Biotest
From Nature for Life

Biotest Group: Creating Value. Living Values

Management Presentation

Biotest AG

September 2010

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 figures reported relate to the Continuing Operations of the Biotest Group after the disposal of the transfusion and transplantation diagnostic activities to Bio-Rad Laboratories Inc. These activities are being reported as Discontinued Operations. With the exception of the statement of financial position, the previous year´s figures have been adjusted accordingly.

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

Biotest at a glance

Key Figures:	FY 2009		H1 2010	
Sales	€ 438.6 m	(+14.2%)	€ 227.1 m	(+4.0%)
Thereof Plasma Proteins	€ 390.1 m	(+14.9%)	€ 200.6 m	(+3.2%)
EBIT	€ 61.6 m	(+4.6%)	€ 23.7 m	(-24.0%)

Business sectors

Pharmaceuticals | **Diagnostics**

Divisions

Plasma Proteins

- Immunoglobulins
- Hyper-immuno-globulins
- Clotting factors
- Albumin

Biotherapeutics

- Monoclonal antibodies

Microbiological Monitoring

- Hygiene monitoring

Financials H1 2010

H1 2010 – At a glance

- H1 Sales increase + 4.0% to € 227.1 million in difficult market environment
- Continued influences on EBIT:
  - further price decrease for plasma protein products
  - continued unabsorbed costs in US (finalisation production facility Boca Raton)
  - increased R&D expenses: € 4.1 million (+19%) incl. consistency batches at BPC and regulatory filing for BLA Bivigam™
- H1 EBIT € 23.7 million (-24%)
- Revised EBIT Outlook




Expectations FY 2010

- **Sales growth in lower single digit range**
- Further price pressures expected for Intratect and Haemoctin
- Negative impact by German Healthcare Reform
- Continued unabsorbed costs in US (production facility Boca Raton)
- Shifting of products in higher margin markets not successful
  - ➢ EBIT level of 2009 will not be reached

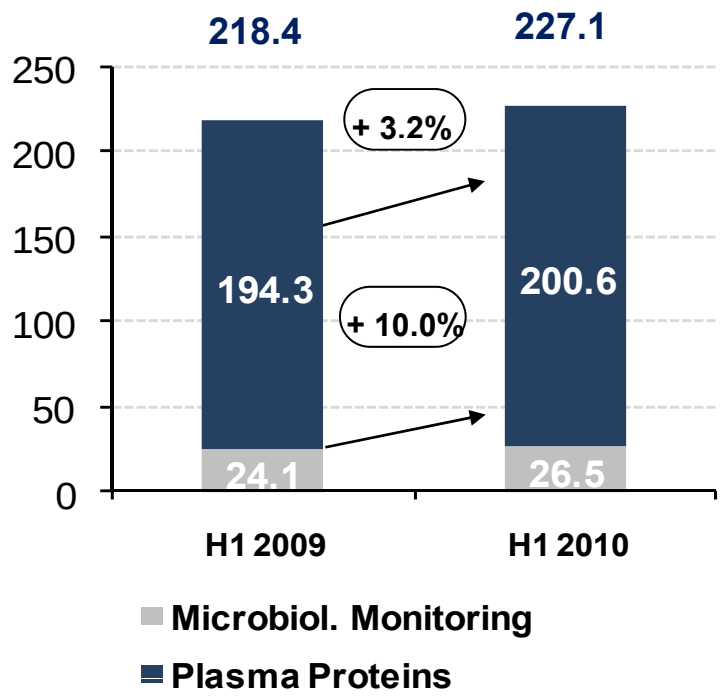
→ New EBIT guidance: € 45 million +/- 10%

EBIT Guidance incl. Discontinued Operations:

€ 45 million +/- 10% plus € 18 million

Sales growth despite difficult environment

Sales of Plasma Proteins & Microbiological Monitoring (€ m)



- Sales in the first half year of 2010 were up by 4.0% to 227.1 million vs. H1 2009
- The Microbiological Monitoring segment increased by a rate of 10.0 %, mainly through products manufactured by heipha
- The Group's Plasma Proteins business grew with 3.2%
- Robust performance in challenging business environment

Sales Plasma Proteins

Sales Plasma Proteins H1 2009	€	194.3 m
Volume effect	€	20.9 m
Price effect	€	-14.6 m
Sales Plasma Proteins H1 2010	**€**	**200.6 m**

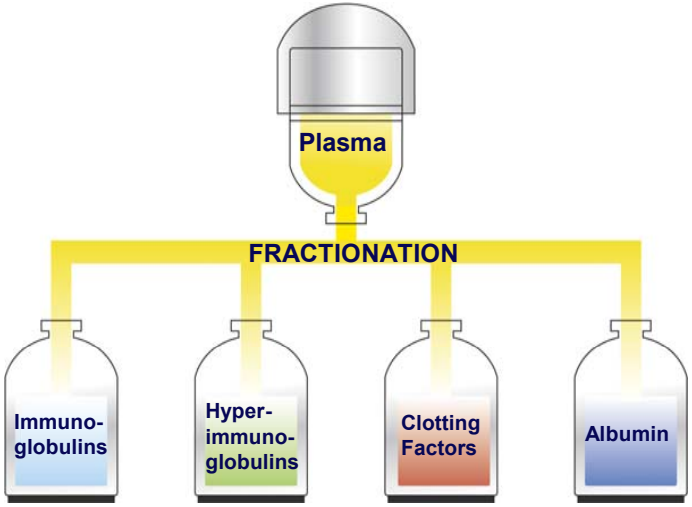
EBIT Plasma Proteins H1 2010 vs H1 2009

EBIT Plasma Proteins H1 2009	€	42.7 m
EBIT from increased volume	€	8.7 m
EBIT loss from reduced prices	€	- 14.6 m
Net changes of other costs/expenses	€	- 1.2 m
EBIT Plasma Proteins H1 2010	**€**	**35.6 m**

Plasma Proteins

Plasma Proteins business at a glance

Biotest Plasma Protein products



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

= Biotest products = lead indications

- Global market share: 3%
- Market share in relevant markets (GER, AUT, CH, GRE, UK): 14%
- Intratect® market share in GER, AUT: > 13%, in UK, CH, I: > 10%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA
- Zutectra ® launch in Feb. 2010
- Biotest covers full value creation chain: plasma sourcing, production, distribution ⇨ vertical integration leads to rationalisation and higher productivity

Major progress in development of Plasma Proteins

Zutectra®

EU-wide approval
(centralised procedure)

Hepatect®CP

Approvals in 13
other European countries
(mutual recognition procedure)

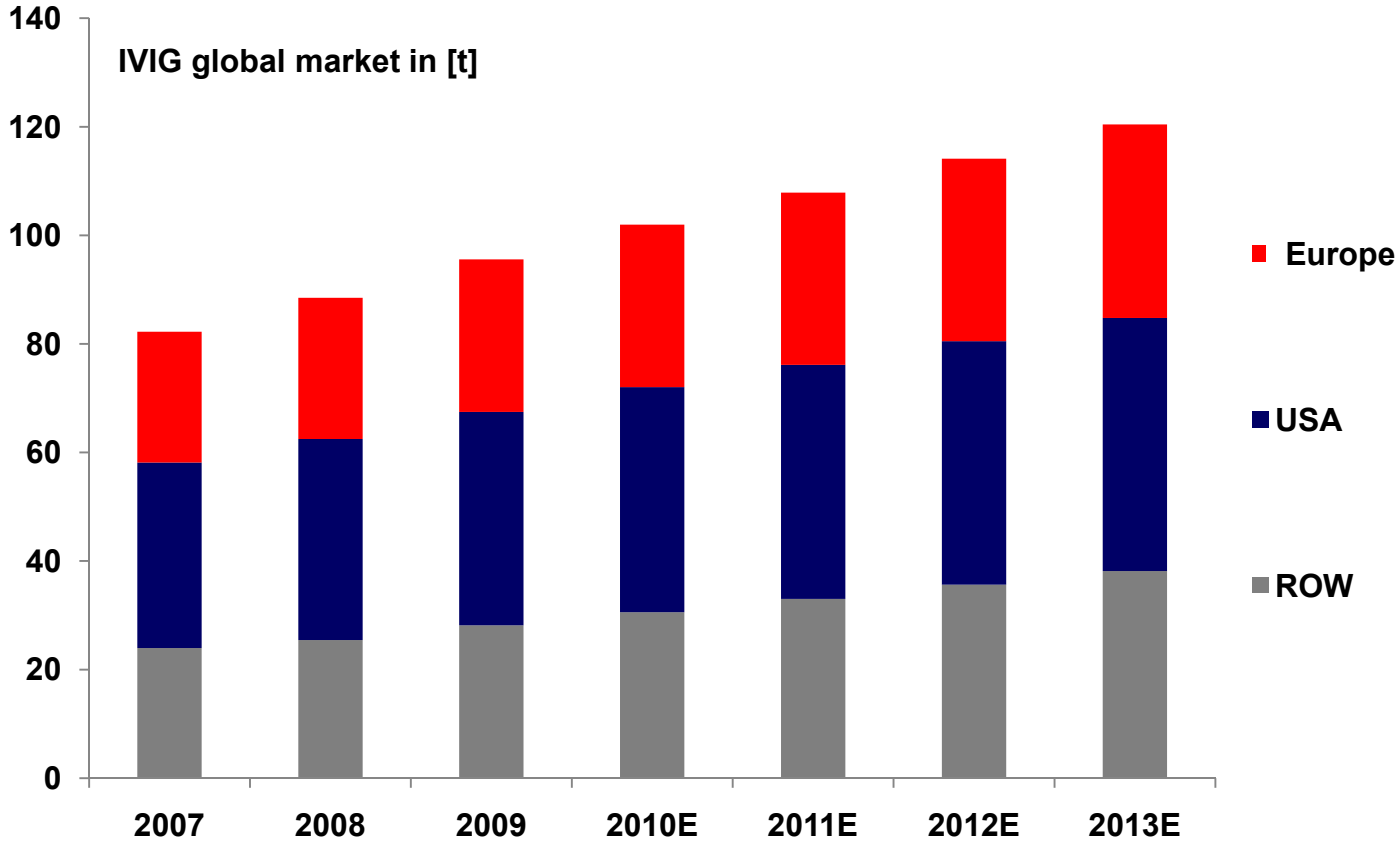
Albiomin®

Approvals in Germany and 10
other European countries

Intratect®

Use in fibromyalgia patients:
trial completed –
scientific publication finalised

Development of IVIG markets by regions



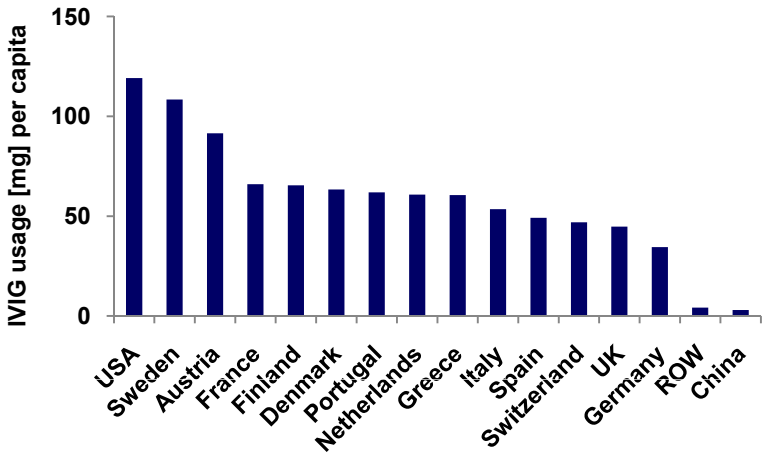
- The IVIG market will continue to grow (5% p.a.), particularly by increased demand in emerging markets

Source: MRB, Analyst Reports, Biotest Market Research

Further growth of immunoglobulin market expected

Demand growth driven by

- Favorable demographics: age, weight
- Improved diagnosis, higher dosing level and longer time on therapy
- Continued clinical evidence supporting established and new indications
- Geographical expansion



Source: Global Insight, MRB, PPTA, APFA

Biotest well positioned by diversified portfolio

- Intratect® – a premium product concerning tolerability *
- IVIG available in US 2011
- Speciality Hyperimmunoglobulines: Hepatect®, Zutectra®, Varitect®, Cytotect®
- sc application: Zutectra®
- Biotest is world market leader in hepatitis B Hyperimmunoglobulin

*: Poster: "A European, multicentre, open and prospective study on clinical efficacy, safety, and pharmacological properties of Intratect® (human normal immunoglobulin for iv administration) in patients with primary immunodeficiency (PID)"; E. Bernatowska et al., 2006

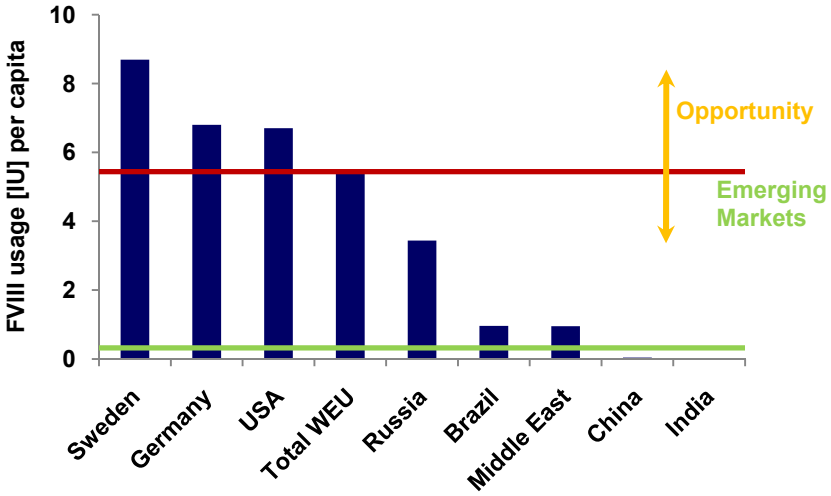
Opportunities in Haemophilia market

Increasing global standards of care

- Improving access to care
- Increasing global penetration of hemophilia therapy
- Optimization of compliance, dosing and prophylaxis treatment

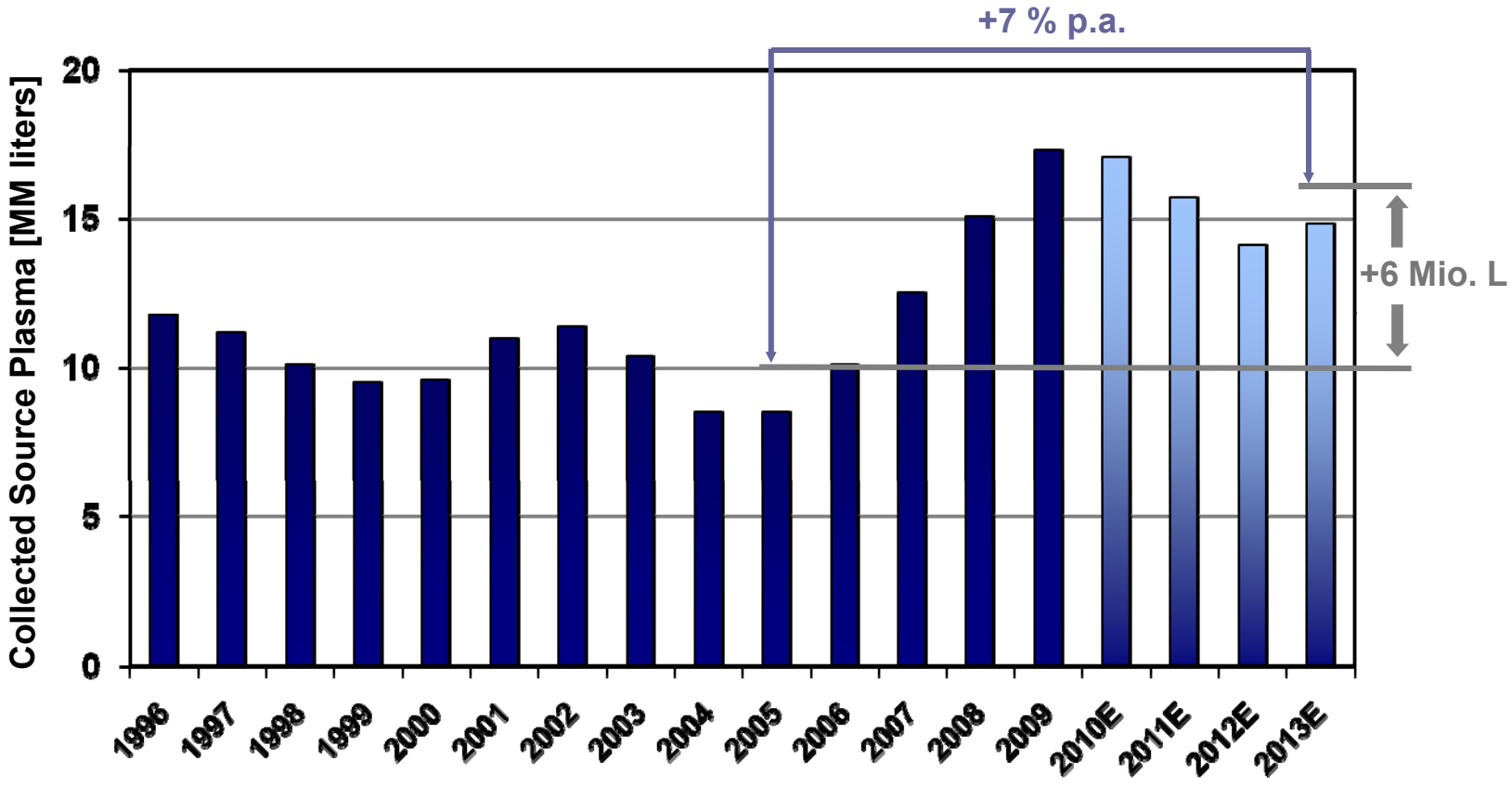
Biotest Products

- Haemonine® (Factor IX) introduced in 2008
- Haemoctin® (Factor VIII) contains high level of von Willebrand factor
- Haemoctin® is stable at RT for 2 years without artificial stabilisers, sugar free
- Haemoctin® has shown to be efficacious in FVIII inhibitor therapy



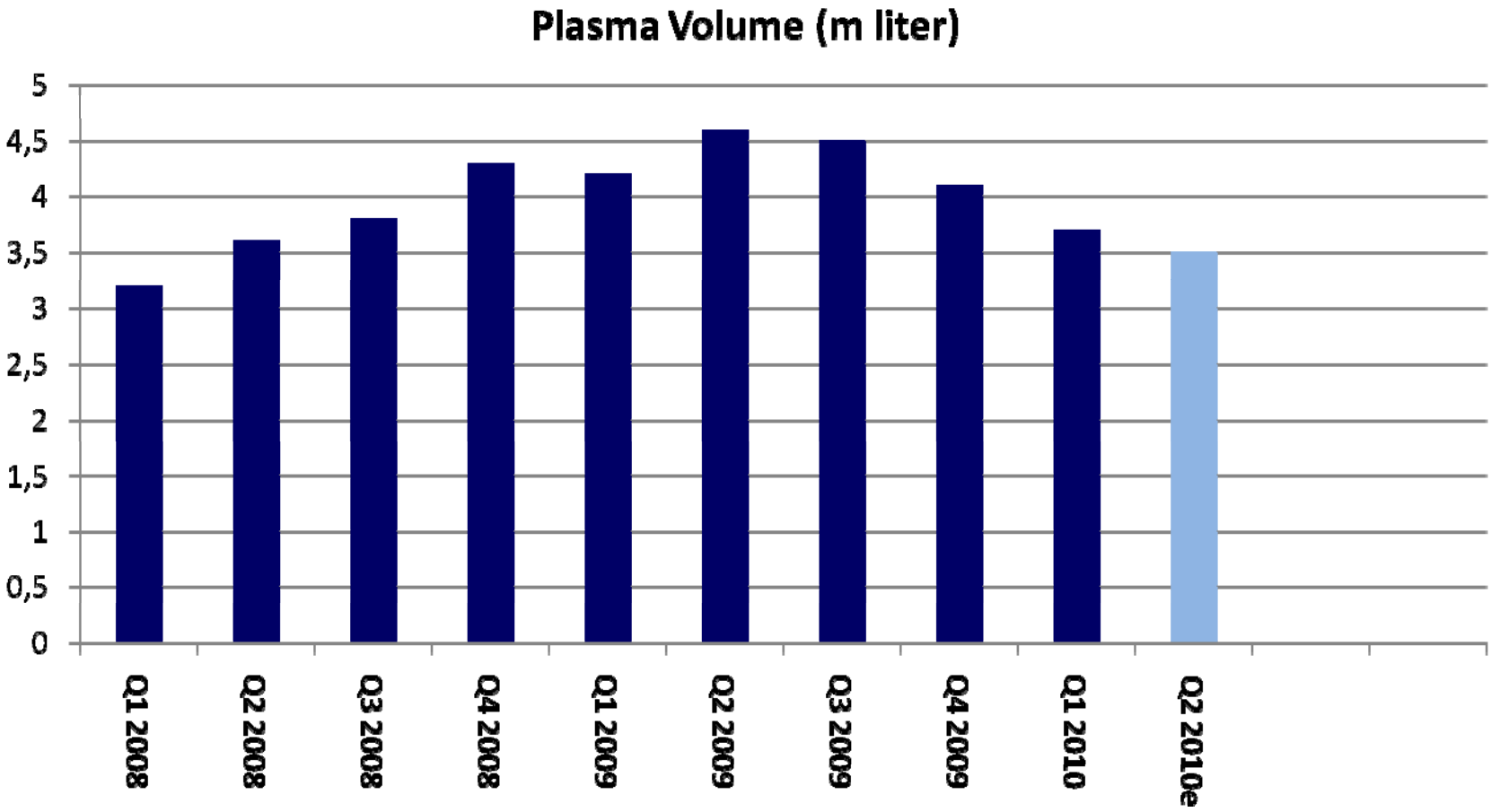
Source: WFH, PPTA

US source plasma collection forecast, 1996 -2013



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

Quarterly volumes of US source plasma



Source: PPTA (July 2010); Q2 2010e: Biotest AG

US manufacturing plant in operation since end of 2009

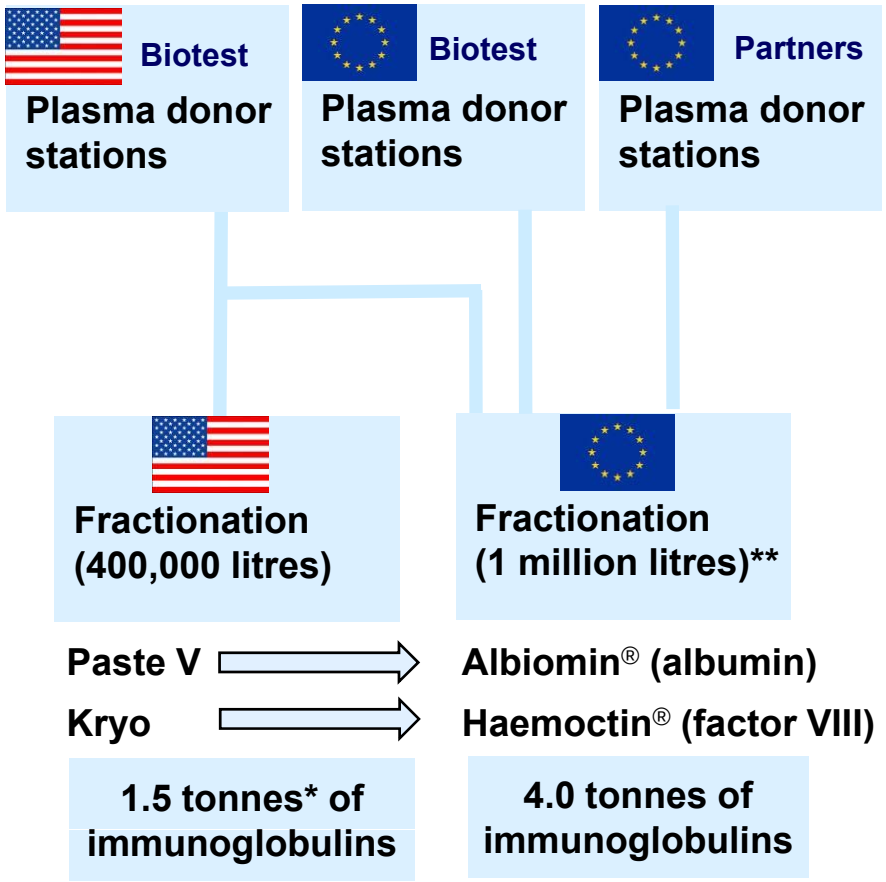
- State-of-the-art manufacturing facility at Biotest Pharmaceuticals Corp. (BPC) in Boca Raton, Florida
- Fractionation: 400,000 litres per annum
- Immunoglobulin production: 1.5 tonnes per annum
- Plasma collection at 11 BPC-owned plasma collection centres

Bivigam™ (IVIG) development nears successful completion

Polyspecific immunoglobulin with a wide indication range (incl. antibody deficiency and autoimmune diseases)

- A polyspecific immunoglobulin comparable to Intratect®
- Clinical development: successful conclusion of phase III
- Production of stability batches completed
- Submission of approval documents in Q3 2010, close to successful completion
- Sales potential after approval: around $100 million per annum

Plasma Proteins – Efficient production network



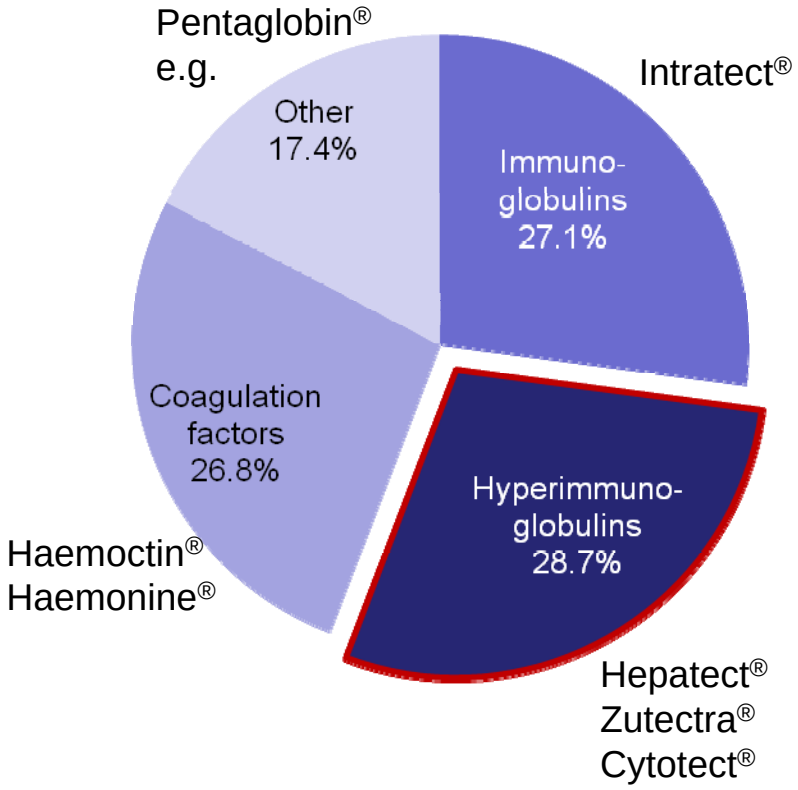
- 21 plasma collection centres
- Level of self-sufficiency: 40% for standard plasma
- Exchange of intermediate products from US to Europe from end of 2010
- Network increases EBIT margin

* Approval will probably be granted end of 2011

** Production in Dreieich and capacities at partners

Biotest: A market leader in special preparations

Biotest plasma proteins in 2009: sales by product category



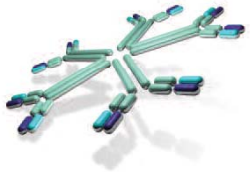
Hyperimmunoglobulins and special preparations are a very attractive segment:

- Stable prices
- High market entry barriers
- Biotest is totally self-sufficient in hyperimmune plasma procurement

Major R&D progress of Plasma Proteins Projects

Zutectra®

Post approval trial to examine convenience and self-medication at home with 70 patients



IgM Concentrate

Phase II to start mid of 2011
Treatment of serious bacterial infections
High functional activity, good tolerability

Cytotect®:

Phase III clinical trial ongoing
Prevention of prenatal CMV infection
Interim evaluation planned for end of 2010

Hepatitis B immunglobulin (subcutaneous / intramuscular) **in neonates**

Phase III trial, recruitment completed
Final Draft of Study Report Dec. 2010
Marketing approval: aiming at Germany first

Biotest R&D activity in Plasma Proteins

- R&D expenses in 2009 in the Plasma Protein segment: € 25.7 million; in H1 2010: € 14.8 million
- Continuous high investments in R&D in Plasma Proteins will guarantee future growth of the Plasma Proteins business
- Goal:
  - ➢ international regulatory registration and approval for all major Biotest products and intermediates



Biotherapeutics

Biotherapeutics: Focused research

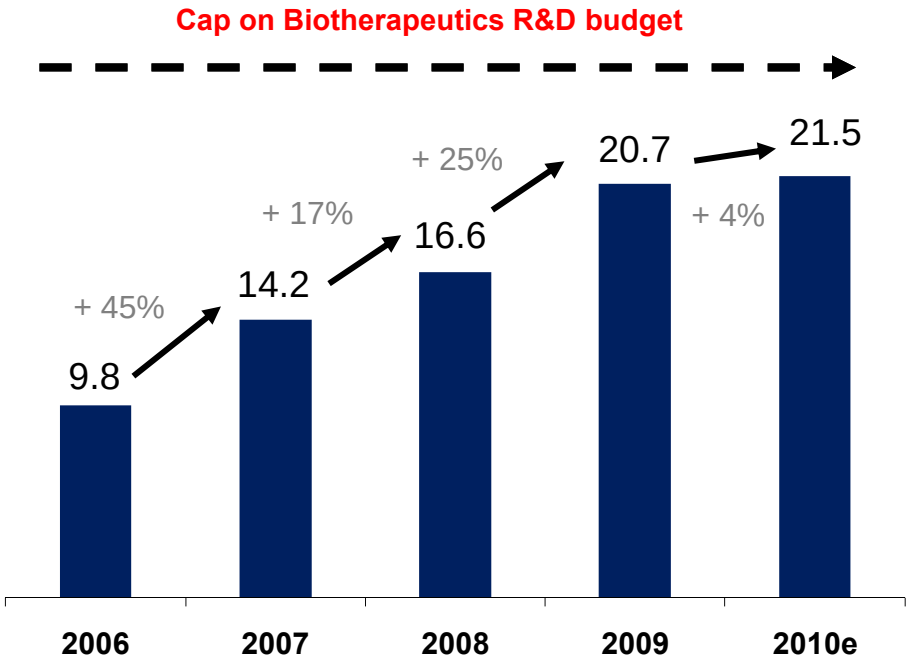
Biotherapeutics: Focused research

- High medical need
- Rapidly growing markets
- Blockbuster potential

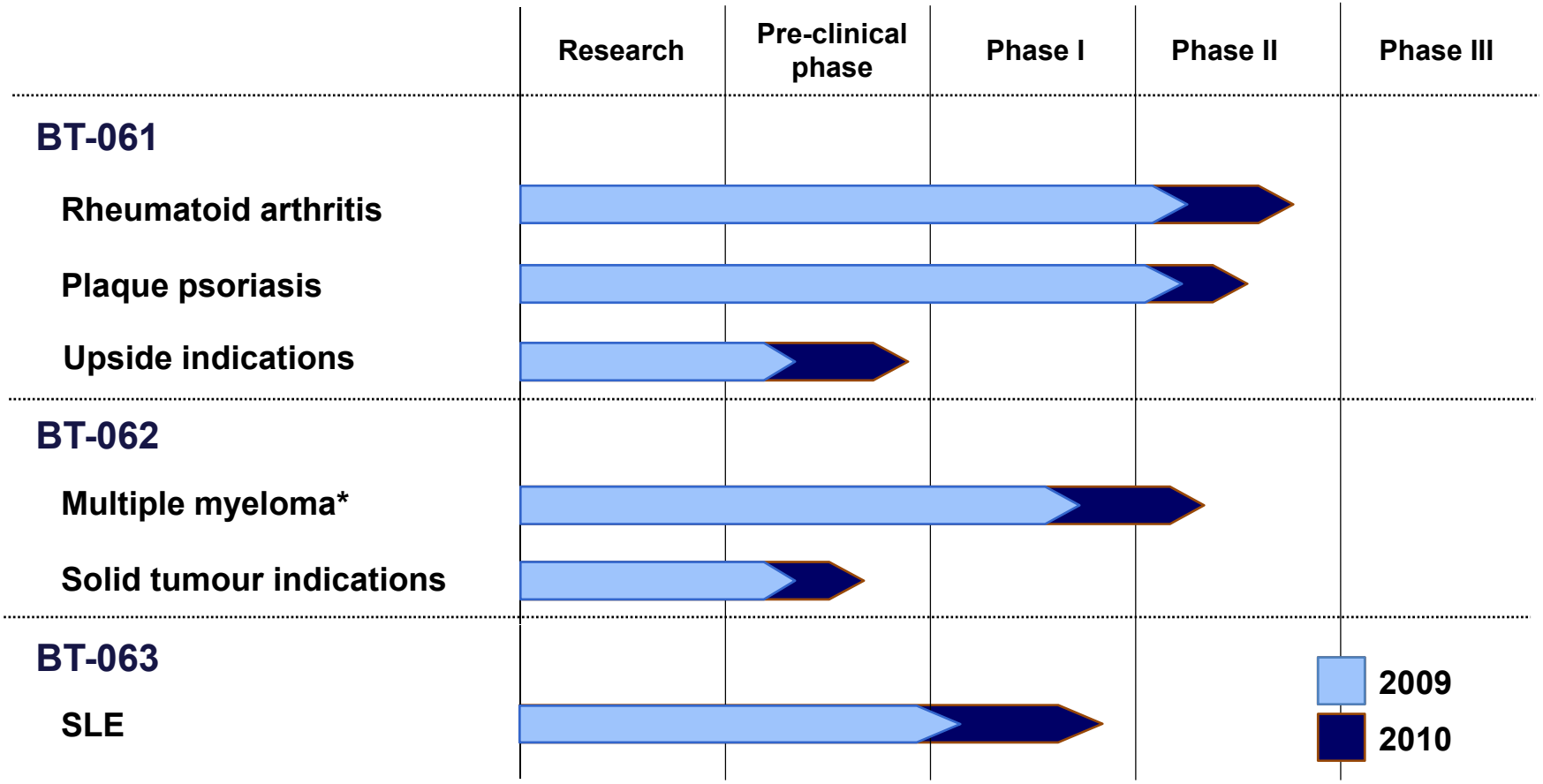
Lead indications

BT-061	Rheumatoid Arthritis, Psoriasis
BT-062	Multiple Myeloma
BT-063	Systemic Lupus Erythematosus

R&D expense – Biotherapeutics (in € million)

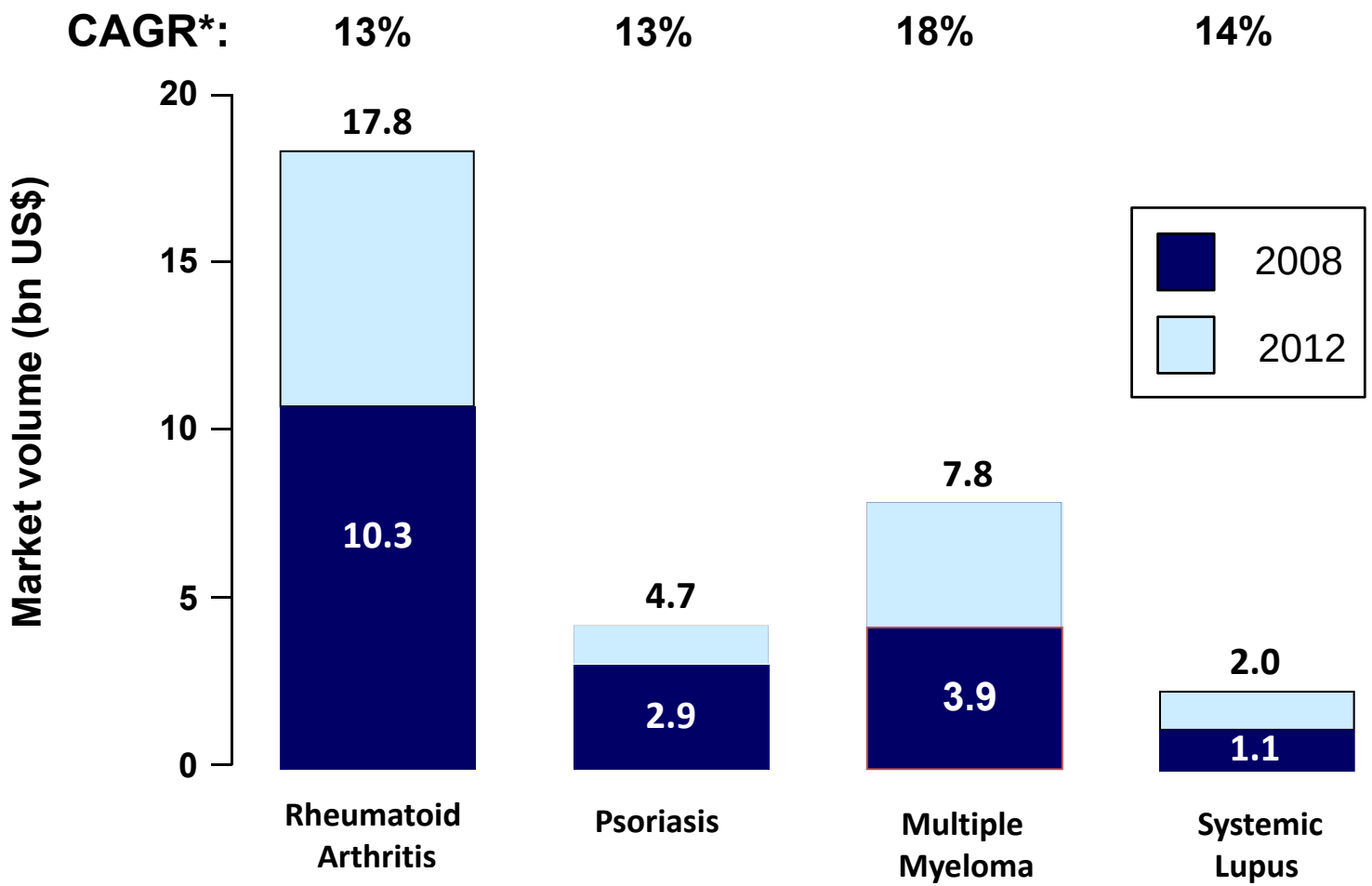


Biotherapeutics: Significant project progress in financial year 2009 and 2010



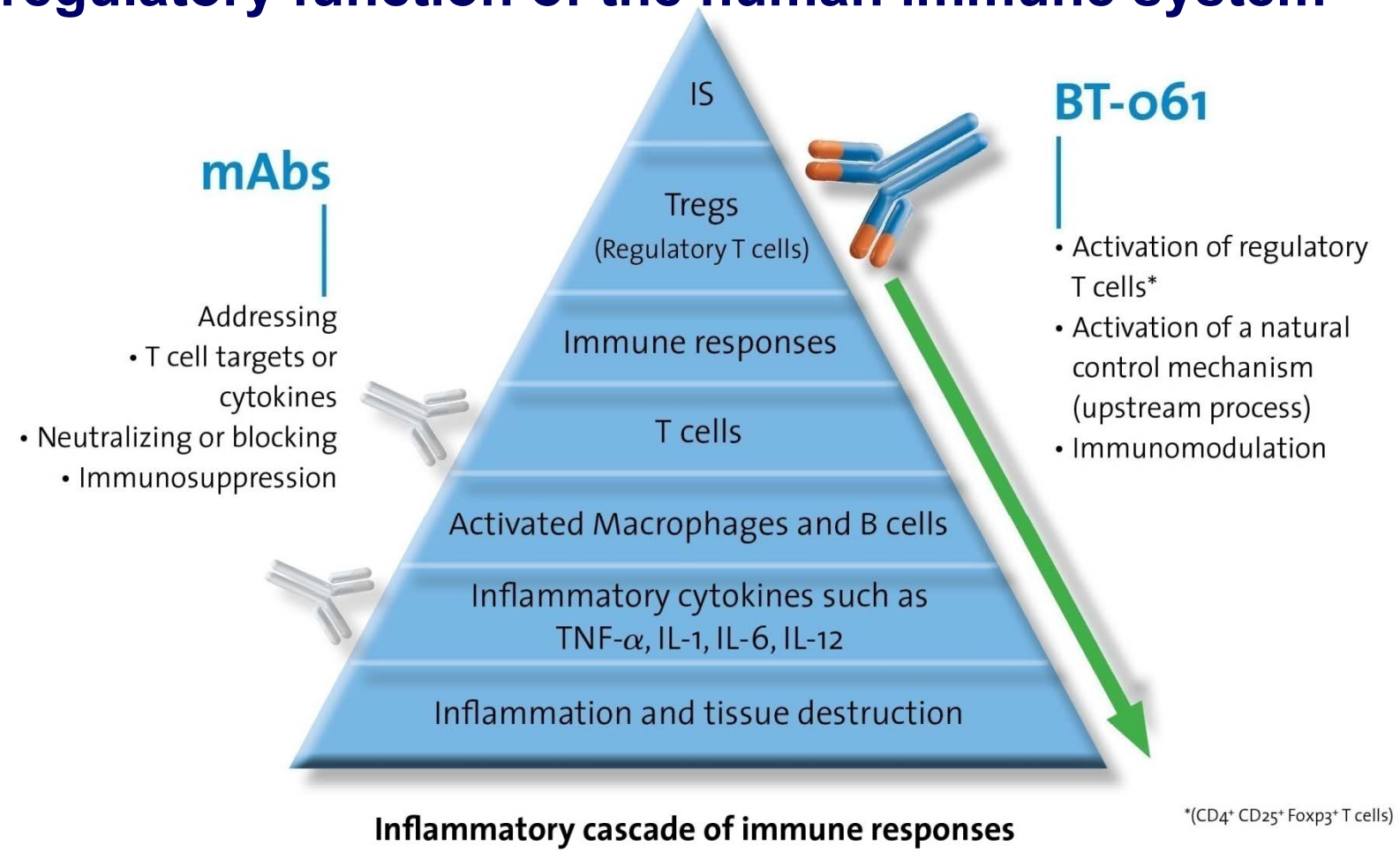
* Phase I/IIa clinical trial approved by FDA (IND)

Biotherapeutics: Continuously growing market potential



Quelle: Datamonitor, Decision Resources, Biotest
*CAGR: Compound Annual Growth Rate

BT-061 – Specific mode of action addressing key regulatory function of the human immune system



Inflammatory cascade of immune responses

Mode of action offers significant potential in several upside indications

BT-061: Goals of clinical trials starting in 2010

Higher patient numbers to confirm product profile seen in early trials

Psoriasis, Phase II (973)

- **Goals:**
  - Increase efficacy by completion of dose finding and repeated administration
  - Benchmarking with biologics gold standard
- **Design:** 48 patients in 6 dose groups, 8 weeks treatment, 12 weeks follow-up

Rheumatoid Arthritis, Phase IIb (979)

- **Goals:**
  - Confirm/establish superior efficacy and tolerability with larger patient basis
  - Establish Proof-of-Differentiation
- **Design:** 175 patients in 3 dose groups, 12 weeks treatment, 12 weeks follow-up

Rheumatoid Arthritis: Competitive market environment

Favourable positioning is key to success

	Cytokine neutralizing (TNFα and others)	Targeting B cells or T cells	Targeting Tregs: BT-061
MoA[1)]	Neutralization of cytokines	Depletion/inactivation of immune cells	Selective activation of Tregs
Weakness/ Threats	• **Black box warning:** risk of infection and malignancy • **FDA alert** for: invasive fungal infections and increased risk of lymphoma in children	• **Black box warning** for PML[2)] • Increased risk of infection • B-cell depletion (up to 1 yr) • Severe infusion reactions	• Late market entry requires clear USP[3)] and positioning
Strength/ Opportunity	• Market dominance • Broad safety database	• Treatment of TNF non responders	• **Superior efficacy** expected • Mode of action supports **good safety profile** (no signs of immunosuppression, cytokine release or lymphocyte depletion)

Positioning of BT-061 by new MoA, which translates into superior efficacy and safety

[1)] Mode of Action [2)] Progressive multifocal leucoencephalopathy [3)] Unique selling point

Current clinical data support targeted product

Positioning clear proof-of-concept in both indications

Rheumatoid Arthritis

Proof of Concept (POC) ✓

Phase II (No. 962 und 971):
Mono- and Combinationtherapy

- up to 70% improvement of clinical symptoms (ACR70)
- good tolerability
- Study 962: Final data available
- Study 971: Final data expected in Q4 2010

Psoriasis

Proof of Concept (POC) ✓

Phase I/IIa (No. 967):

- up to 88% improvement of clinical symptoms (PASI)
- long duration of therapeutic effect (up to 90 days after single administration)
- good tolerability

Study completed

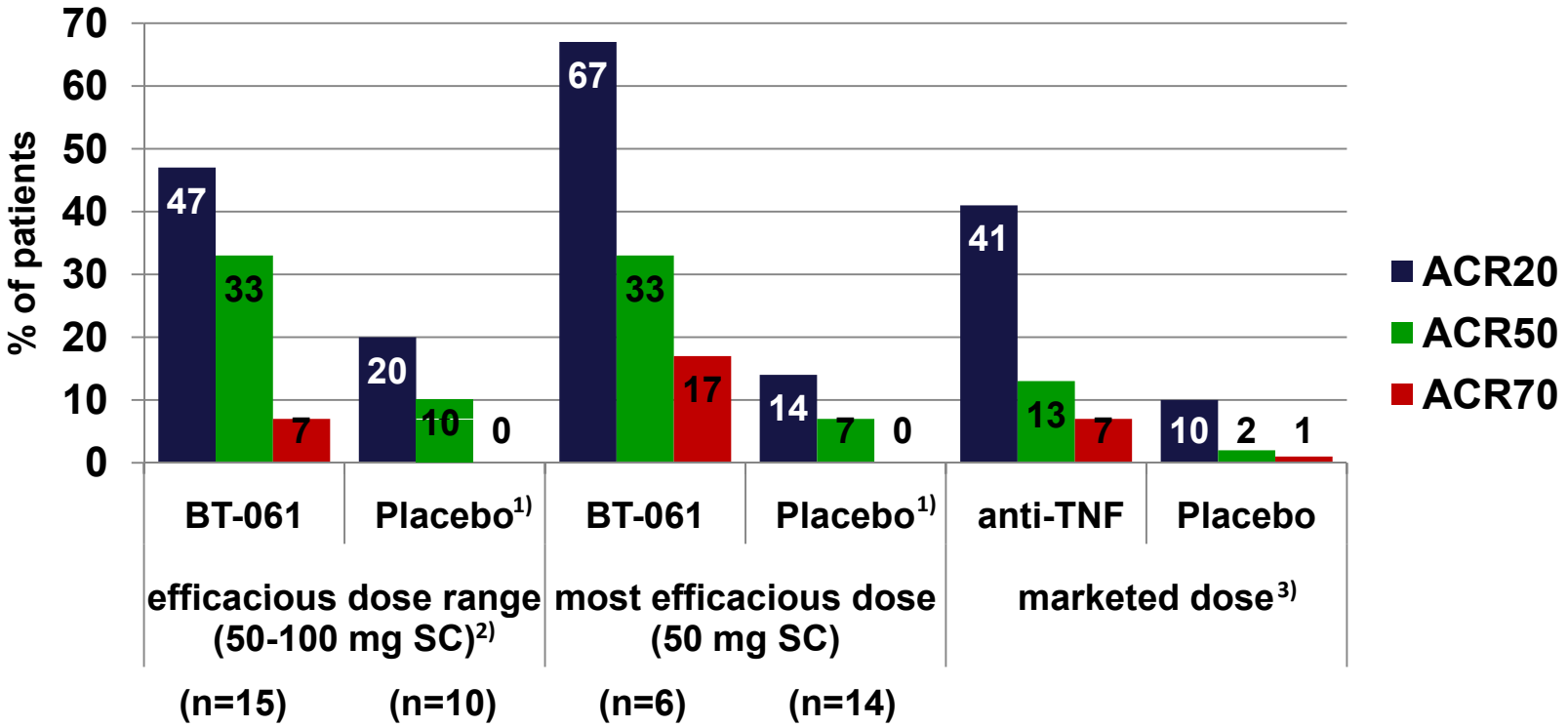
Potential to position BT-061 via

- **efficacy**
- **safety**
- **convenient administration**

(**self-administration**, every other week, **1 ml subcutaneously**)

Repeated treatment of RA patients with BT-061 (monotherapy)

Benchmarking against gold standard of biologic therapy



1) Two patients from each completed SC dose group; 2) Only patients that received all treatments over the 6 week periode

3) Phase III trial results of anti-TNF monotherapy in DMARD non-responders at week 7

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

Clinical development BT-061
Overview

Study no.	Indication	Design	Subjects/ Patients Planned	Status
961	Healthy volunteers	single dose iv; and sc up to 180 mg	57	Study completed
967	Phase I/IIa:Psoriasis	single dose, placebo controlled iv and sc	55	Study completed
973	Phase II: Psoriasis	multiple dose, placebo controlled	48	Recruitment ongoing
962	Phase IIa: Rheumatoid Arthritis	Multiple dose, Placebo controlled	96	Study completed
971	Phase II: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	110	Recruitment completed
979	Phase IIb: Rheumatoid Arthritis	BT-061 + MTX Multiple dose, Placebo controlled	175	Submitted to regulatory authorities

Biotherapeutics: Established own production capacities

Development structures in the segment:

- GMP production of monoclonal antibodies established in Boca Raton (BPC)
- Manufactured first large-scale batches of BT-061 in own production facility
- Start of GMP production of BT-062 at BPC in 2011

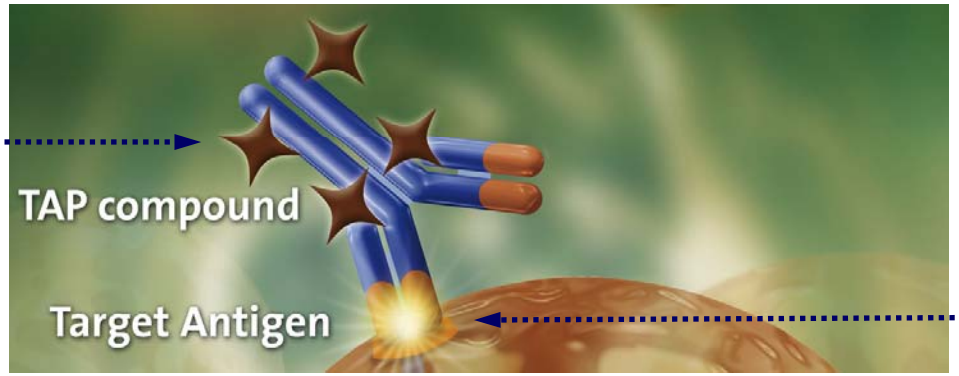
BT-061 partnership

Biotest strategy:

Cooperation with partner from clinical phase III

- Negotiations with international pharmaceutical companies ongoing
- High level of interest
- Request for confirmation of positive trial results via further phase II clinical trials
- Stand-alone further development of mAb until agreement is reached

Competitive edge BT-062: Intrinsic properties provide basis for product positioning



Toxin moiety mediates high efficacy

- **High potency independent of patient´s immune system**
- Toxin technology with best track record: Sanofi Aventis, Biogen Idec, Bayer, Roche/Genentech amongst licensees
- First filing of TAP[1)] mAb expected in 2010 (Genentech)

Antibody moiety mediates high specificity

- Unique targeting to CD138
- CD138 highly overexpressed in MM and other cancer cells
- **CD138 not expressed on bone marrow stroma cells**
- Good tolerability up to 160 mg/m^2

[1)] TAP: Tumor activated payload

BT-062 competitive edge: Specificity and high potency provide potential for competitive positioning

	Small molecules	mAbs	Immunoconjugate BT-062
MoA[1)]	Unspecific cellular toxicity	Specific cellular target	Specific targeting combined with high potency drug
Weakness/ Threats	AEs in > 30% of patients • **Myelosuppression** • **Thromboembolic events/ DVT**[2)] • **Peripheral neuropathy** • **Gastrointestinal AEs**[3)]	• **Dependent on patients immune system** • Broad tissue expression/ potential cross reactivity	• Limited safety data basis
Strength/ Opportunity	• Dominant market position • Validated targets • Comprehensive safety data base	• High specificity	• **High potency** independent from patient's immune system • **High specificity** • **No myelosuppression** and liver toxicity expected

[1)] Mode of Action [2)] Deep Vein Thrombosis· [3)] Adverse events

BT-062: Single-dose study 969 in Multiple Myeloma

First efficacy data, August 2010

Number of patients	Total	Percentage	Objective response	Clinical benefit (%)
treated with BT-062*	32			
efficacy data available	**25**	**100%**		
- disease progression within 6 weeks	11	44%		
- stable disease ≥ 9 weeks	12	48%		**56%**
- minor response	1	4%	8%	
- partial response	1	4%		

- **BT-062 shows anti-tumor activity already in repeated single dose schedule**
- **Further patients were enrolled in MTD** cohort up to a total of 13**

*Median number of prior chemotherapies: 7 (range: 2-15); 33% of patients had 10 or more prior chemotherapies
**MTD: Maximum tolerated dose; Response criteria as defined by International Myeloma Working Group

BT-062: Next steps

Establishment of commercial treatment schemes

Phase I/II: Repeated Dosing / Monotherapy – USA (Recruitment started August 2010)

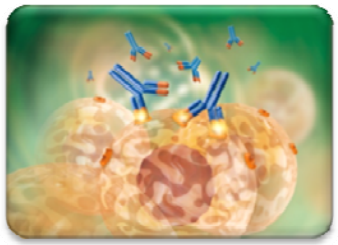
- **Goals**:
  - Selection of commercial treatment scheme
  - Establish Proof-of-Differentiation in mono therapy
- **Design**:
  - Up to 70 patients, open label escalation study with intensified dosage scheme
  - Extension cohort of up to 29 patients

Phase II: Repeated Dosing / Combination – Europe (Planned start: 2011)

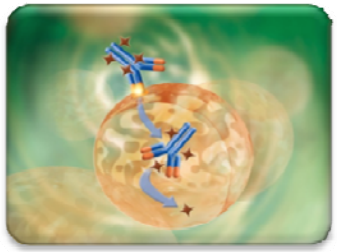
- **Goal**: Establish Proof-of-Differentiation in combination therapy
- **Design**: Open label combination study

Due to lower number of pre-treatments, patients are expected to show improved response rate and longer duration of benefit

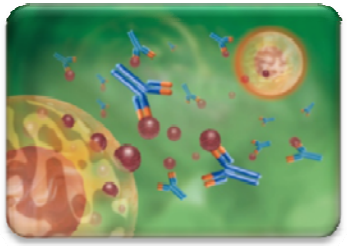
Outlook Biotherapeutics:
Next steps in clinical development initiated



BT-061:
- First encouraging clinical data from both lead indications
- Phase II trial in Psoriasis started
- Phase IIb in RA initiated
- Discussion with strategic partners ongoing



BT-062:
- First indications of efficacy from dose-escalating study
- Multiple dose phase I/IIa trial approved by FDA
- Study initiated



BT-063:
- Phase I study approved in Sept. 2009
- Treatment at 7th dose level completed (02 2010)

Outlook for 2010

Further outlook Biotest Group

- Despite difficult business environment we continue to invest into R&D of Plasma Protein Projects and Biotherapeutics
- Full pipeline of Plasma Protein products and Biotherapeutics with a potential to reach the market within the next years
- BPC/ USA: access to the single biggest plasma protein market
  - Q3 2010 BLA submission of Bivigam™ on track
  - Launch of Bivigam™ (IVIG) expected to take place in H2 2011
  - Additional market potential of $ 100 million

Contact and Financial Calendar 2010/2011

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Financial Calendar 2010/ 2011

Nov 08, 2010	**Q3 Report 2010/ Analyst's Conference**
Mar 22, 2011	**FY 2010/ Analyst conference**
May 10, 2011	**Q1 Report 2011**
May 12, 2011	**Annual General Meeting**
Aug 11, 2011	**Q2 Report 2011**
Nov 10, 2011	**Q3 Report 2011/ Analyst conference**