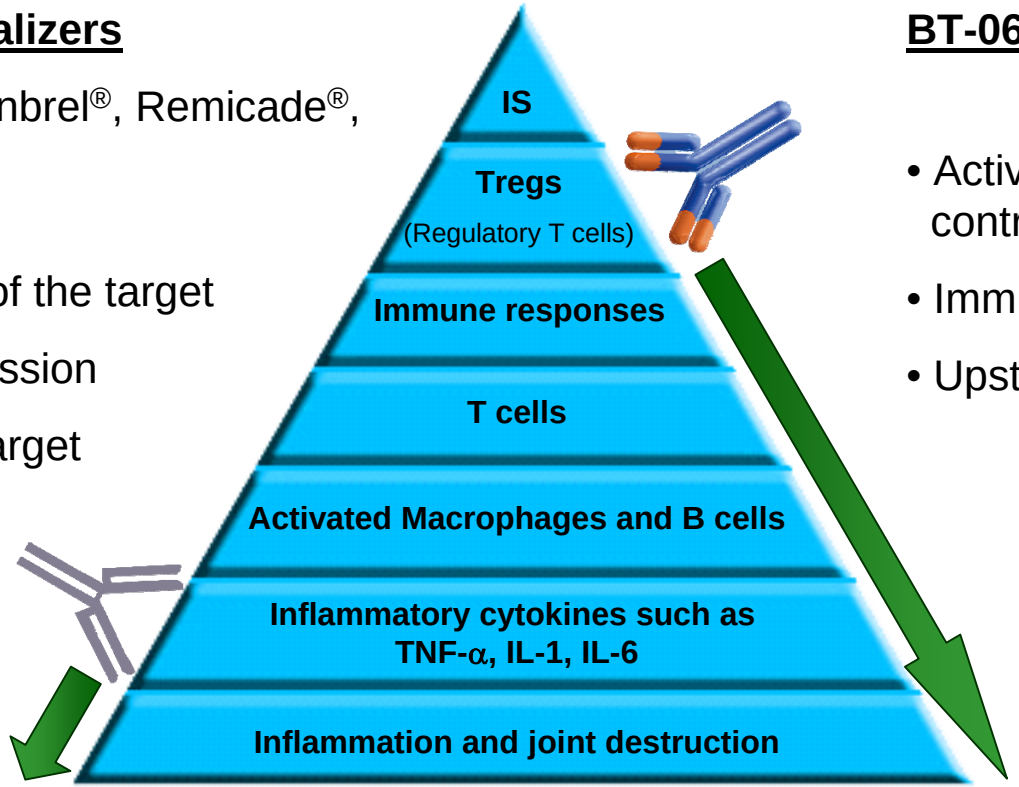
Unique mode of action of BT-061:

Effect on key regulatory function of the human immune system

Cytokine Neutralizers

(e.g. Humira®, Enbrel®, Remicade®, Actemra®)

- Neutralisation of the target
- Immunosuppression
- Only a single target



BT-061

- Activation of a natural control mechanism
- Immunomodulation
- Upstream process

Complex and versatile process of inflammatory cascade

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Unique mode of action of BT-061:
Comparison to T cell interacting mAbs

	anti-CD3 mAbs	other anti-CD4 mAbs[1]		BT-061
		depleting	non-depleting	
Depletion ADCC	+/-	+ [2]	-	-
Depletion CDC	+/-	+ [2]	-	-
Activity correlates with CD4 antagonism/down-modulation high doses required → broad immune suppression	-	-	+ [2]	-
Activation of Tregs	+	-	-	+
Activation of T helper cells	+	-	-	-
Dosage	narrow therapeutic window	high doses required [2]		high efficacy already at low doses

□ Efficacy not sufficient for clinical success ○ Safety profile potentially problematic

[1] comparison of BT-061 with 14 other anti-CD4 antibodies
[2] Ref.: Strand et al. 2007 and cited therein

Clinical Development of BT-061

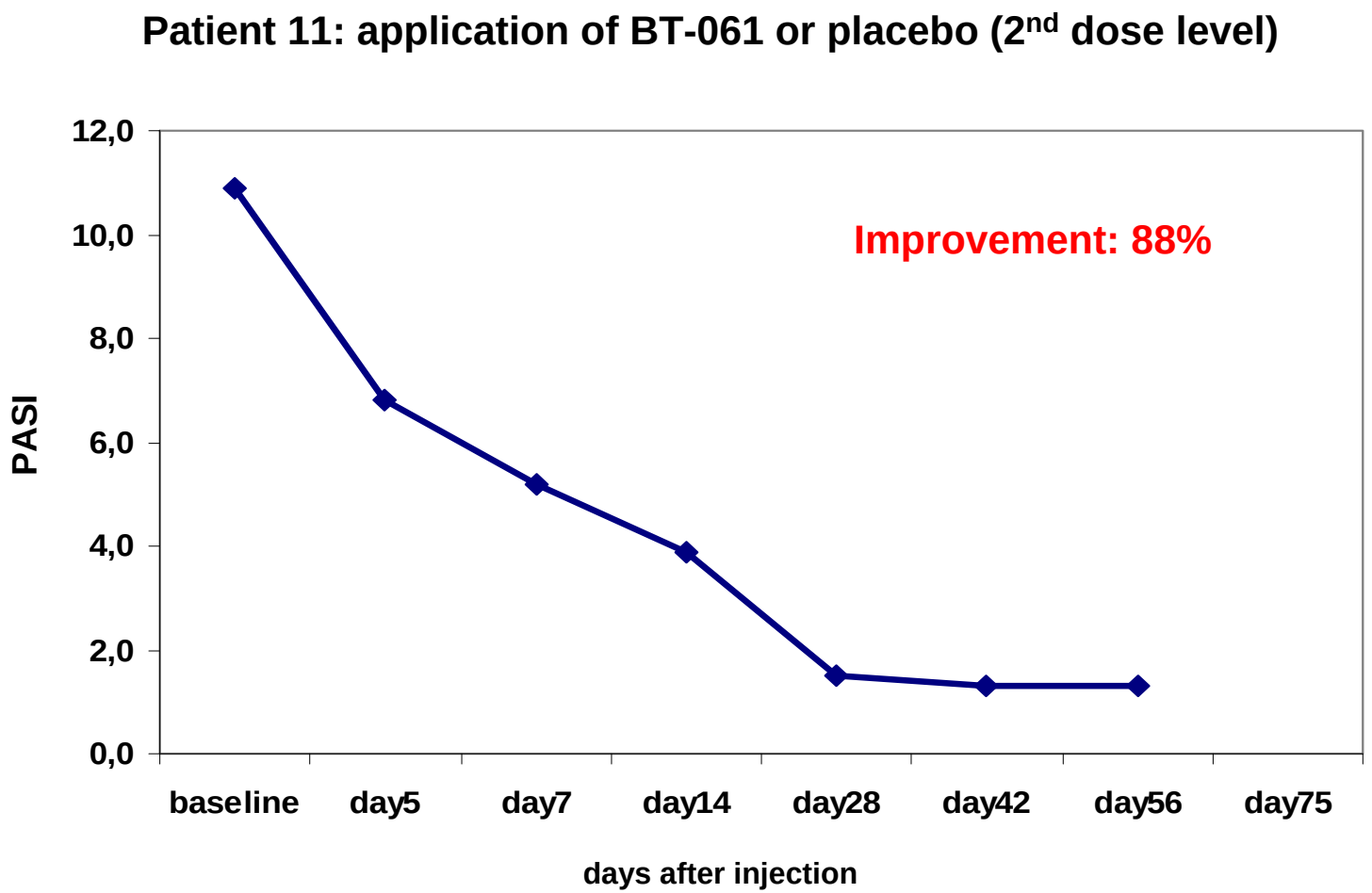
Clear improvement of clinical symptoms after single application with very low dosages in Psoriasis*

Improvement PASI Score (as of Sept 15)	**Dose level 1**	**Dose level 2**
≥ **40%**	75% patients	75% patients
≥ **50%**	50% patients	62.5% patients
≥ **60%**	12.5% patients	25% patients
≥ **75%**	0% patients	12.5% patients

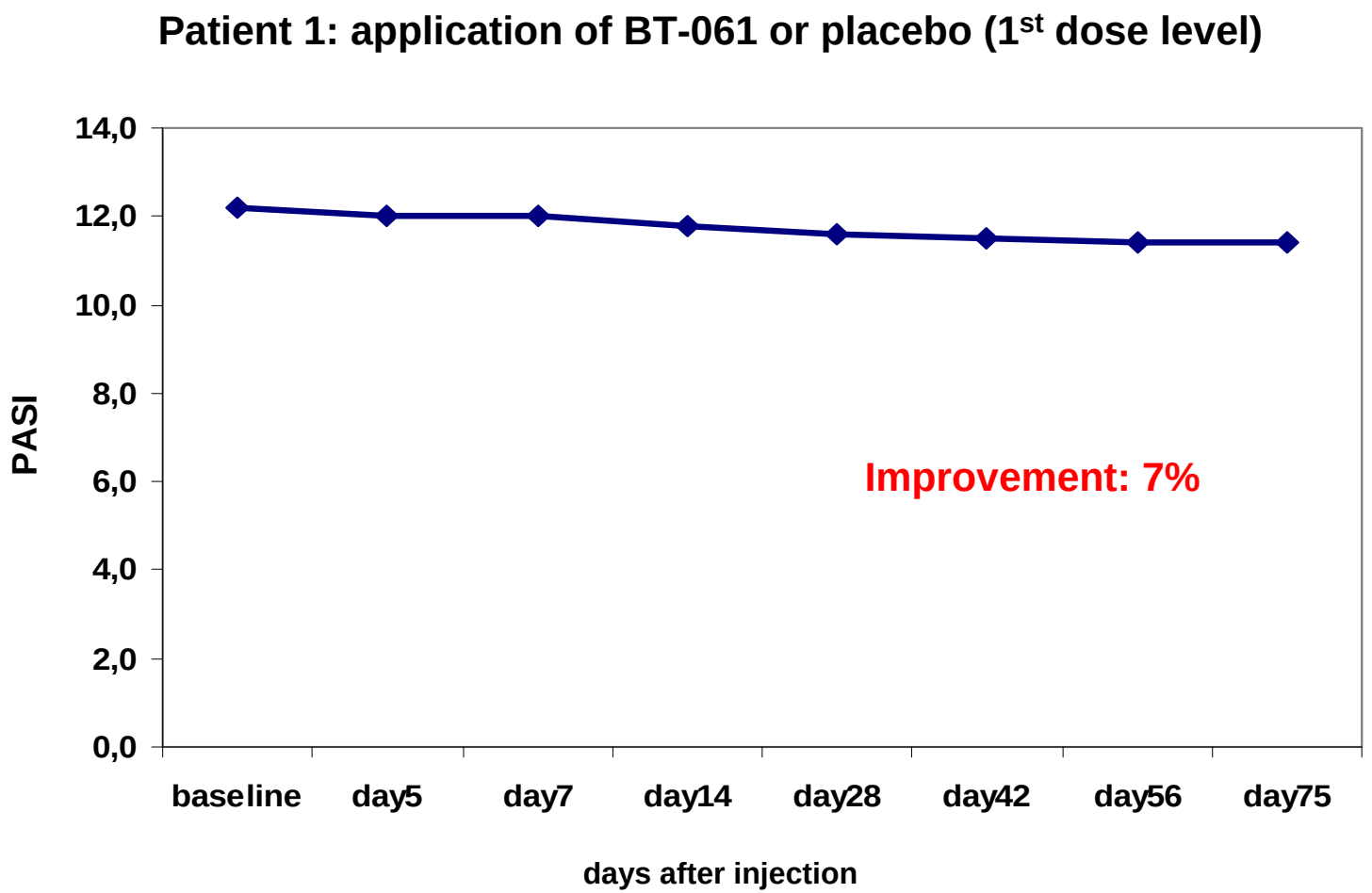
***75% of the patients received BT-061, 25% of the patients received placebo**

Status Sept 24th - minimum follow up 28 days

Kinetic of clinical response after single i.v. application in Psoriasis (1 responder)



Kinetic of clinical response after single i.v. application in Psoriasis (1 non-responder)



BT-062: highly potent immunoconjugate for the treatment of multiple myeloma

BT-062 Target

- vast majority of MM patients are positive for the target antigen
- target antigen highly overexpressed on MM cells

BT-062 Drug:

- New generation of immunotoxin
- Immunotoxin acts specifically on target cells
- gets activated after entering the target cell

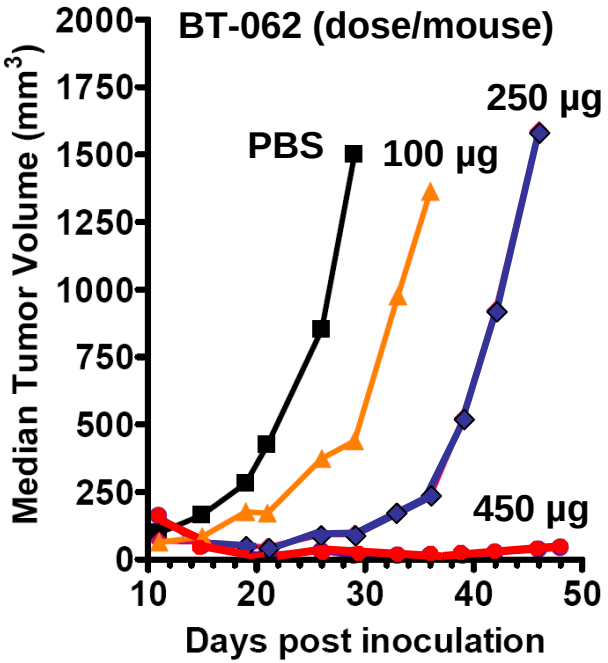
⇨ **Minimization of unspecific side-effects**

BT-062 - competitive advantages:

- BT-062 efficiently kills primary multiple myeloma (MM) cells
- but does not kill healthy blood and bone marrow cells
- BT-062 significantly reduces tumor size in MM SCID mouse xenograft model
- Immune effector functions not necessary in patients

⇨ **Therapy for immuno-suppressed patients**

BT-062 shows high *in vivo* efficacy in mouse model after single dose injection



Preclinical Xenograft data

BT-062
Development status

Antibody humanized	☑
Exeptional efficacy by improvement of molecular design	☑
Production process established	☑
GMP production (outsourced)	☑
Preclinical toxicology	☑
Clinical design established	☑
Orphan Drug Designation granted by the FDA	☑
Investigational New Drug Application (IND) accepted by the FDA	☑
Institutional review board (Ethical committee) approval	☑

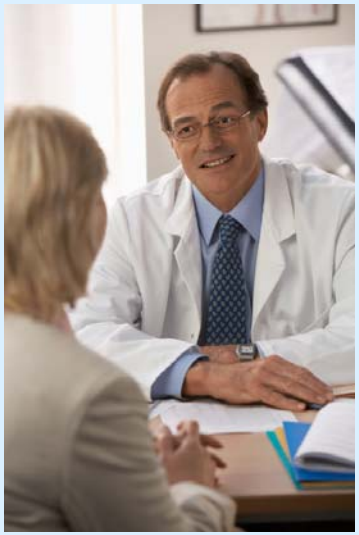
Phase I trial: started 2008

BT-062 – Clinical Development

Phase I: Dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma

Concept

- Multi Center trial in 4 US centers, open label, repeated single dose
- Primary Objectives:
  => Dose limiting toxicity
  => Maximum tolerated dose
- Secondary Objectives:
  Anti-tumor activity
  Qualitative and quantitative toxicities
  Pharmacokinetics
- Prior therapies
  Previous treatment with both an immunomodulator and a proteosome inhibitor therapy

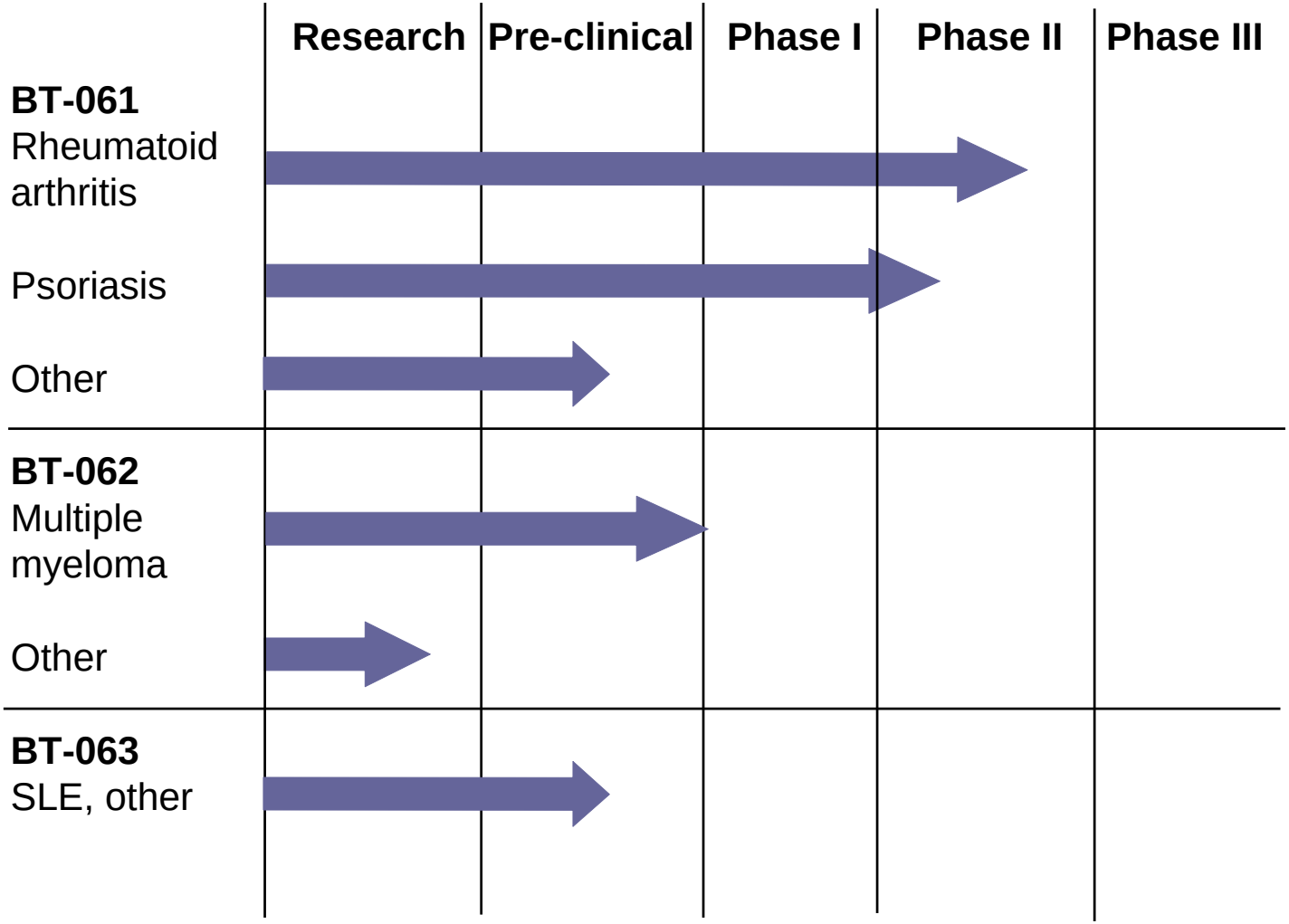


Status

- 3 out of 4 centers are already recruiting
- Recruitment of patients for 1st dose level completed - 40 patients are to be enrolled

So far the medication was generally well tolerated by critically ill patients

Monoclonal antibodies development - current status



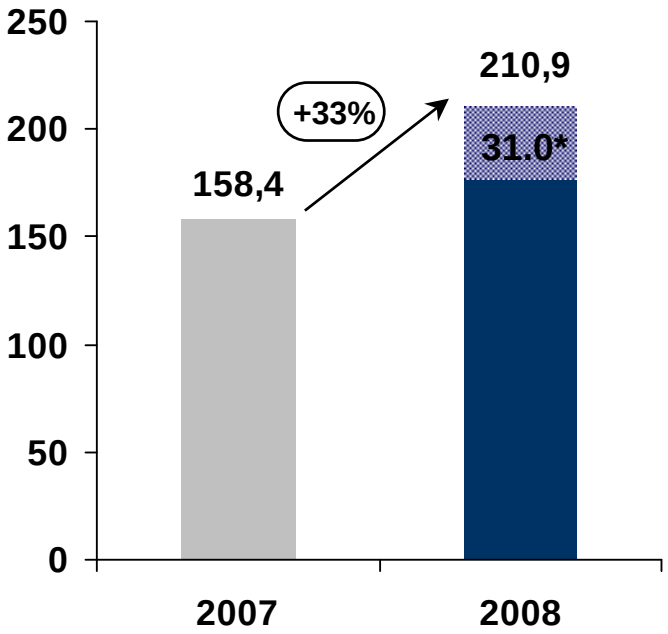
Financials 2007 &

Key figures 1st half year 2008

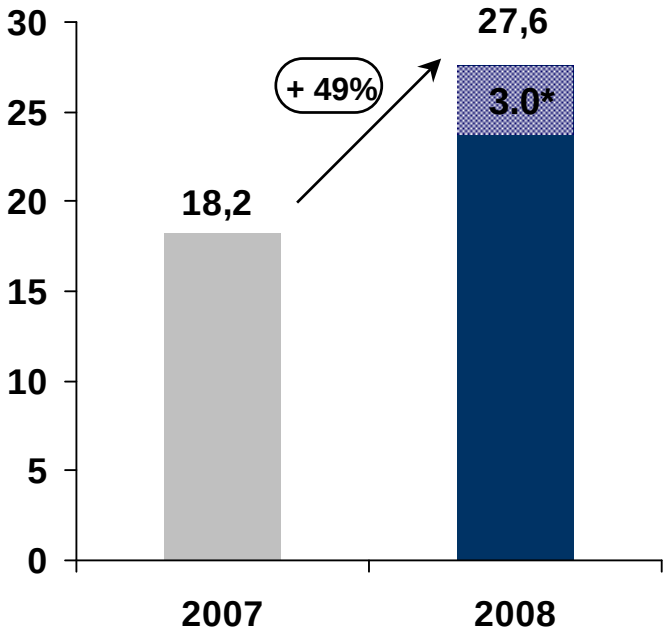
Biotest AG

Successful 1st half year of 2008

Sales in the first half year (€m)



EBIT in the first half year (€m)

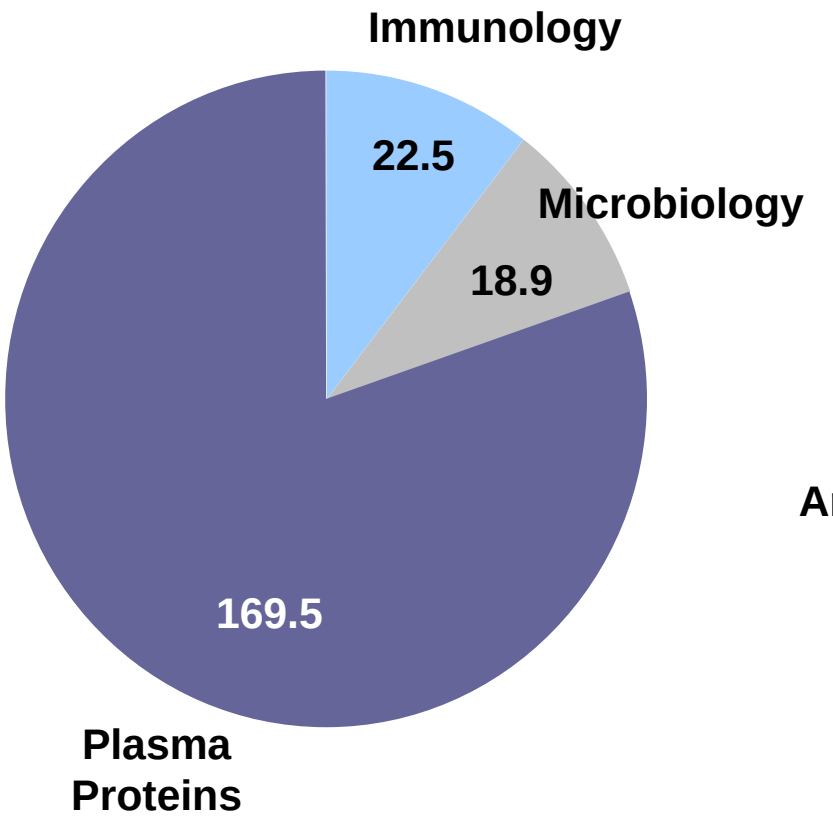


- EBIT rises at faster rate than sales
- Even without BPC, significant rise in sales and profit
- Targets for full year: sales of €420 million, growth in EBIT > €50 million

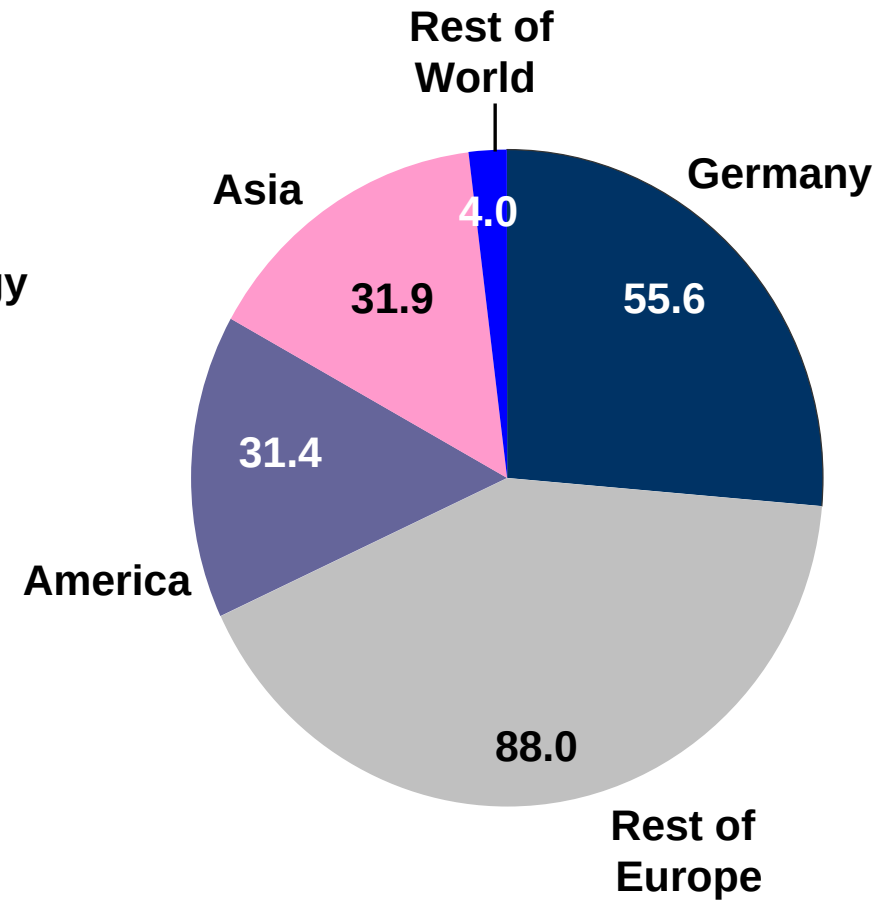
* BPC contribution

Sales 01-06 2008 in €m

Sales by segment



Sales by region

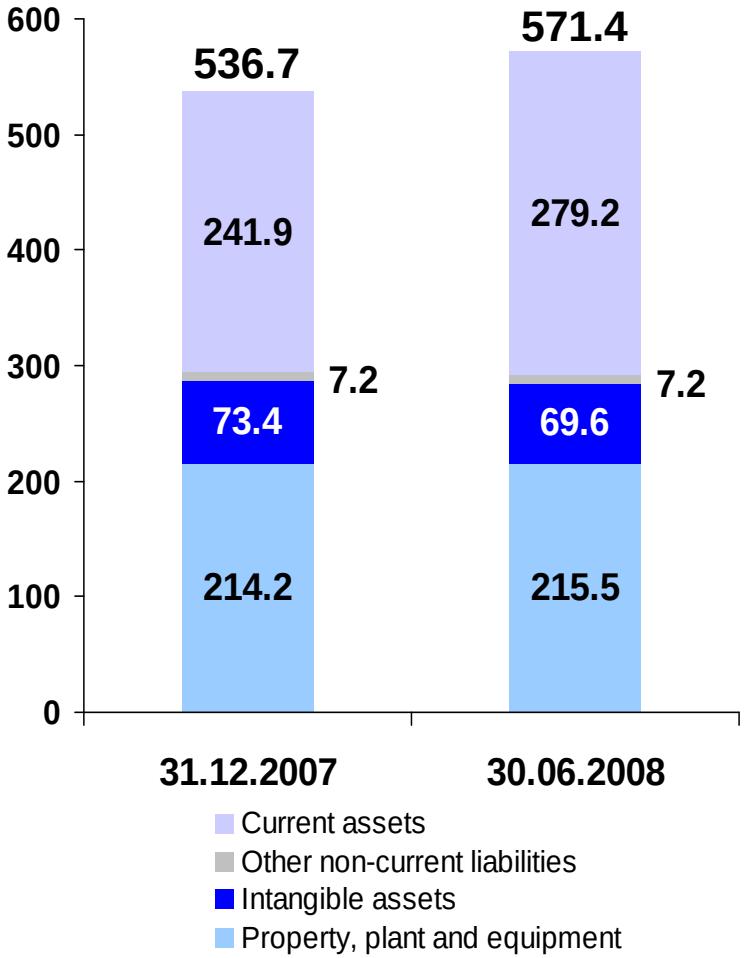


EBIT H1 in €m

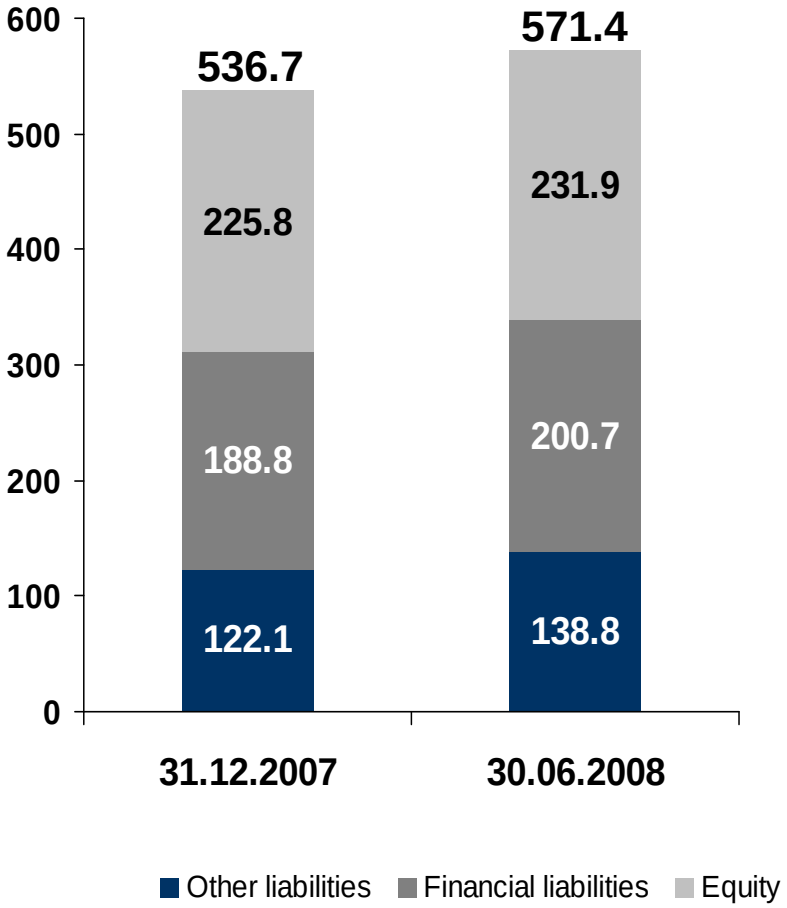
	H1 2008	H1 2007	Delta in %
Plasma Proteins	38,6	28,3	36%
Immunology	-1,9	-2,2	14%
Microbiology	2,8	2,9	-3%
Corporate	-4,8	-2,8	-71%
Biotherapeutics	-7,1	-8,0	11%
Biotest Group	**27,6**	**18,2**	**52%**

Balance sheet

Assets

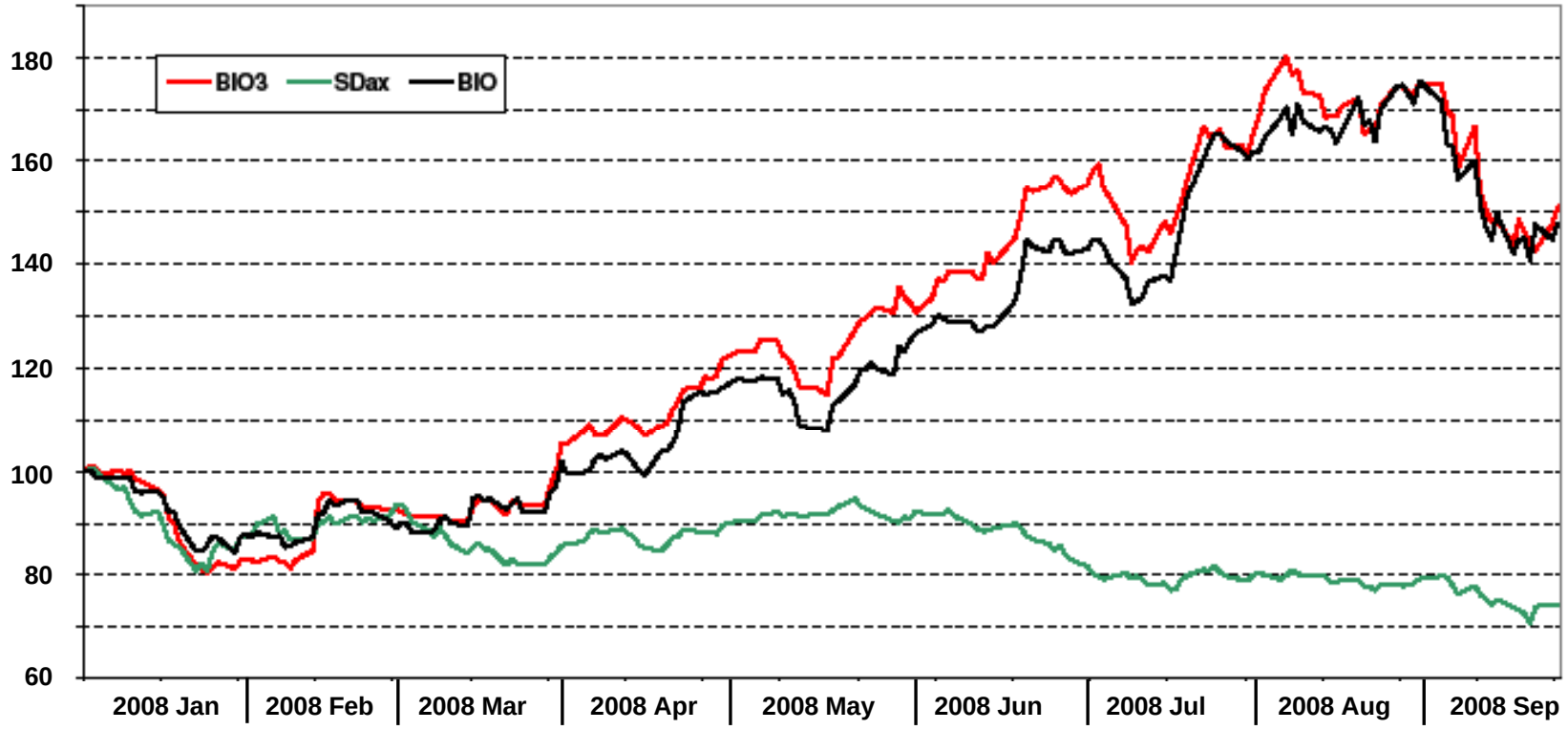


Equity and liabilities



Performance of Biotest shares vs. SDAX
1st January, 2008 - 23rd September, 2008

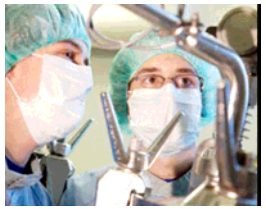
Preference shares: red line **Ordinary shares: black line**



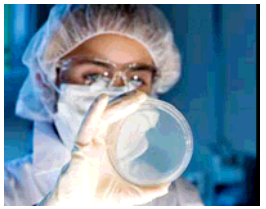
Summary: The Biotest strategy

“Biotest – a global specialist in innovative immunology and haematology”

- Internationalisation of business – strengthening of the position in the USA in particular
- Plasma proteins: new products, new indications and new markets
- Capacity expansion
- Diagnostics: focus on core markets with high growth potential
- Biotherapeutics: achievement of important milestones triggers partnering with global pharma





Disclaimer

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