
Biotest AG

**Smart Equities Conference
Frankfurt/Main, 14 Nov 2006**



Agenda

- **Nine-month figures**
Dr. Michael Ramroth, Chief Financial Officer

- Projects and strategy: global specialist in growing markets
Prof. Dr. Gregor Schulz, Chief Executive Officer

Continued profitable growth – highlights of the first nine months of 2006

Global growth

- Sales rise by 17.5% with significant impetus from plasma proteins
- Particularly dynamic development in key European markets

Increased earnings strength

- Despite a marked increase in R&D expense, EBIT + 19%
- Further improvement in the financial result: EBT + 56%, EAT + 32%

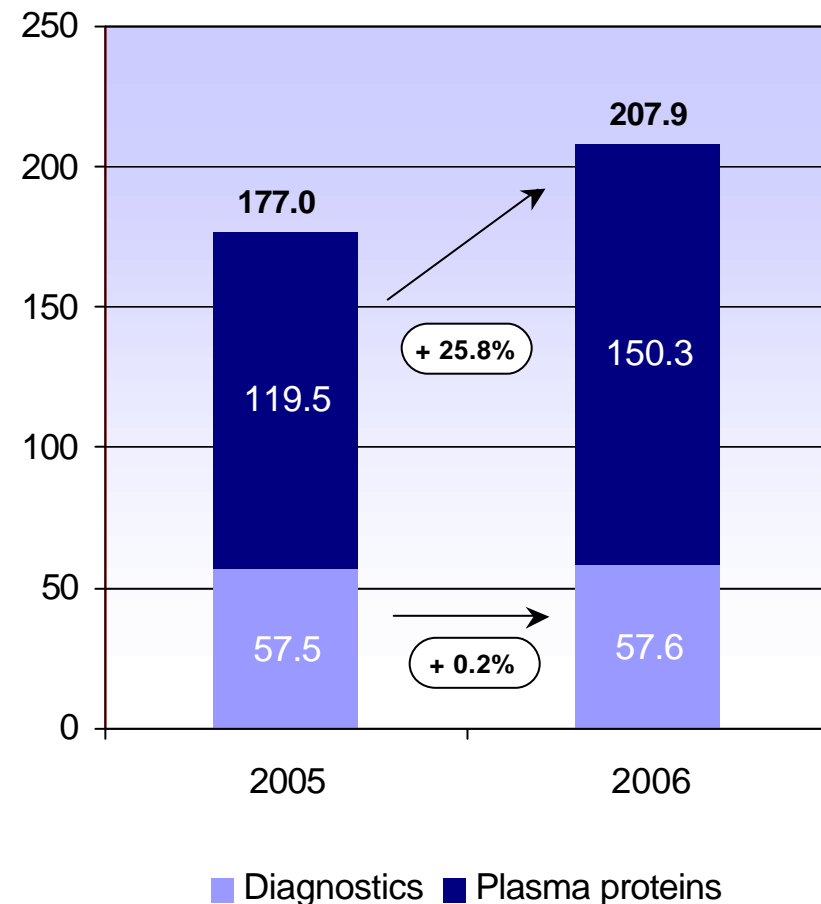
Basis for continued successful development

- Approval of Hepatect FH[®] in six EU countries
- Great success for Intratect[®] in UK
- Orphan drug status for Cytotect[®] in the EU
- Licensing agreement between Biotest and ImmunoGen
- Financial structure further enhanced

Sales rise by 17.5% with significant impetus from plasma protein business

- Sales in the Pharmaceutical division grow by more than 25%
- Expansion of positioning in core European markets
- Toll manufacturing moderate – focus on own high margin products
- Diagnostics at previous year's level: transfusion/transplantation difficult, HYCON/Heipha continue dynamic growth

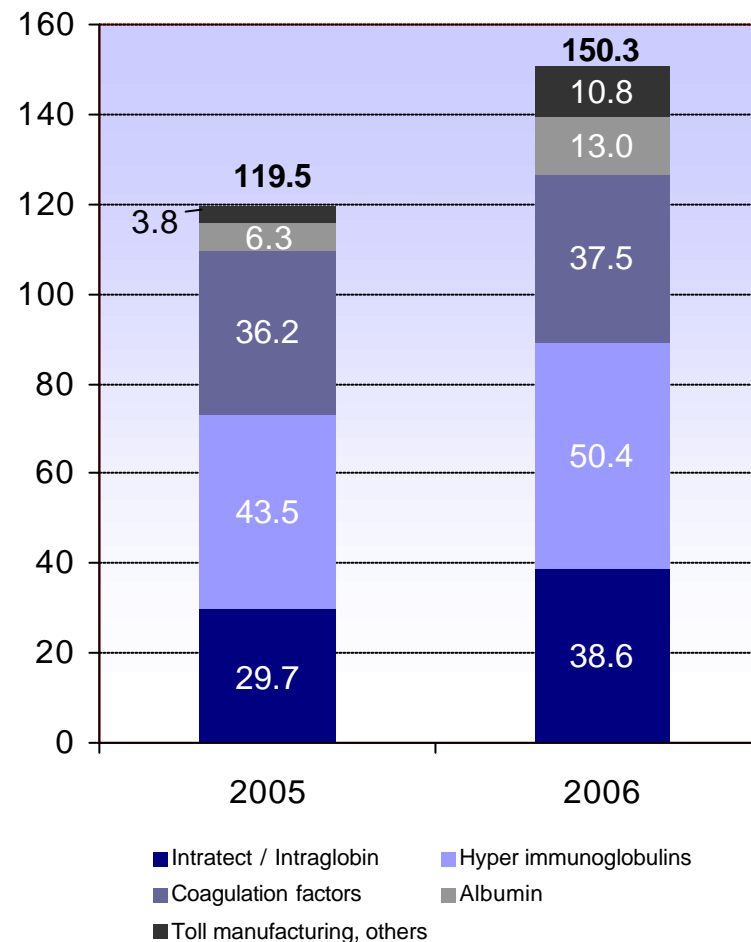
Sales Q1-Q3 (€ m)



Plasma proteins: immunoglobulins drive growth, considerably higher sales with Pentaglobin

- Intratect® expands positioning, share in Germany: > 20%, initial sales very positive in the UK
- Dynamic growth recorded by Hepatect®
- Coagulation factors: successful business in Russia (Biotest market share: > 40%)
- Pentaglobin®: higher sales, especially in Russia and Greece
- Price recovery for Albumin, increased sales from bids for tender

Sales Q1-Q3 (€ m)



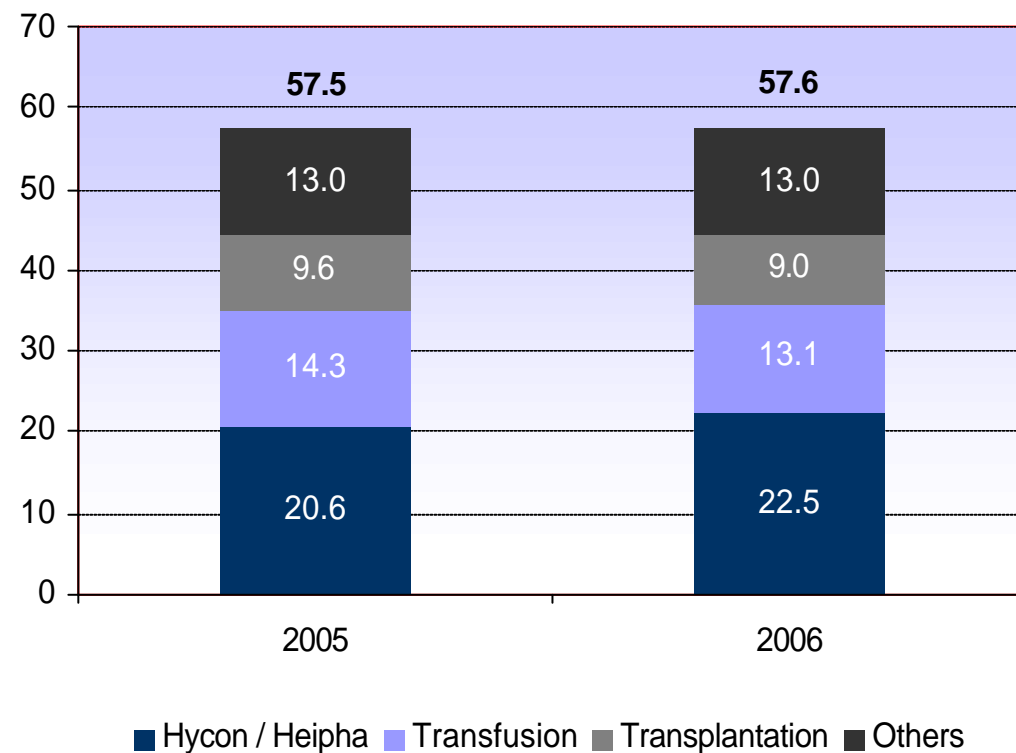
Polyspecific IGGs of Biotest: substantial increase of market share in core markets

<u>Country</u>	<u>Market share 2005</u>	<u>Market share Q3 2006</u>
Germany	18.6%	21.2%
Austria	22.1%	24.9%
Greece	22.4%	38.2%
UK + Scotland	0.0%	5.9%
Tot. major markets	11.0%	16.2%

Diagnosics: sustained success for Hycon, transfusion und transplantation sales down

- Difficult market conditions in Europe lead to a decline in sales in transfusion and transplantation diagnostics
- Positive development in the Middle East
- US operations with TANGO® remain below expectations – change in sales strategy
- Hygiene monitoring products (HYCON/Heipha) remain very successful

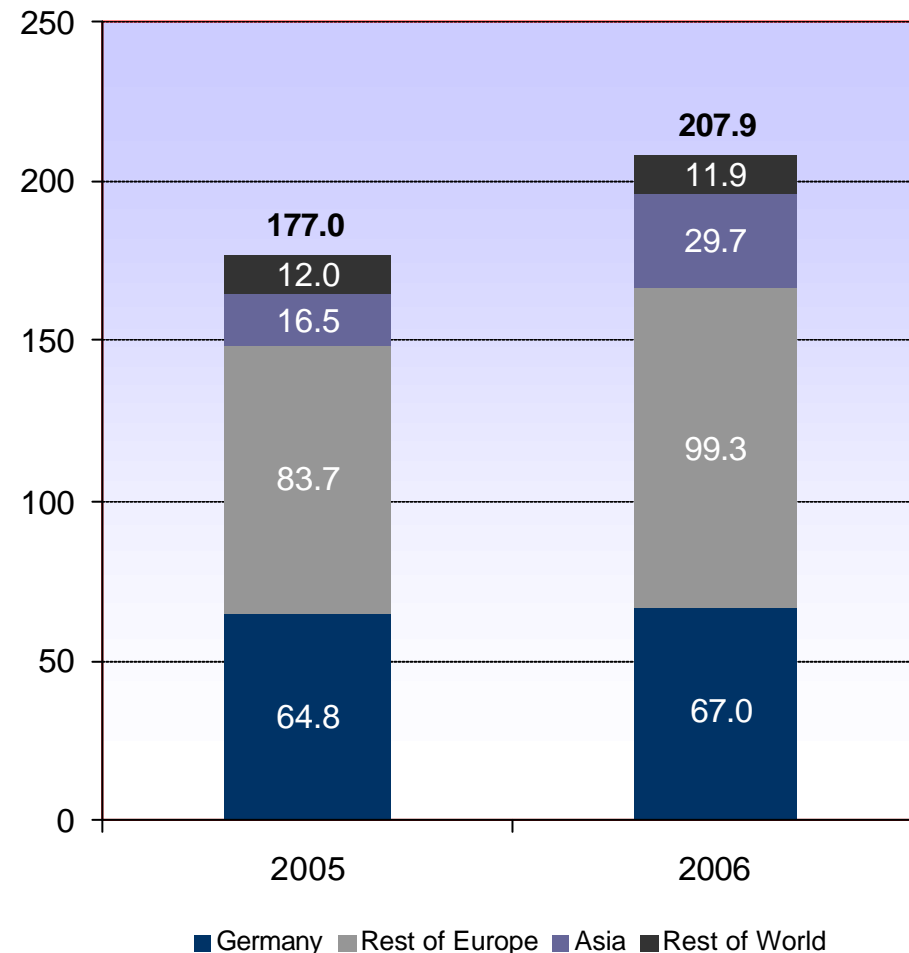
Sales Q1-Q3 (€ m)



Sales by region: strong growth in the core markets

- Strong growth in Pharmaceutical sales in the core European markets
- Moderate increases in Germany
- Marketing launch of Intratect® reflected in other EU markets
- Expansion of market position in Russia (coagulation factors, Pentaglobin®)
- Growth in Asia: influenced by high additional sales of plasma proteins in the Middle East (tender, toll manufacturing)

Biotest Group: sales Q1-Q3 (€ m)



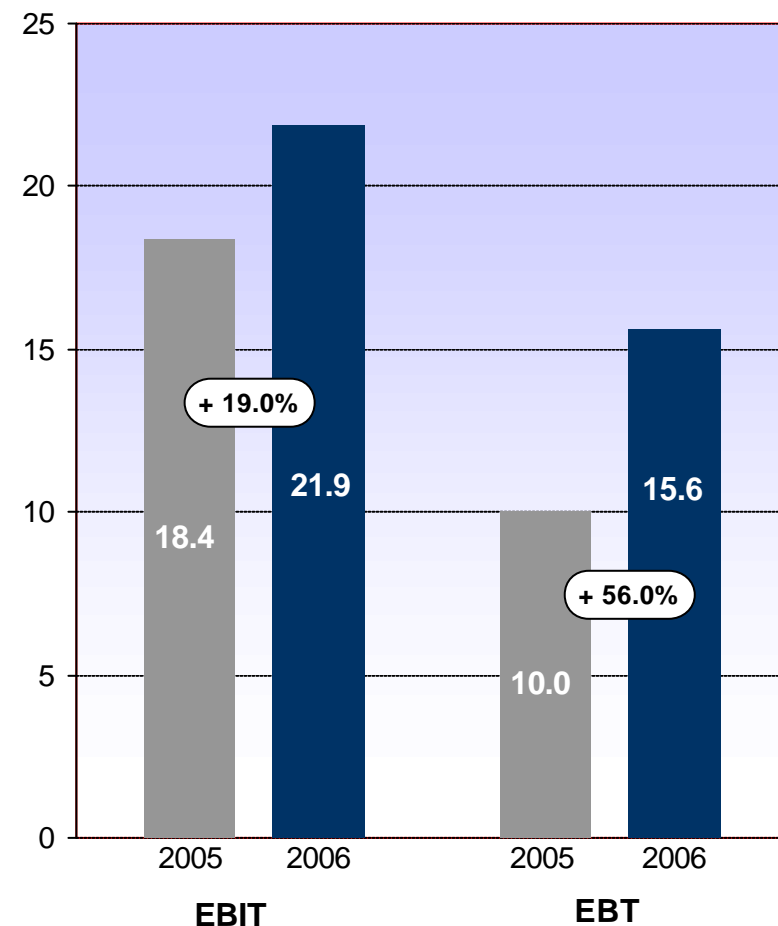
Earnings growth exceeds increase in revenue

- Increase in EBIT over course of the year clearly exceeds previous year's level
- Jump in earnings for plasma proteins: EBIT €33.6 m (+64.7%), EBT: €28.5 m (+111.1%)
- Diagnostics below previous year's level: EBIT: €0.9 (-73.5 %), EBT: €0.0 (Q1-Q3 05: €2.4 m)
- Return on sales (EBIT): 10.5% (previous year: 10.4%)
- RoCE*: 8.9% (previous year: 7.5%)
- Further marked improvement in financial result to €-6.3 m (2005: €-8.4m)
- Earnings per share: €0.80** (previous year: €0.79)

* annualized

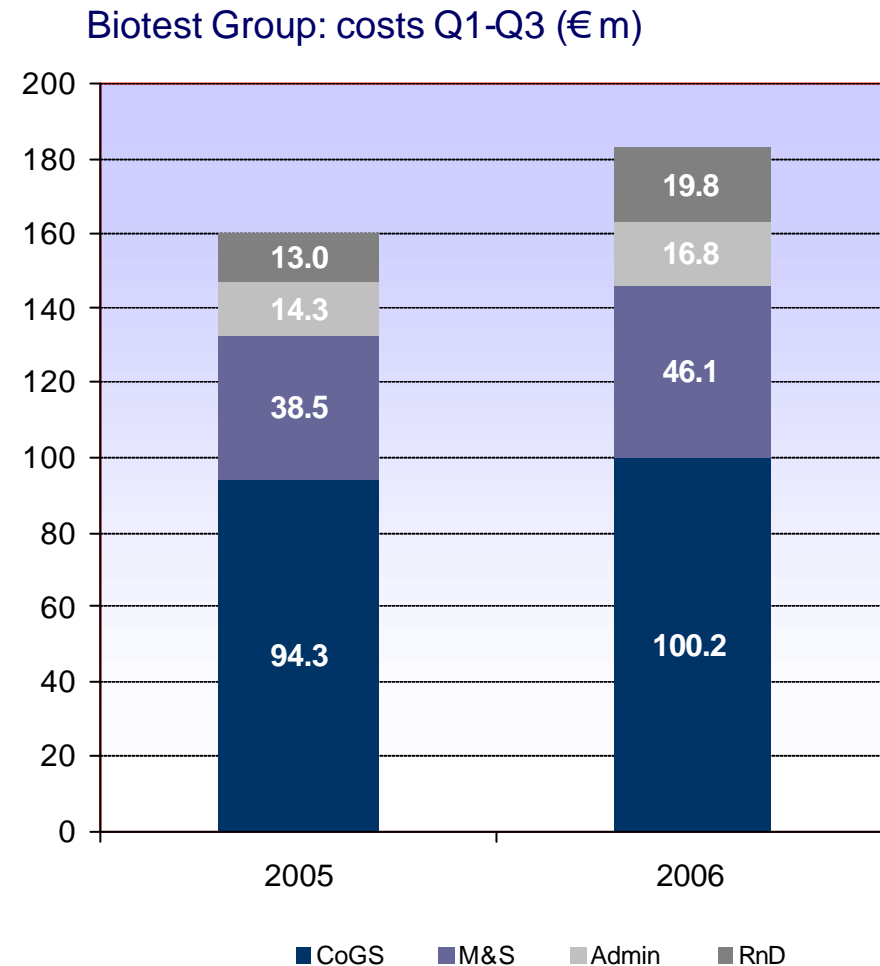
** on a comparable basis: €0.87

Biotest Group: EBIT and EBT Q1-Q3 (€ m)



Expenditure: marked increase in R&D expense

- Costs rise only moderately in comparison to sales
- Considerably lower manufacturing costs ratio thanks to increase in efficiency in the production of plasma proteins
- Costs for sales and marketing rise with higher sales volumes
- R&D expense extended by more than 50% in year-on-year comparison – progress of the mAb projects



Financing, accounting: further improvement in cash flow and financial result

- Cash flow from operating activities considerably higher than the previous year at €16.3 m
- Investments totalling €9.0 m fully funded from internal resources
- New financing agreement replaces former syndicated loan: one-off effect on the financial result in Q4 06 of approx. €0.8 m will be more than offset by considerably more favourable conditions in subsequent quarters
- Stretching of the balance sheet through growth-related expansion in inventories and trade accounts receivable
- Equity ratio stable at 48.3% (previous year: 48.5%)

Agenda

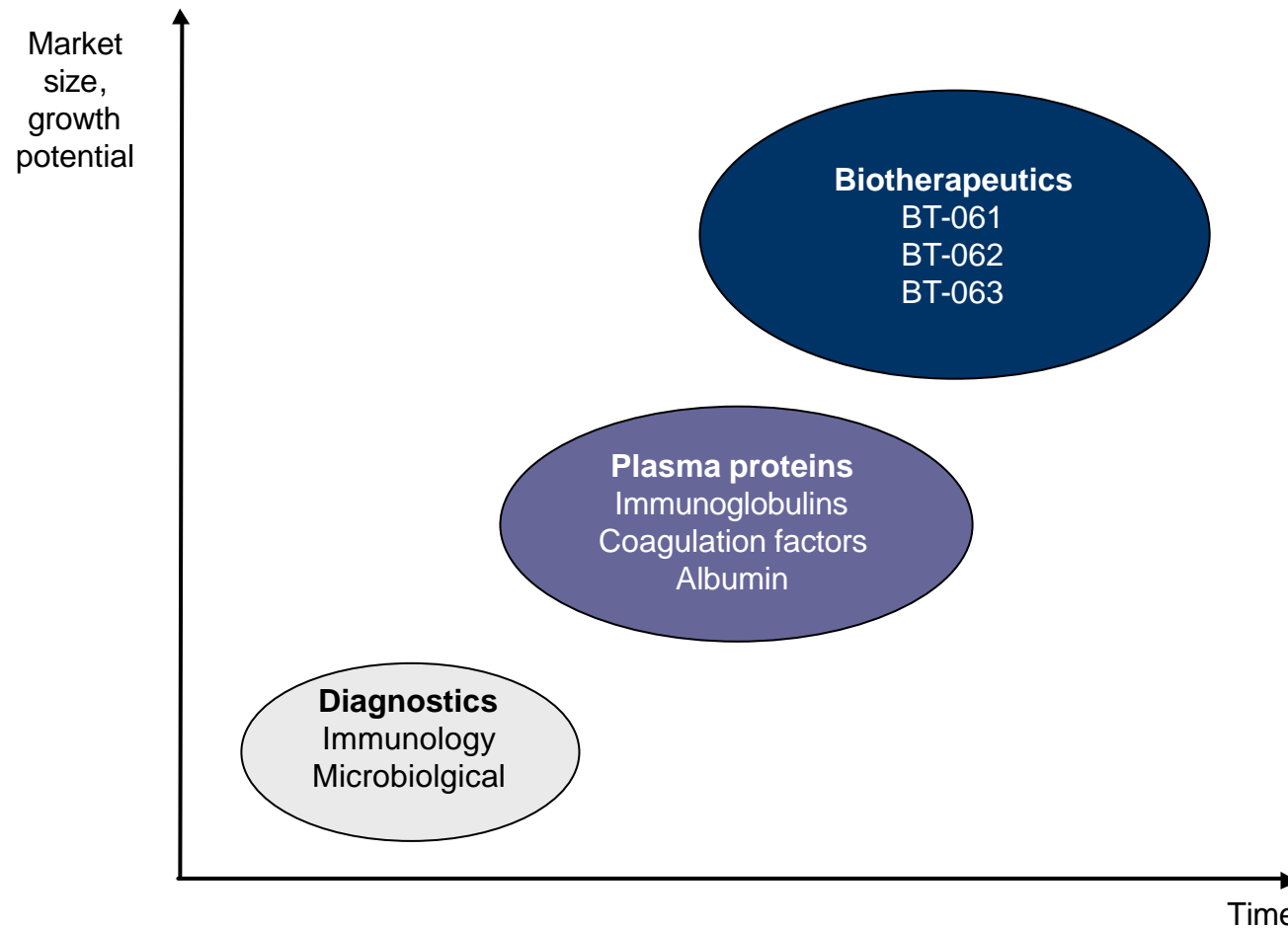
- Nine-month figures

Dr. Michael Ramroth, Chief Financial Officer

- **Projects and strategy: global specialist in growing markets**

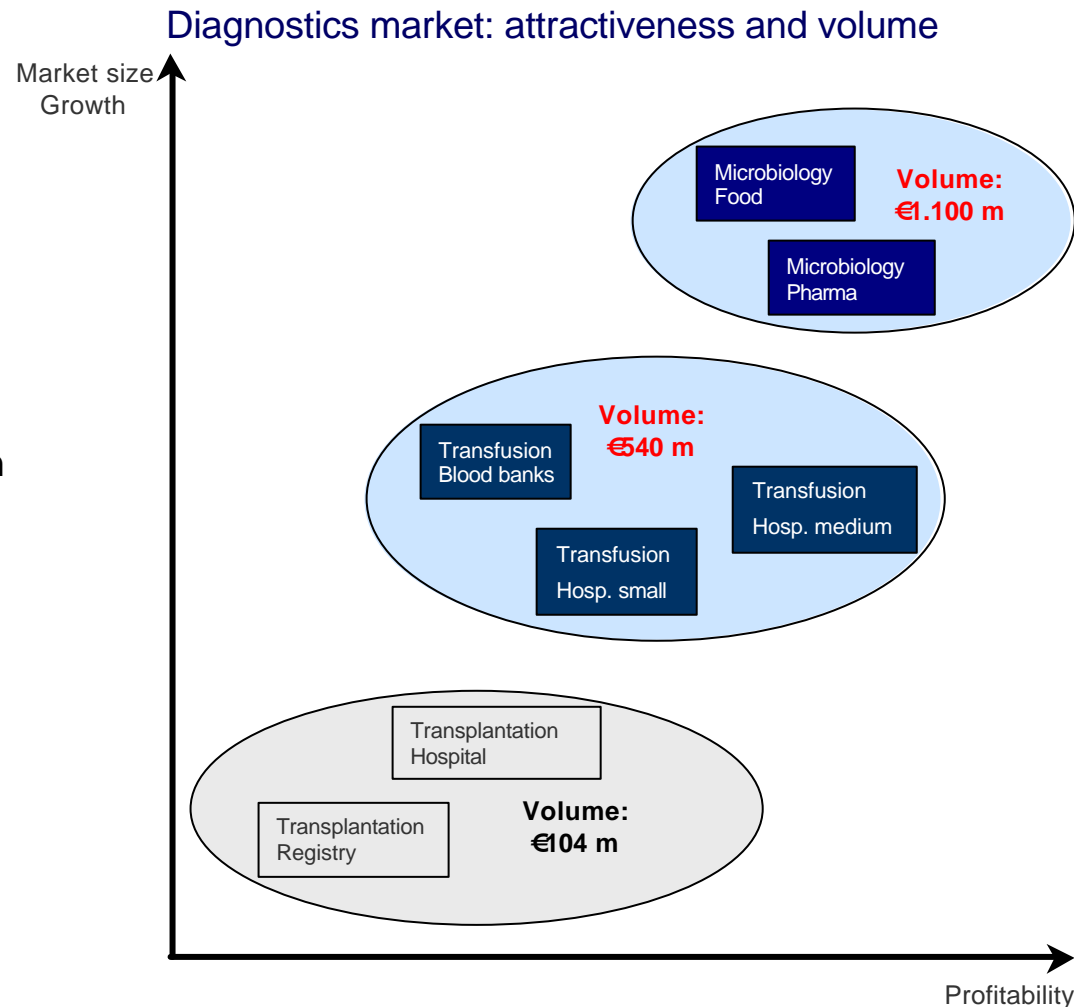
Prof. Dr. Gregor Schulz, Chief Executive Officer

Biotest strategy: focusing on growth and high margin markets



Diagnostics: focusing on segments and markets with the highest growth potential

- Focus on immunological diagnostics and industrial microbiology
- Infectious diseases and transplantation do not constitute core areas
- Investment in broadening position in the US, the world's largest and most profitable market



Diagnostics: strategy for immunological diagnostics and industrial microbiology

Immunological diagnostics: strengthen activities in the US market

- Completion of product range: market authorisation of further TANGO® reagents by the FDA in October 2006, approval of manual reagents planned Q4 2007
- Development of a Biotest marketing & sales organisation for transfusion diagnostics
- Redefined relationship Biotest – Olympus: Biotest sells to small and medium-sized hospitals, Olympus sells to donor centre market and provides service teams
- Construction work begins for a new fill facility with full FDA compliance at Dreieich

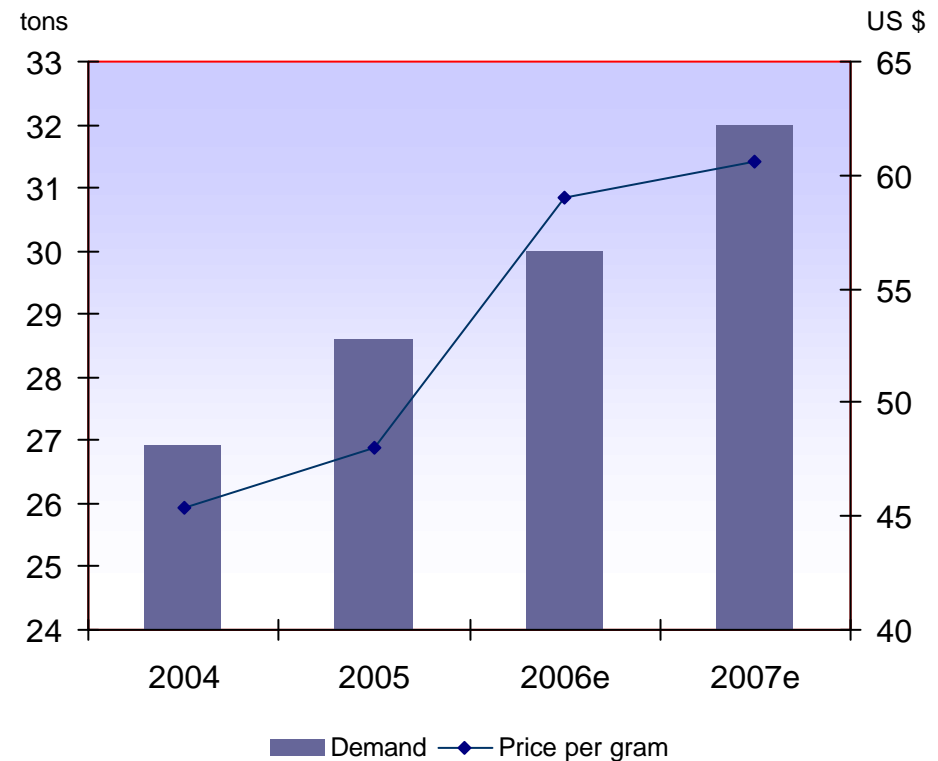
Microbiology: broadening product range and market base

- Ensuring rapid market expansion through investments in marketing and sales in 7 core markets (Austria, France, Germany, Italy, Japan, Spain, Switzerland, USA)
- Access to new market segments: food and cosmetics industry
- Investment into the development of new ground-breaking technologies (PCR platform combined with Heipha expertise)
- Development of BSE-free production conditions (to facilitate US market entry)

Plasma proteins: markets with sustained upward trend

- Increase in demand for immunoglobulins in Europe and the US
- Demand for plasmatic coagulation factors remains stable
- Albumin continues to recover: price increase

Market volume (in tons) and price (US\$ per gram) of IVIGs in the US



Plasma proteins: further modernisation of the product range

- Hepatect[®]: production adopts modern filter aid procedure (higher degree of purity, better use of raw materials)
- Approval received for six European countries, marketing launched immediately, other countries to follow
- 2007 schedule:
 - Haemonine[®] (Factor IX): approval in Europe - focus on Germany, followed by other markets
 - Haemoctin[®] (Factor VIII): approval in Europe (MR), increasing market presence
 - Human albumin FH: new generation (filter aid product), European approval
 - Intratect[®]: introduction of nanofiltration (additional virus removal step)

Plasma proteins: significant increase in market potential for Cytotect®

- According to clinical studies, Cytotect® dramatically reduces severe disorders in newborn babies caused by cytomegalovirus infections in embryos
- Market potential €30 m in Europe, €40 m in the USA
- Orphan drug status: awarded by EMEA in Europe, application submitted in the USA. Market exclusivity (Europe ten, USA seven years), accelerated approval, other benefits e.g. tax benefits
- Discussion with specialist committees concerning “off-label” use (doctors, health insurance companies regarding reimbursements)
- In 2007: clinical studies for approval of new indication (phase III, open, prospective, randomised, controlled multi-centre) – duration approx. 2 years

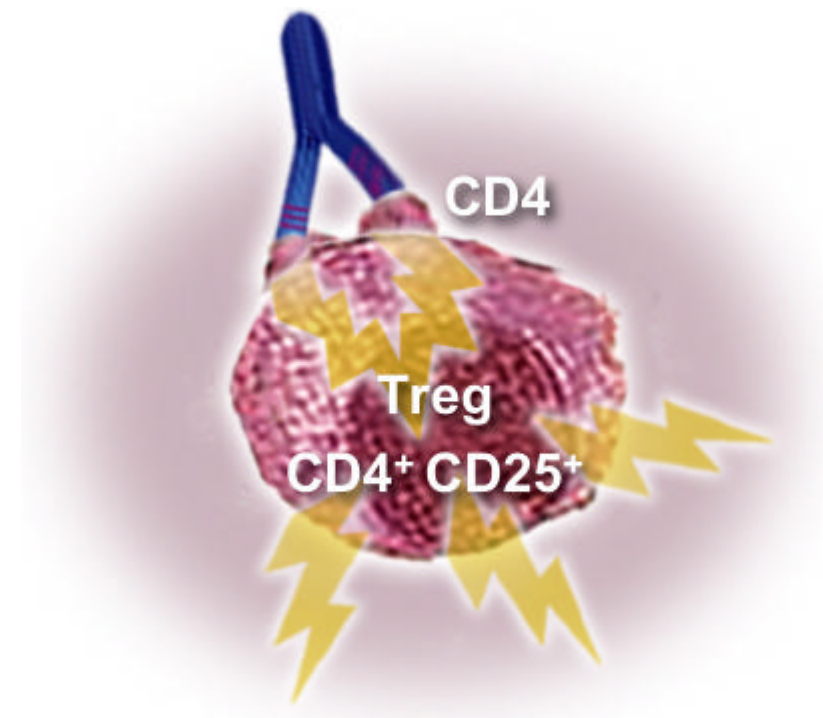
Plasma proteins: strategic alliance with Sanquin for the production and development of plasma proteins

- **Current results of ongoing negotiations:**
 - Closer cooperation in Research and Development
 - In-licensing (PPSB product Cofact® in 2007, C1 Esterase Inhibitor Cetor® in 2009), out-licensing and production (Multigam®)
 - Sanquin production plant and intermediates are included in the international registration process of Biotest products
 - Companies can share intermediates and reduce costs for process development and registration
- Proposal from Biotest to take over assets of Sanquin. Still awaiting a decision from the Sanquin management board.

Biotherapeutics: further progress in the development of three mAbs

Three monoclonal antibody (mAb) projects:

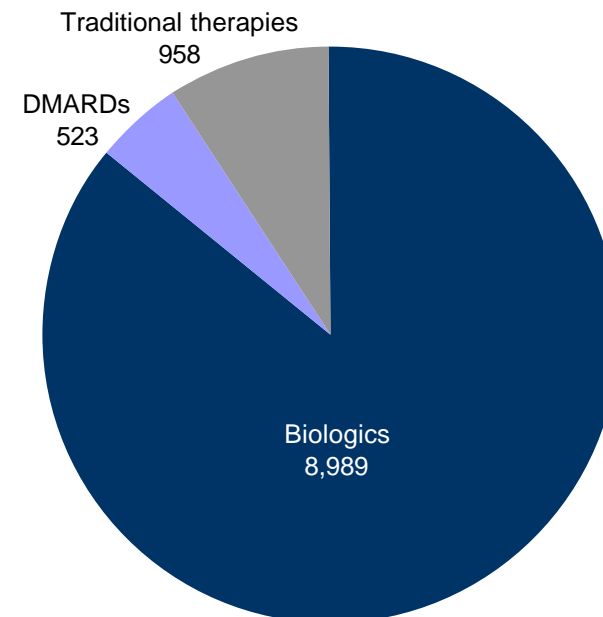
- BT-061: rheumatoid arthritis, Psoriasis
- BT-062: multiple myeloma
- BT-063: Systemic Lupus Erythematoses and other autoimmune diseases



BT 061 – medical need: biologics facilitate progress in treatment of RA, but far from long-lasting remission

- 50% of patients stay on their drug for less than 2 years due to adverse events or loss of effectiveness ("secondary non-responder")
- 25% of patients do not respond to TNF- α antagonist therapies
- 30% of patients do not have adequate control (ACR 50) with most effective current therapies, 60-80% of patients do not display major clinical response (ACR 70)
- 80-90% of patients do not reach remission
- No drug so far has gained approval for remission or at least complete clinical response
- BT-061 with unique mode of action: highly effective – significant market share seems to be realistic
- So far only 25% of patients worldwide (approx. 6 m) are treated with biologics

Estimated revenue of drugs for treatment of rheumatoid arthritis in 2008 (US\$ m)



Development of BT-061: milestones reached in 2006 and those planned for 2007



Production system

- | | |
|--|--|
| <ul style="list-style-type: none"> • Completion of production, analytics and product release (by partner) • Significant optimisation of yields | <ul style="list-style-type: none"> • Completion of optimisation programme • Proof of comparability and consistent quality of the clinical batches • Production for further clinical studies |
|--|--|

Preclinical development

- | | |
|---|---|
| <ul style="list-style-type: none"> • Completion of pharmacological and toxicological studies | <ul style="list-style-type: none"> • Completion of the long-term toxicology study in animals |
|---|---|

Clinical research

- | | |
|--|--|
| <ul style="list-style-type: none"> • Submission of the clinical trial application to regulatory agency (PEI) • Approval of clinical protocol from the Ethics Commission at Heidelberg University | <ul style="list-style-type: none"> • Start phase I in Psoriasis • Start phase I/II in RA |
|--|--|

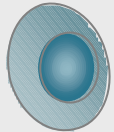
Additional pre-clinical studies for BT-061 successfully completed

- The production of BT-061 for clinical testing was completed on schedule in March 2006.
- Severe adverse effects caused by TeGenero antibody TGN1412 in a clinical phase I study in UK caused an increase in regulatory and safety requirements.
- Additional pre-clinical studies have been successfully completed by Biotest and confirmed the high quality and safety standards of BT-061.
- Launch of clinical studies now imminent.
 - Psoriasis: CTA submission for phase I to Paul-Ehrlich-Institut in September.
 - Rheumatoid arthritis: preparation of clinical trial almost complete, clinical trial application for phase I/II in preparation

BT-062: significant potential for treatment of highly aggressive multiple myeloma (MM)

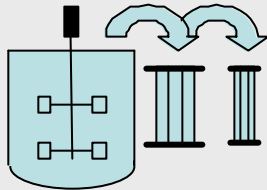
- MM remains an incurable malignancy (mortality rate at 95% after 10 years).
- Growing incidence and prevalence of disease (2005: 5-6/100,000 with ~ 144,000 diseased patients in 7 major markets)
- **BT-062 with competitive advantages:**
 - High-level expression (50 – 200 x increased compared to normal plasma cells) of target antigen in the vast majority of patients
 - High specificity of target. No expression on haematopoietic bone marrow precursor cells and B cells
 - Binding exclusively to membrane-bound antigen
- **Preclinical results indicate that BT062 could provide a meaningful benefit to patients:**
 - Immunotoxin with murine antibody is 5-10x more effective than competitive agents (in vitro and in vivo experiments)
 - Could overcome resistance mechanisms mediated by myeloma-bone marrow interaction
 - The outstanding results have been confirmed with new generation of immunotoxin using humanised (chimerised) antibody.

BT-062: cooperation agreements accelerate development and enhance efficacy



Cell line

Generated at AERES Biomedical Ltd.



Manufacturing of GMP grade mAb

Partner identified.

Letter Agreement signed, final contract to be signed in December



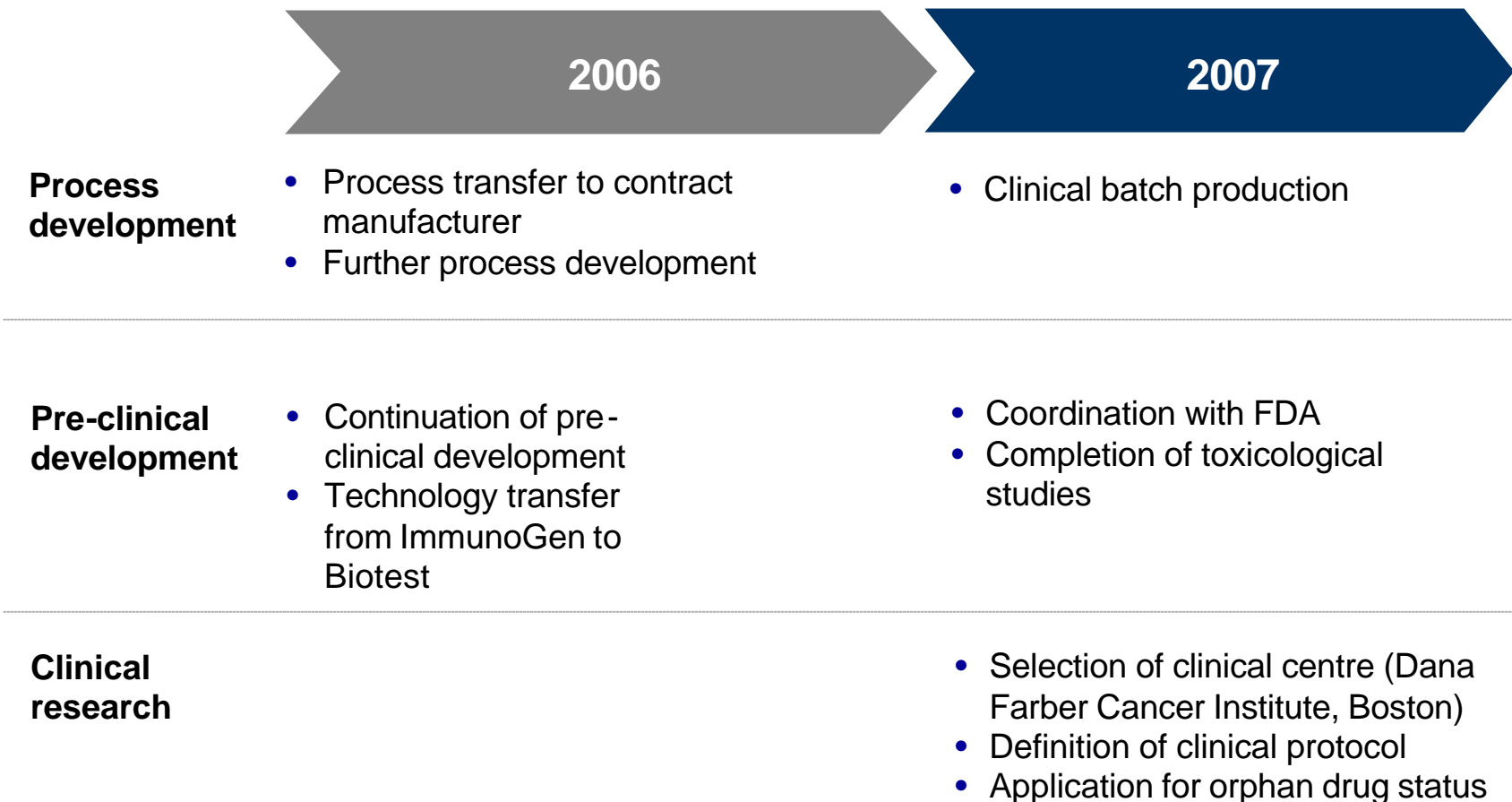
TAP Technology (Tumour-activated prodrug technology)

Toxin which is highly efficient at destroying tumour cells

Immunotoxin (BT-062 /TAP) specifically kills multiple myeloma cells with high efficacy.

Through licensing agreement with ImmunoGen Inc.:
exclusive access to TAP technology for antibody BT-062

Development of BT-062: milestones reached in 2006 and those planned for 2007



Outlook for 2006 as a whole: renewed growth in sales and earnings

Biotest Group

- Target for 2006: sales +15%, growth in EBIT by at least 10%
- Target for 2007: renewed double-digit sales increase, further rise in EBIT

Plasma proteins

- Expansion of immunoglobulin business
- Preparation of clinical study Cytoect® for use in pregnant women

Diagnostics

- New focus on microbiology and immunology
- New sales structure and approval of manual reagents in the USA – basis to be able to tap the full potential of TANGO®

Biotherapeutics

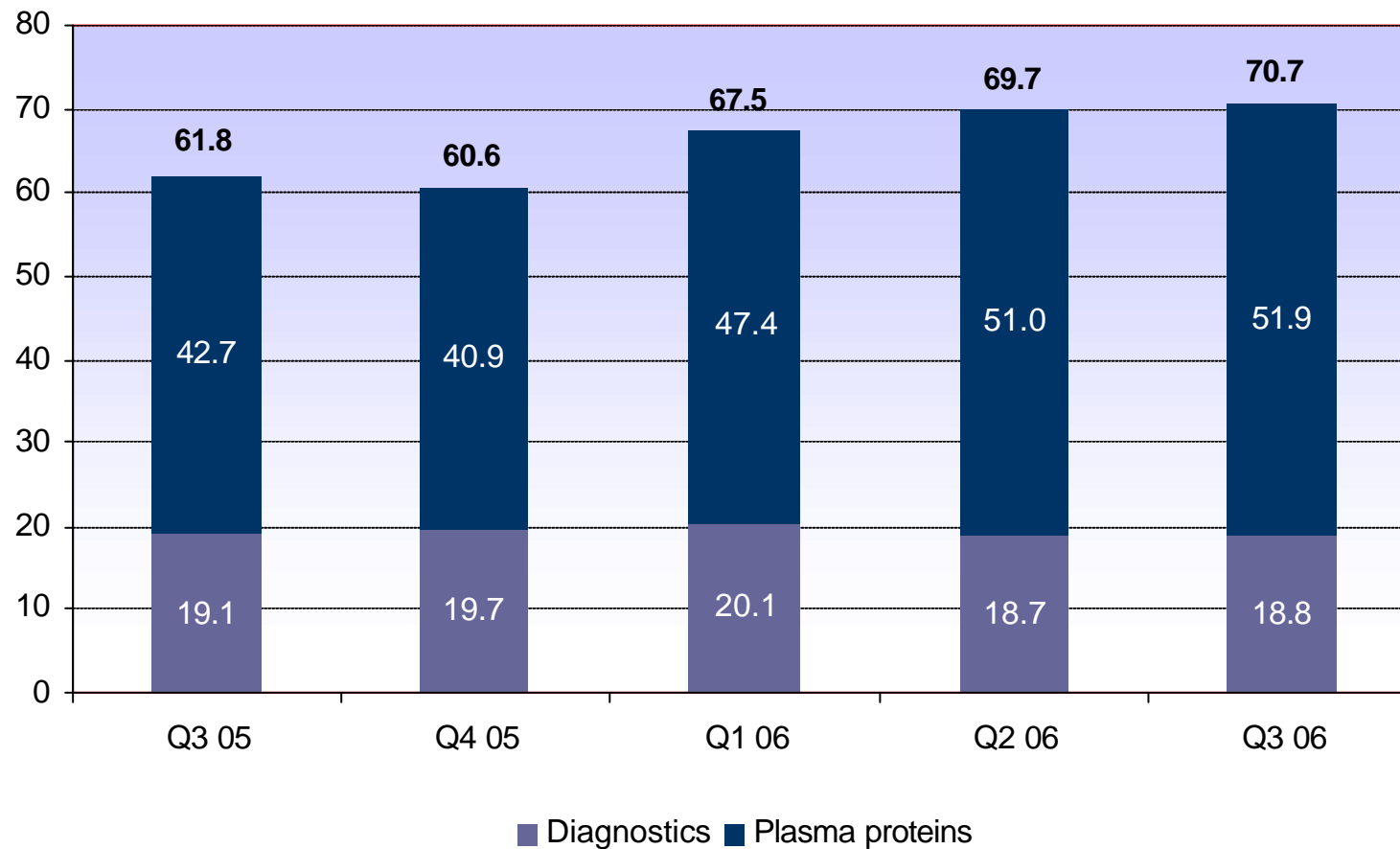
- Projects progress
- Next milestone: Continuation of clinical testing of BT-061, start of GMP production of BT-062

Vielen Dank für Ihre Aufmerksamkeit!

Backup-Material

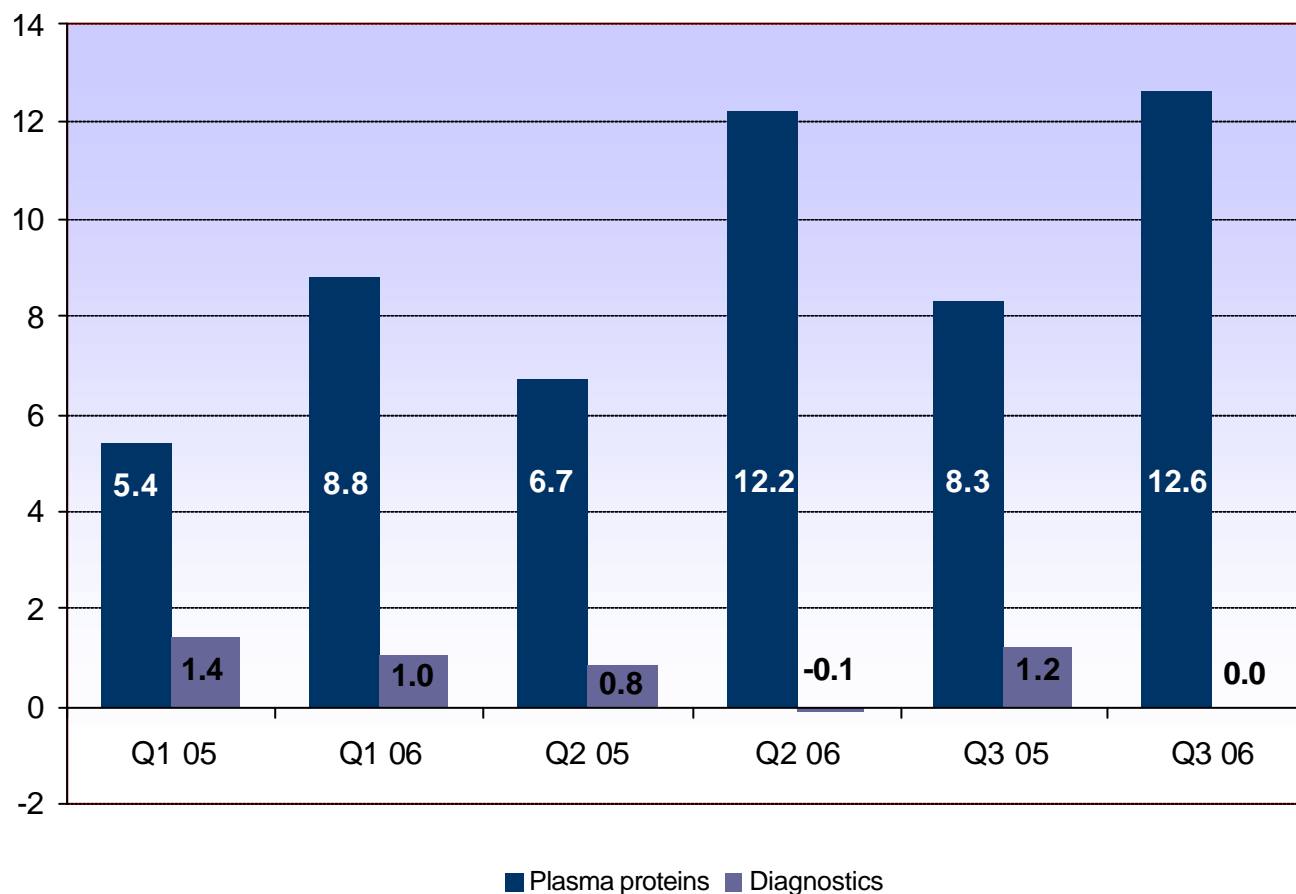
Quarterly sales: growth achieved over the course of 2006

Sales by segment (€ m)

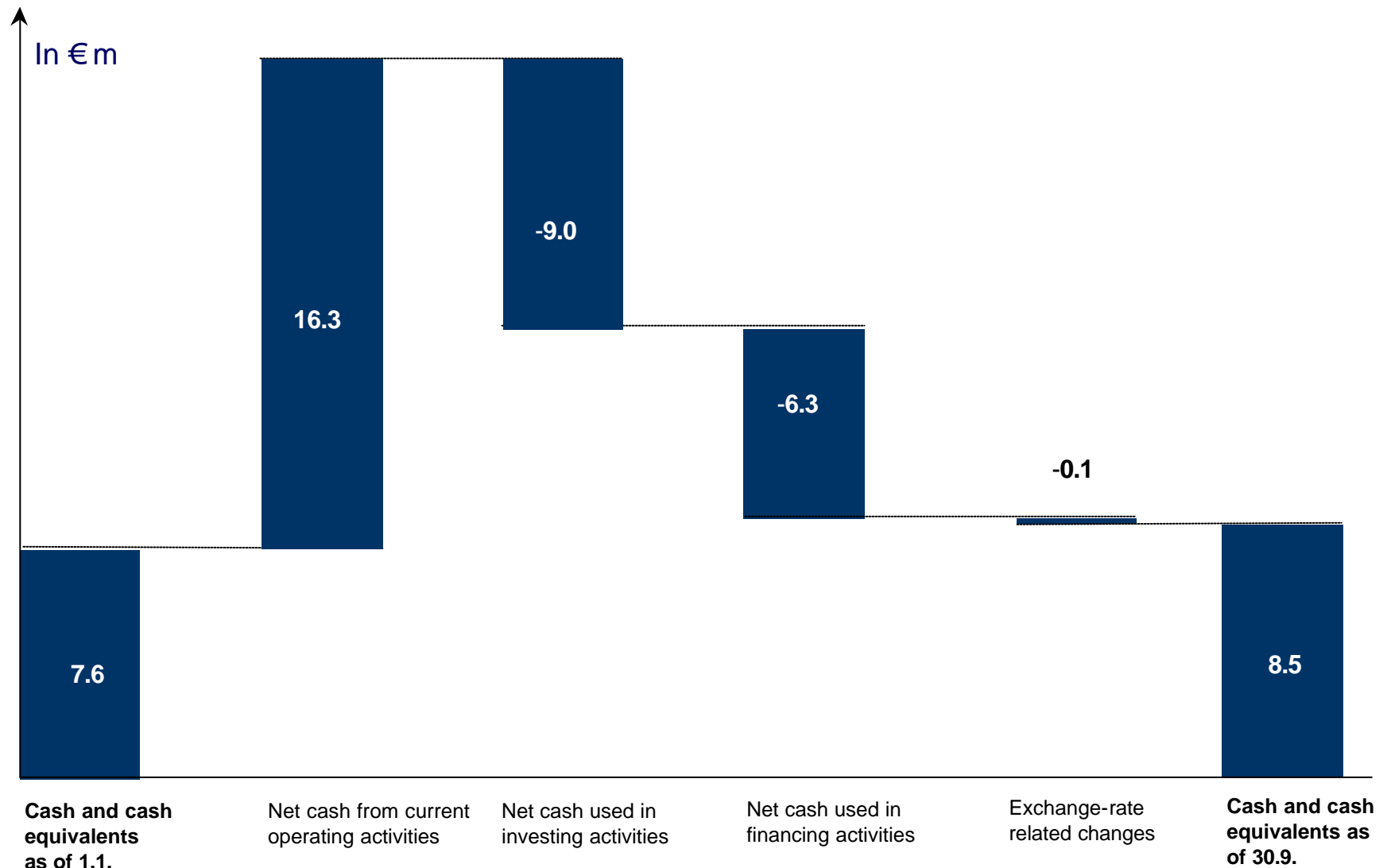


Quarter-on-quarter comparison: strong performance in Plasma protein business

EBIT per segment/quarter (€ m)



Biotest Group: cash flow statement



Biotest Group: balance sheet

	31.12.2005	30.09.2006
	<i>€ m</i>	<i>€ m</i>
Assets		
Non-current assets	160.1	156.6
Inventories	108.4	115.8
Trade receivables	66.1	74.0
Cash and cash equivalents	7.6	8.5
Other assets	6.4	8.1
Equity and liabilities		
Equity	169.0	175.3
Non-current liabilities	111.9	105.5
of which	Financial liabilities	63.3
	69.2	
Current liabilities	67.7	82.2
of which	Trade payables	27.3
	25.1	
	Financial liabilities	21.6
	19.3	
Total equity and liabilities	348.6	363.0

Biotest Group: nine months at a glance

	2005	2006	Delta
Revenue (€ m)	177.0	207.9	17.5%
of which			
Germany	64.8	67.0	3.4%
RoW	112.2	140.9	25.6%
EBIT (€ m)	18.4	21.9	19.0%
as % of revenue	10.4	10.5	
Profit before tax (€ m)	10.0	15.6	56.0%
as % of revenue	5.6	7.5	
Net profit, EAT (€ m)	7.2	9.5	31.9%
as % of revenue	4.1	4.6	

Study on the use of Cytotect® in pregnant women: design und development

- Clinical phase III: open, prospective, randomised, controlled, multi-centre
- Start: 2007, duration: approx. 2 years
- Group A: systematic serological CMV screening (IgG) every 4 weeks until pregnancy week 36; in case of verified sero-conversion start of treatment
- Group B: routine pregnancy precautions without further serological CMV screening and without treatment
- Screening of approx. 25,000 pregnant women, inclusion approx. 10,000 pregnant women, in order to have at least 50 evaluable cases in each group



Orphan drug designation (ODD)

	Europe (EMEA)	USA (FDA)
Market exclusiveness following approval	10 years	7 years
1. Financial support 2. Fee waiver	1. Financial payments possible during development 2. Consulting costs 100%; 50% of all other fees	1. Financial payments possible during development 2. No fee waiver
Accelerated review procedure	Possibly fast track procedure	Possibly abbreviated registration process
Tax privileges	Different regulations in member countries	50% of clinical costs tax deductible
Registration	Access to central process	USA

Development of BT-063: milestones reached in 2006 and those planned for 2007

