Biotest Autumn Conference for

Journalists and Analysts

Frankfurt/Main, November 22, 2004

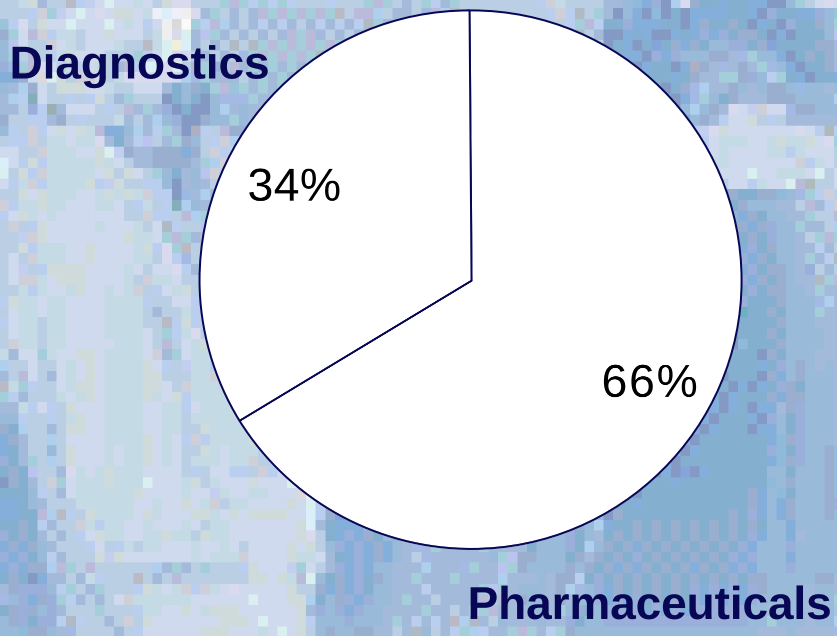
Contents - Report by Prof. Dr. Gregor Schulz

APPENDIX

Company activities

Innovation by tradition – Biotest AG, an international pharmaceutical and diagnostics company

- **Sales EUR 222 m (2003)**



Biotest produces and sells special products and diagnostics systems for treatment and diagnosis of life threatening diseases with focus on clinical immunology and haematology.

Biotest production sites and distribution centers

Biotest AG focuses on pharmaceutical and diagnostic products – 4 production sites, 10 subsidiaries worldwide

Biotest – group overview

ORGANIZATIONAL STRUCTURE

Biotest AG, Dreieich

Pharmaceuticals

Plasma products for

- Immunoglobulins
- Hyperimmunoglobulins
- Clotting factors
- Intensive care (Humanalbumin)

66% of total sales (2003)

Diagnostics

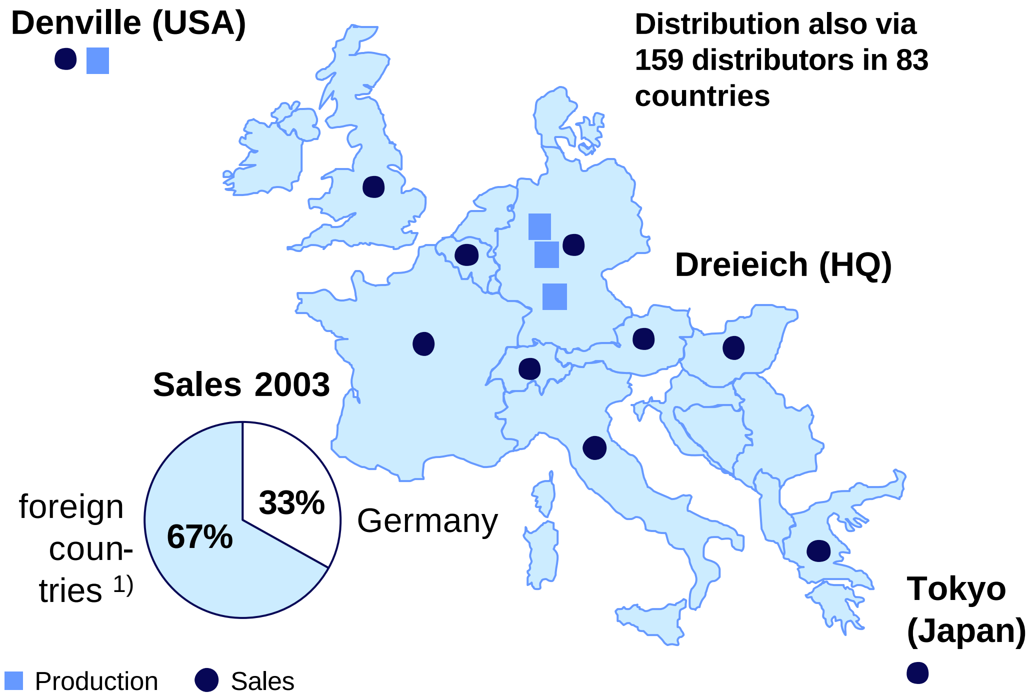
Products/systems for

- Transfusion
- Transplantation
- Hygiene monitoring

34% of total sales (2003)

~ EUR 222 m sales (2003)
1,037 employees worldwide

PRODUCTION SITES/DISTRIBUTION CENTERS[1)]



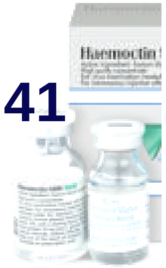
1) Belgium, Italy, Greece, Austria, Switzerland, Hungary, UK, Japan, USA, France

Pharmaceutical division - product portfolio

In the pharmaceutical division mainly products in the field of immunology and clotting factors are sold (1)

PRODUCT GROUP	MAIN PRODUCTS	INDICATIONS	SALES BIOTEST 2003 [EUR m]
Immunology	**Immunoglobulins:** - Pentaglobin - Intraglobin - Intratect (since 10/2004)	- Autoimmune diseases - Antibody deficiency syndrome - Protection against infections	**42** 
	Hyperimmunoglobulins: - Cytotect/CP-Z - Hepatect/CP - Varitect/CP	Special immunoglobulins for treatment and prophylaxis of hepatitis, cytomegaly, varicella-infections and after liver transplantations	**40** 

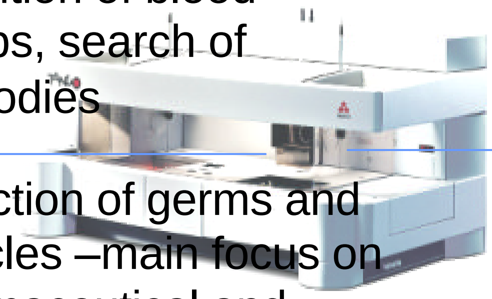
In the pharmaceutical division mainly products in the field of immunology and clotting factors are sold (2)

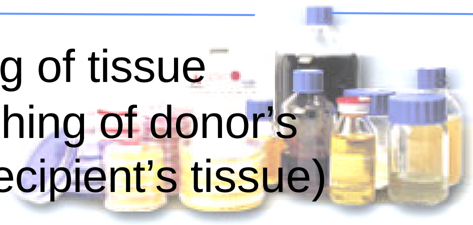
PRODUCT GROUP	MAIN PRODUCTS	INDICATIONS	SALES BIOTEST 2003 [EUR m]
Clotting factors *(Haemophilia)*	- Haemoctin SDH (Factor VIII) - Factor IX SDN	Inherited Haemophilia A and acquired coagulation disorders	**41** 
Volume substitution and protein substitution	- Humanalbumin (5%/20%) - Biseko		**22** 

Diagnostic division - product portfolio

Biotest's diagnostic business is based on three main product groups

PRODUCT GROUP	MAIN PRODUCTS	INDICATIONS	SALES BIOTEST 2003 [EUR m]
Transfusion	- TANGO (blood typing system) - Erytype - Solidscreen	Definition of blood groups, search of antibodies	**20**
Hygiene monitoring	- Agar Strips - RCS device (Germ collector) - RSC foil (consumable material)	Detection of germs and particles –main focus on pharmaceutical and cosmetics industry	**26**
Transplantation	- HLA-plates - HLA-DNA - Systems (QuickStep, ELPHA)	Typing of tissue (matching of donor's and recipient's tissue)	**14**

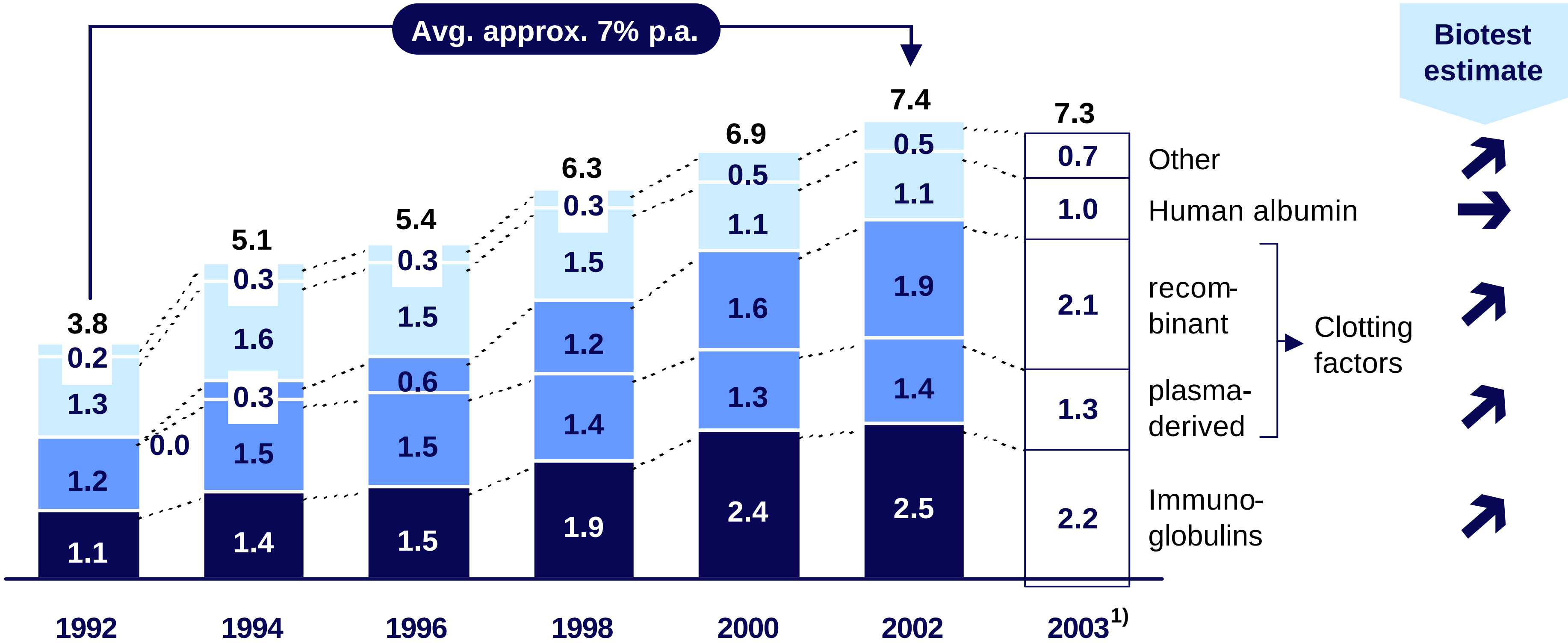




Pharmaceutical division - markets and competitors

Historically the world market has grown 7% p.a. – after a recession in 2003 Biotest looks optimistically into the future (1)

Global market for plasma protein [USD bn]



1) Biotest estimate
Source: MRB 2002

Biotest restructuring program

The company responded to its crisis situation in 2003 with an extensive restructuring program

Working-Capital and Cost-Management	Redirection Division Pharmaceuticals	Development international markets	Optimization of assets	Implementation of special topics
Reduction of accounts receivable	Strategic Partnering	Performance increase USA	Disinvestment associated companies	New group structure
Cutbacks on inventories	Product approvals	Establishing a distribu-tion company in Greece	Disinvestment real estate	
Human resources program	Strategic development of new foreign markets			
Material costs program	Expansion of toll fractioning e.g. Iran			

Biotest strategy pharmaceutical division - new products

Biotest

There are numerous products in the R&D and licensing pipeline

Pharmaceuticals products in the launch and R&D stages

STATUS	LAUNCH 2004-2005	R&D 2006-2007	PRE-DEVELOPMENT (to be marketed starting 2008)
Products with marketing launch	- **Intratect** (October 2004) - **Hepatect FH** (in the last six months of 2005) - **Faktor IX** (in the first six months of 2006)	- **C1-inhibitor** license as of 2006 - **PPSB** license as of 2007 - **VWF** 2008 - **Hepatect sc** as of 2007	- **MAB BT-061** (anti-CD4/CD25) - **MAB BT-062** (anti CD 138) - **MAB BT-063** (anti-IL 10)
Descrip-tion	- Marketing about to begin - Launch of the new product generation (FH*) - Growth via expanding indications	R&D in process	Early stage of development

* FH: Filter-Hilfs-Verfahren (filter-auxiliary-method)

Intratect®: Evolution in immunoglobulin technology

A new technology guarantees a high purity of the preparation and an unmodified antibody structure as well as high quality and tolerability.

- Gentle treatment of plasma proteins by use of filtration aid substance
- Higher yield of IgG
- Complete elimination of impurities
- High safety by multiple donation screening and a 3-step virus reduction process
- Constant protein-chemical properties

Intratect® for

- Substitution treatment in patients with antibody deficiencies
- Immunomodulation in autoimmune diseases
- Prophylaxis after bone marrow transplantation

Intratect® in comparison to competitors

Decisive parameters for the selection of an immunoglobulin preparation by physicians and pharmacists:

- High purity and unmodified protein structure
- High virus safety
- Ready-to-use solution and storage at room temperature
- Excellent tolerability (sugar-free and low amount of impurities)

Intratect® meets highest demands upon intravenous immunoglobulins, and it is one of the best commercially available preparations.

Intratect®, Gamunex® 10%, Octagam®

Flebogamma®, Polyglobin®, Gammonativ®

Gammagard® S/D, Sandoglobuin®, Venimmun® N

Endobulin® S/D,

Biotest

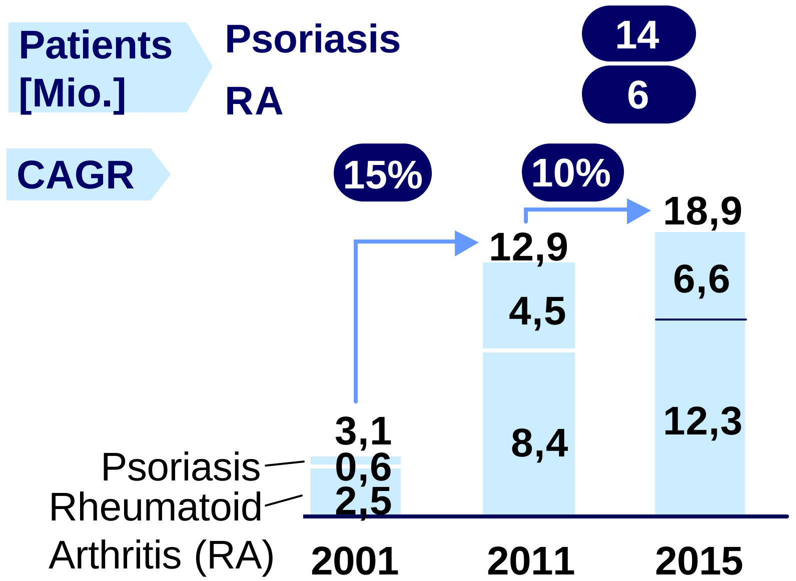
Three Monoclonal Antibodies With a Total Sales Potential of More Than 1 Bn. US$ Are in Development – Promising Efficacy Data Available

- BT-061 Rheumatoid Arthritis (RA) und Psoriasis
- BT-062 Multiple Myeloma (a form of leukemia)
- BT-063 Systemic Lupus Erythematosus (butterfly rash)

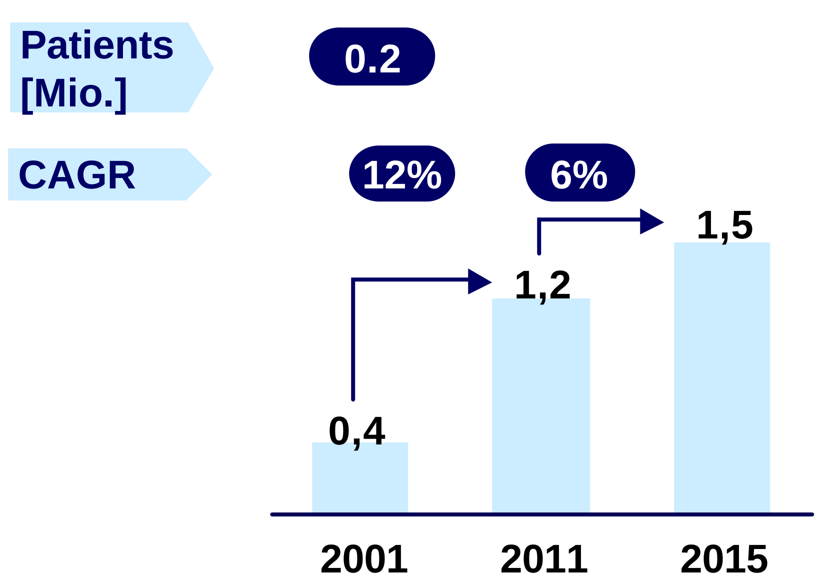
BT-061 and BT-062 - Market and market growth

Markets for Biotest´s Antibody Candidates Grow Rapidly – The Medical Needs Are High

MARKET FOR RA AND PSORIASIS [Bn. US$]

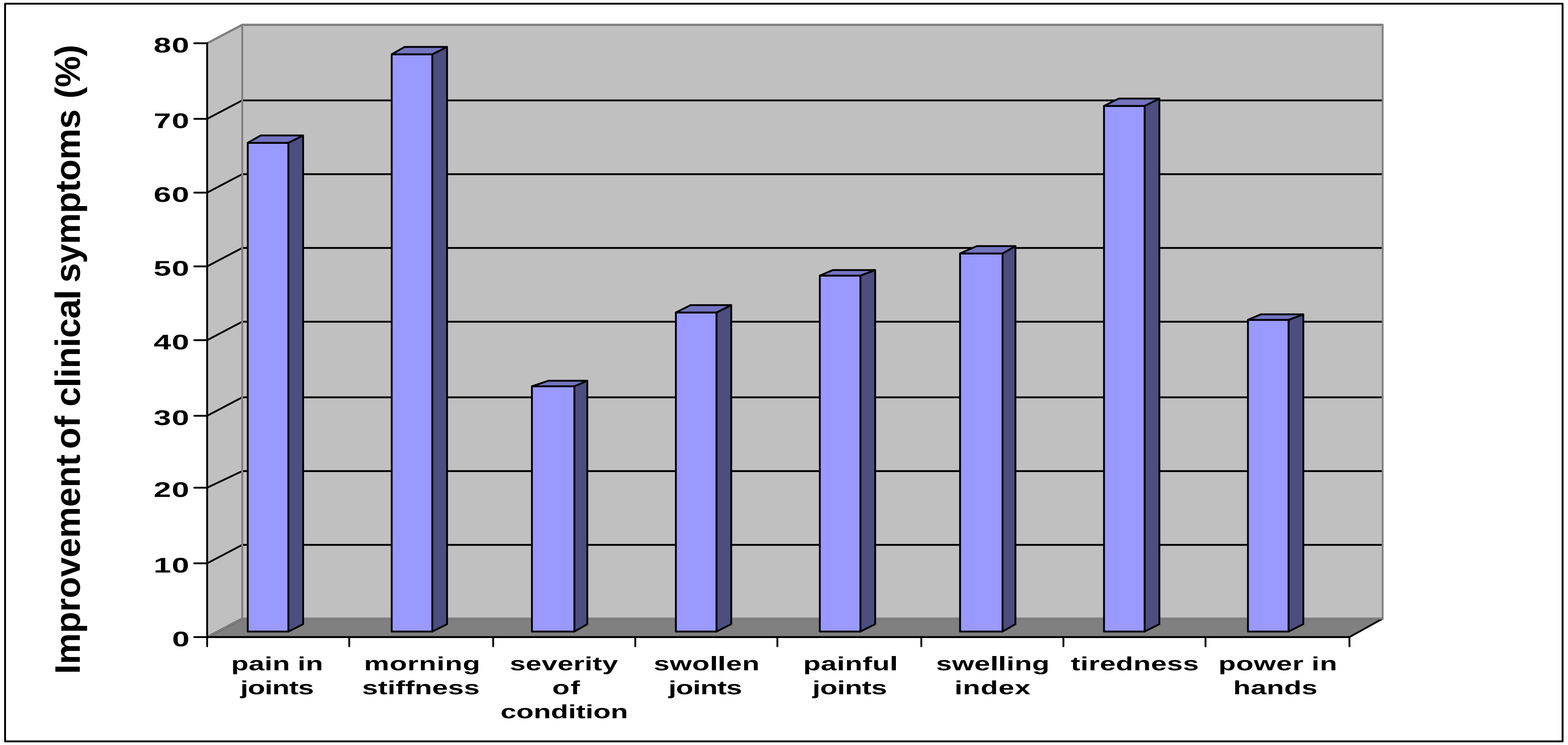


MARKET FOR MULTIPLE MYELOMA [Bn. US$]



Biotest

Severe Symptoms of RA Patients Improve Rapidly and Persistently – BT-061 Is Well-Tolerated

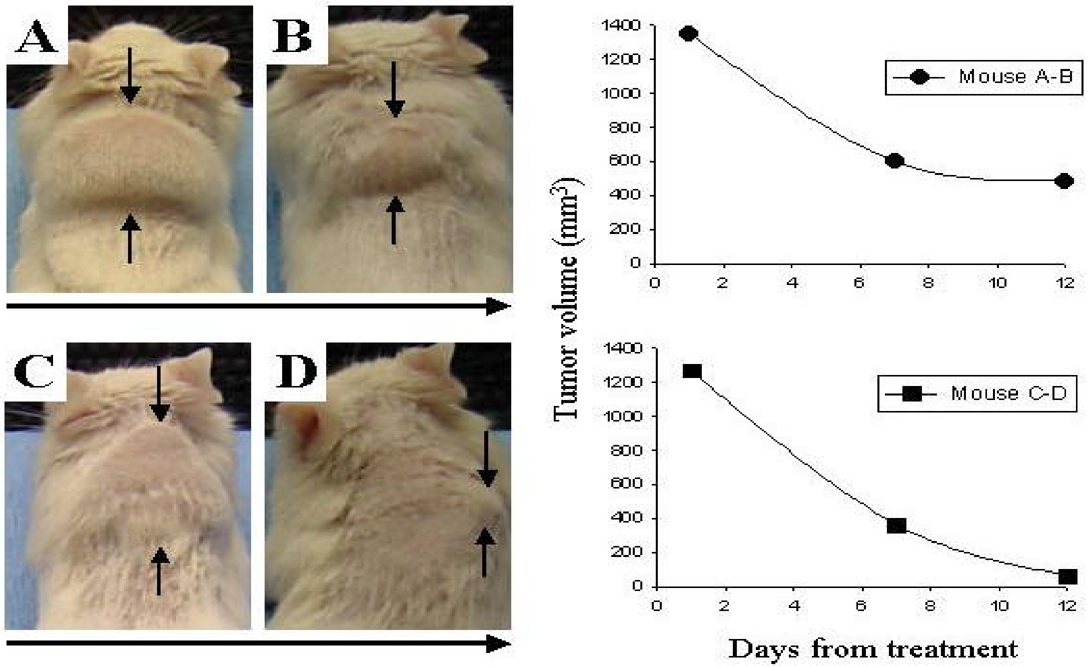


Changes in clinical symptoms after 10 days of therapy (5 x 5mg every second day). The improvements lasted between 3 and 12 months. All changes are statistically significant (p<0.01).

Biotest

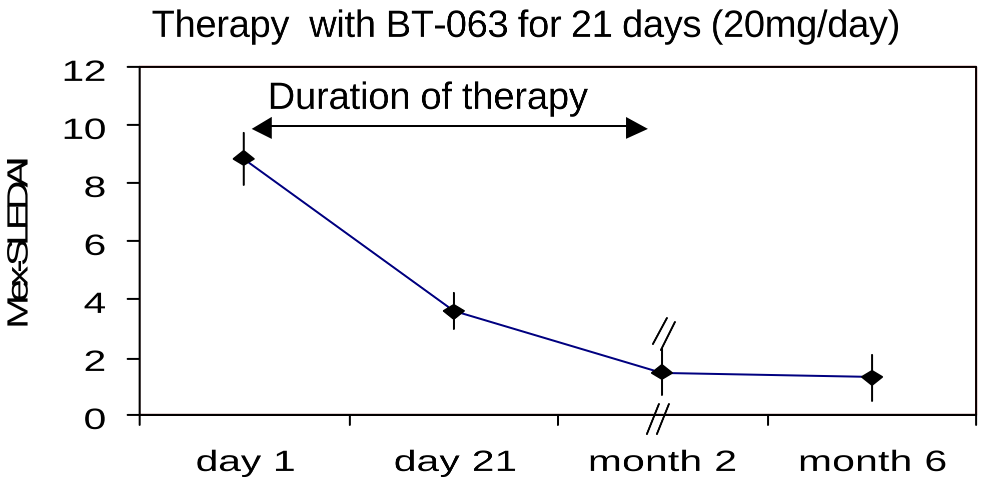
Promising Efficacy of BT-062 Could Be Shown in Mice With Very Large Human Tumor Xenografts – in Humans BT-062 Will Be Used after Cytoreductive Chemotherapy

Activity of BT-062 on Very Large Tumor Xenografts of Human Multiple Myeloma



Biotest

After a Three Week Therapy, Patients Benefit for at Least Six Months – BT-063 Is Well-Tolerated



- BT-063 administration (21 days, 20mg/day) continuously improved clinical symptoms in all 6 patients.
- The SLE Disease Activity Index decreased by approx. one third during therapy. The decline persisted after the end of therapy (1.50 ± 0.84 at month 2, 1.33 ± 0.80 at month 6 (P<0.001).
- The level of immune hyperactivation could be decreased long-term.
- Anti-dsDNA antibody serum titers decreased to normal levels within 3 months in one patient.
- At the end of follow-up, approx. 5 month after the end of therapy, the disease was clinically inactive in 5 of the 6 patients.

Internationally Renown Experts Have Evaluated the Antibodies and Confirm the High Potential – Interest in Clinical Development Is Large

BT-061

Rheumatoid Arthritis

- **Prof. Dr. F. C. Breedveld**, Leiden University, Medical Center, Department of Rheumatology, Leiden
- **Prof. L. Klareskog**, Rheumatology Unit, Karolinska Institut, Stockholm

Psoriasis

- **PD Dr. Friedrich**, Psoriasis-Studienzentrum, Klinik für Dermatologie, Venerologie und Allergologie, Charité Berlin
- **Prof. Dr. med. A. Enk**, Universitäts-Hautklinik, Heidelberg

BT-062

- **Prof. Dr. Kenneth C. Anderson**, Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, Boston
- **Prof. Dr. H. Goldschmidt**, Medizinische Klinik und Poliklinik V Hämatologie/Onkologie, Universität Heidelberg

BT-063

- **Prof. Dr. F. Hiepe**, Klinik mit Schwerpunkt, Rheumatologie und Klinische Immunologie, Charité, Berlin

Biotest strategy pharmaceutical division: new facilities/equipment

The strategic direction in the division pharmaceuticals is mainly based on new production plant that offers cost and quality benefits

- The **technology leap** in the new production plant opens **strategic options**
  - Considerable investments completed (approx. 70%)
  - New production processes for higher quality products
  - Improved authorization status for markets and products facilitates access to high-end markets

- By **setting up its own plasmapheresis centers,** Biotest **ensures** the availability of **supplies**
  - Quality assurance starts with raw materials
  - Supply dependency will be reduced (target: 40% own supply of raw materials)

- In addition, there are **significant cost advantages** along the **value chain**
  - Marked efficiency increase with core products
  - Throughput times reduced
  - Efficiency increased through larger batch sizes

Biotest strategy pharmaceutical division: new facilities/equipment

In a multi-level process pharmaceutical products are extracted from plasma

Production process pharmaceuticals

Plasma-pooling	Kryo	Fractions	Processing		Bottling/Packaging		SALES
			Unfinished	Finished	Sterile production	Packaging	

Biotest strategy pharmaceutical division: expansion

Market entry for the new pharmaceutical products will be handled by Biotest's subsidiaries and business partners, focussing on Europe

Market entry strategy Europe

COUNTRY	PRODUCTS: Intraglobin	Intratect	Hepatect	Haemoctin
Italy	Already being marketed	Market entry planned	Already being marketed	Market entry planned
Austria	Already being marketed	Market entry planned	Already being marketed	Already being marketed
Switzerland	Already being marketed	Market entry planned	Already being marketed	Market entry planned
Hungary	Already being marketed	Market entry planned		
Greece	Already being marketed	Market entry planned	Already being marketed	Already being marketed
Benelux	Market entry planned	Market entry planned	Already being marketed	Market entry planned
Ireland	Market entry planned	Market entry planned	Already being marketed	
Spain	Market entry planned	Market entry planned	Already being marketed	Market entry planned
Scandinavia	Market entry planned	Market entry planned	Market entry planned	Market entry planned
UK	Market entry planned	Market entry planned	Market entry planned	
France	Market entry planned	Market entry planned	Market entry planned	

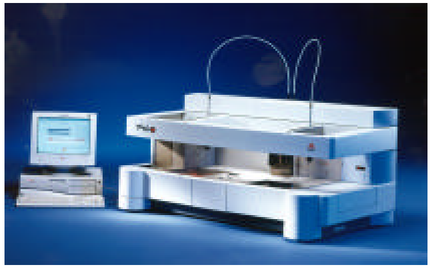
■ Already being marketed ■ Market entry planned

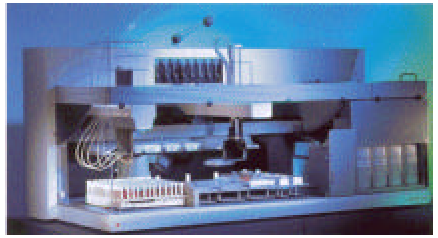
	NOTES
Own subsidiaries with pharmaceuticals platform	- Subsidiaries already established in pharmaceuticals sales - Subsidiary Hellas (Greece) founded in March 2004
Sales partners already available	Partners available (they also have their own field force)
Partner search	Active search for partners ongoing

The diagnostic division strategy focuses on entering the US market with TANGO – FDA audit nearly completed

Strategy Diagnostics

PRODUCT GROUP	STRATEGIC FOCUS FOR BIOTEST
Transfusion	• **Focus** on **highly regulated markets:** Europe, **USA**, Japan • Obtain **FDA registration** to market product **TANGO** in **USA** till Q1/2005 • Using **micro filter plate systems** with economical advantages compared to gelcard system
Hygiene monitoring	• **International** marketing of **high quality products** focusing on highly **regulated pharmaceutical market**





Biotest is prepared for its future...

- Entering high-margin markets
- Obtaining regulatory authorization for facilities and products in Europe
- State-of-the-art facility and processes ("maximum yield")
- Own raw material/plasma sourcing (PSE/PDT) and flexible procurement of plasma and intermediate products
- Capacity utilization because of toll-manufacturing
- Expansion of product portfolio and access to recombinant/biotechnological based products
- Strengthening of market position in USA with diagnostic products

A P P E N D I X

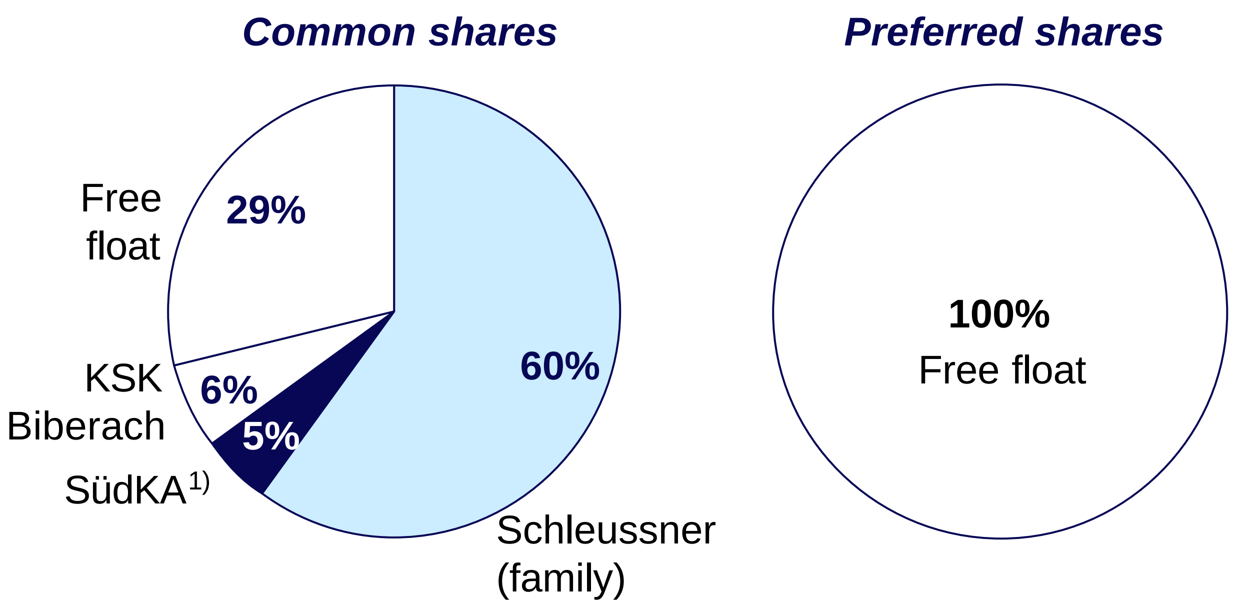
Biotest is a Prime-Standard company – 60% of the ordinary shares are held by the founder‘s family

Shareholders

CAPITAL STOCK AND SHARES

- **Capital stock: EUR 20.5 m**
- **4 m** no-par value **common shares**
- **4 m** no-par value **preferred shares** (without voting rights)
- Traded on the **open market**

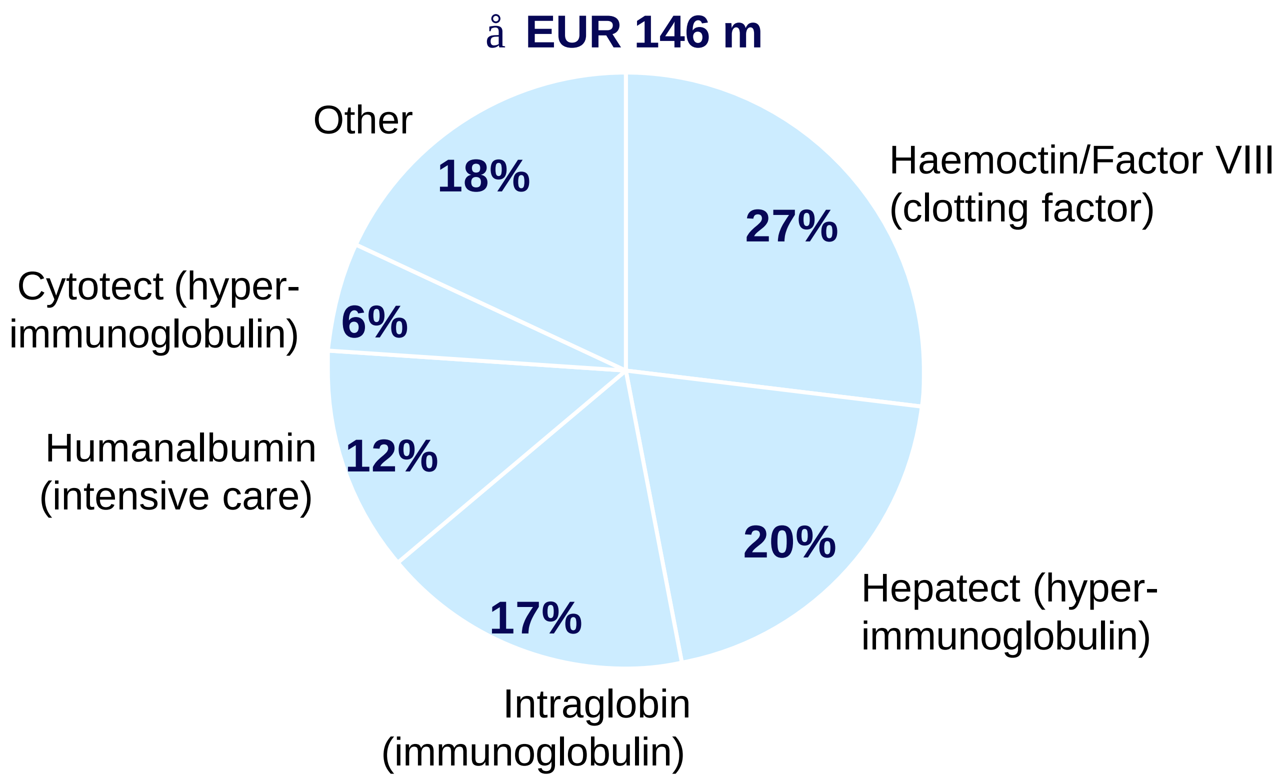
STRUCTURE OF SHAREHOLDERS AS OF 07-2004



1) Capital investment company of LBBW and Sachsen LB

Pharmaceutical division - sales by product groups (2003)

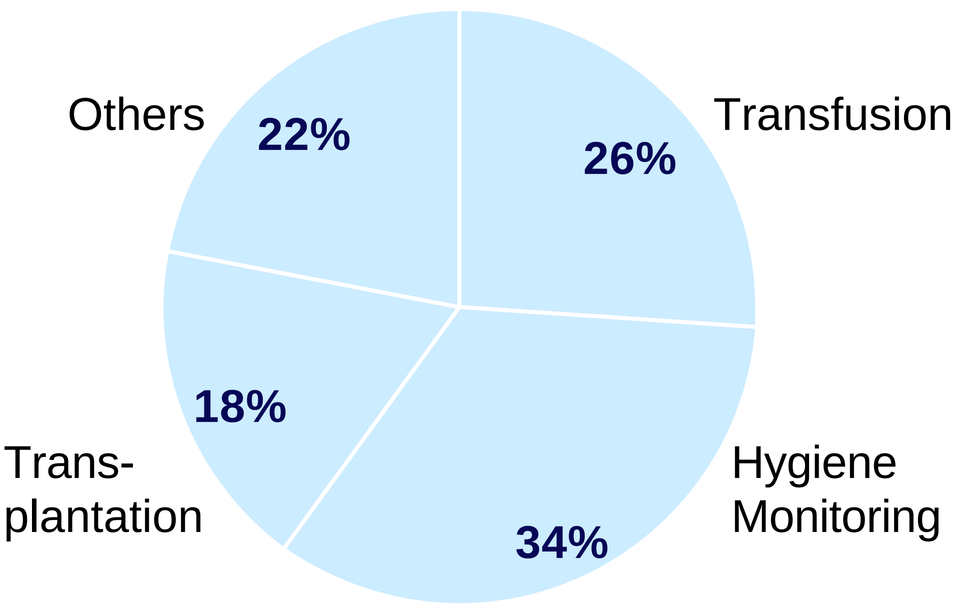
Biotest's 5 key pharmaceutical products generate 82% of the divisions’ sales

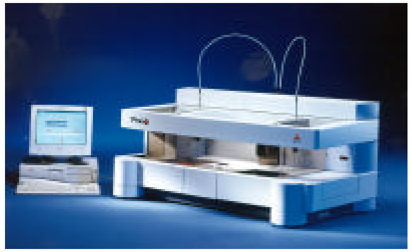


Diagnostic division - sales by product groups (2003)

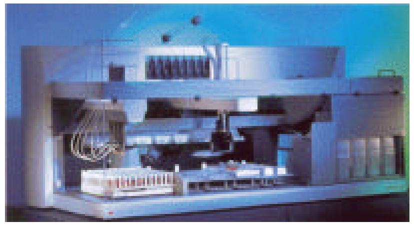
Product groups: Transfusion, hygiene monitoring and transplantation generate 77% of the diagnostic’s sales

å **EUR 76 m**

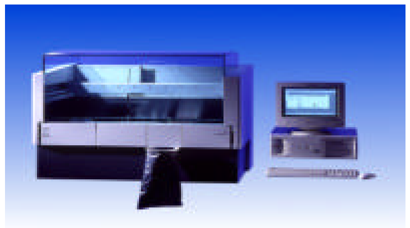




TANGO: Innovation in immuno-haematology



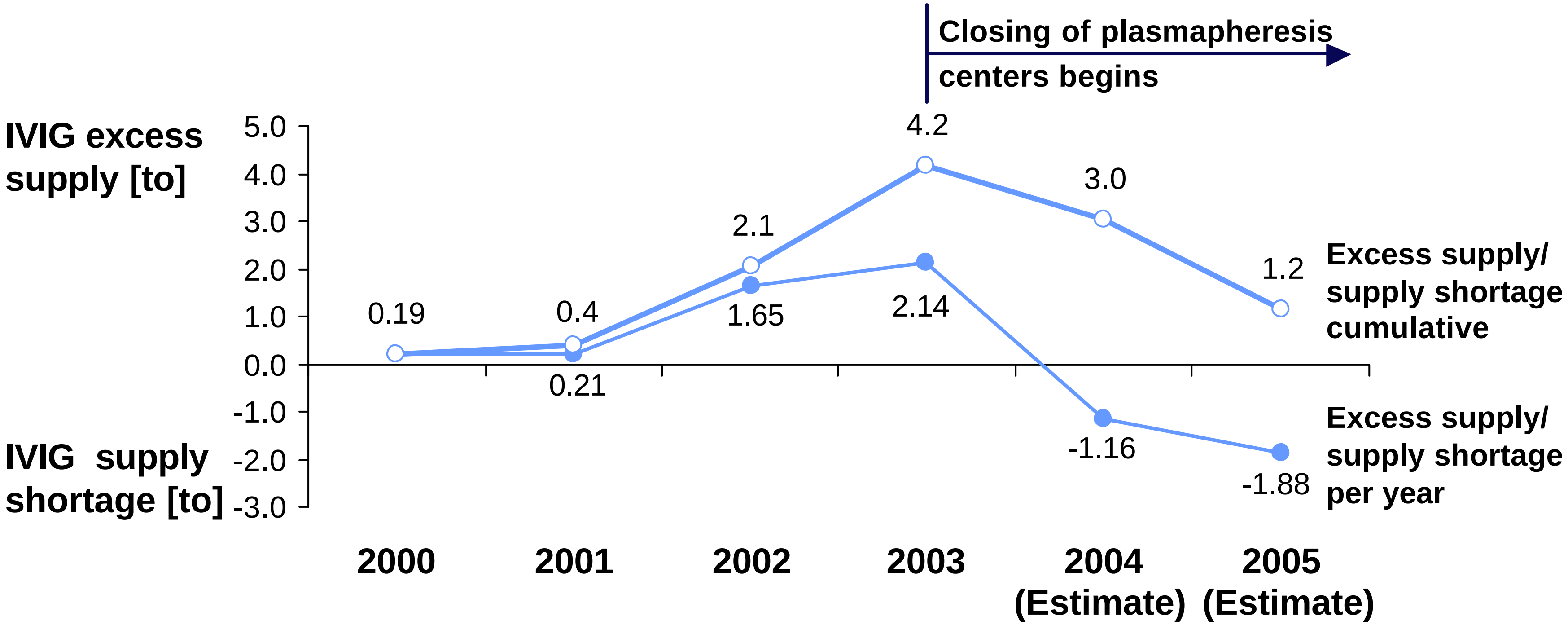
ELPHA-Typer: for HLA diagnostics



QuickStep: for transplantation diagnostics

A shortage of IVIG is expected due to the reduction of plasmapheresis centers

Example: Impact of plasma sourcing in USA on the IVIG[1)] supply



1) Intravenous Immunoglobulins

Source: MRB, Salomon Smith Barney

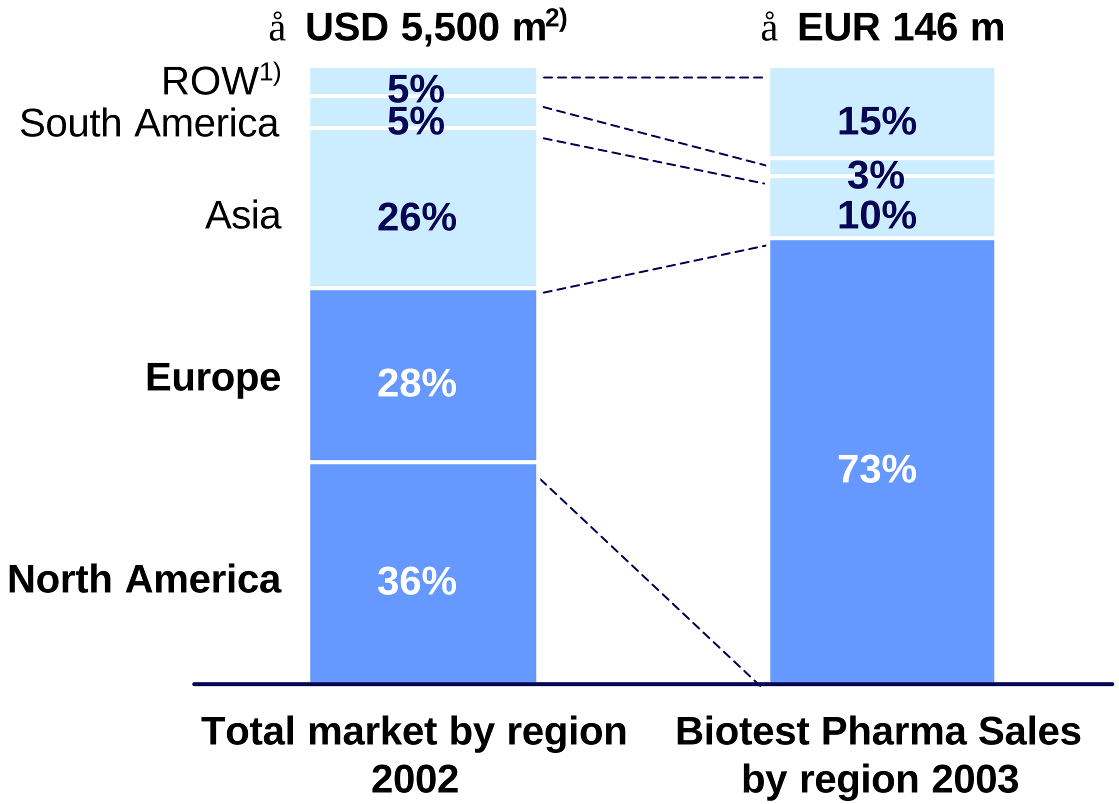
Concentration on 7 main players reflects the ongoing consolidation pressure in the industry

Example: Consolidation of major plasma protein business companies

UNTIL 1985	1985-1995	1995-2000	2000-2004
• Baxter • Immuno	• Baxter	• Baxter	• Baxter
• Bayer-Miles	• Bayer	• Bayer	• Bayer
• CSL • ZLB	• CSL • ZLB	• CSL/ZLB	• ZLB Behring
• Behringwerke • Armour	• Centeon	• Centeon/Aventis	
• Alpha • Grifols	• Alpha • Grifols	• Alpha • Grifols/Probitas	• Probitas
• Octapharma • Schwab	• Octapharma	• Octapharma	• Octapharma
• Kabi	• Kabi	• Kabi	
• Kedrion	• Kedrion	• Kedrion	• Kedrion
• Biotest	• Biotest	• Biotest	• Biotest
Total 14	**Total 11**	**Total 10**	**Total 7**

North America and Europe are the most important plasma protein markets worldwide – Biotest holds a strong market position in Europe

Worldwide plasma fractions market 2002, Biotest sales 2003 [EUR m]



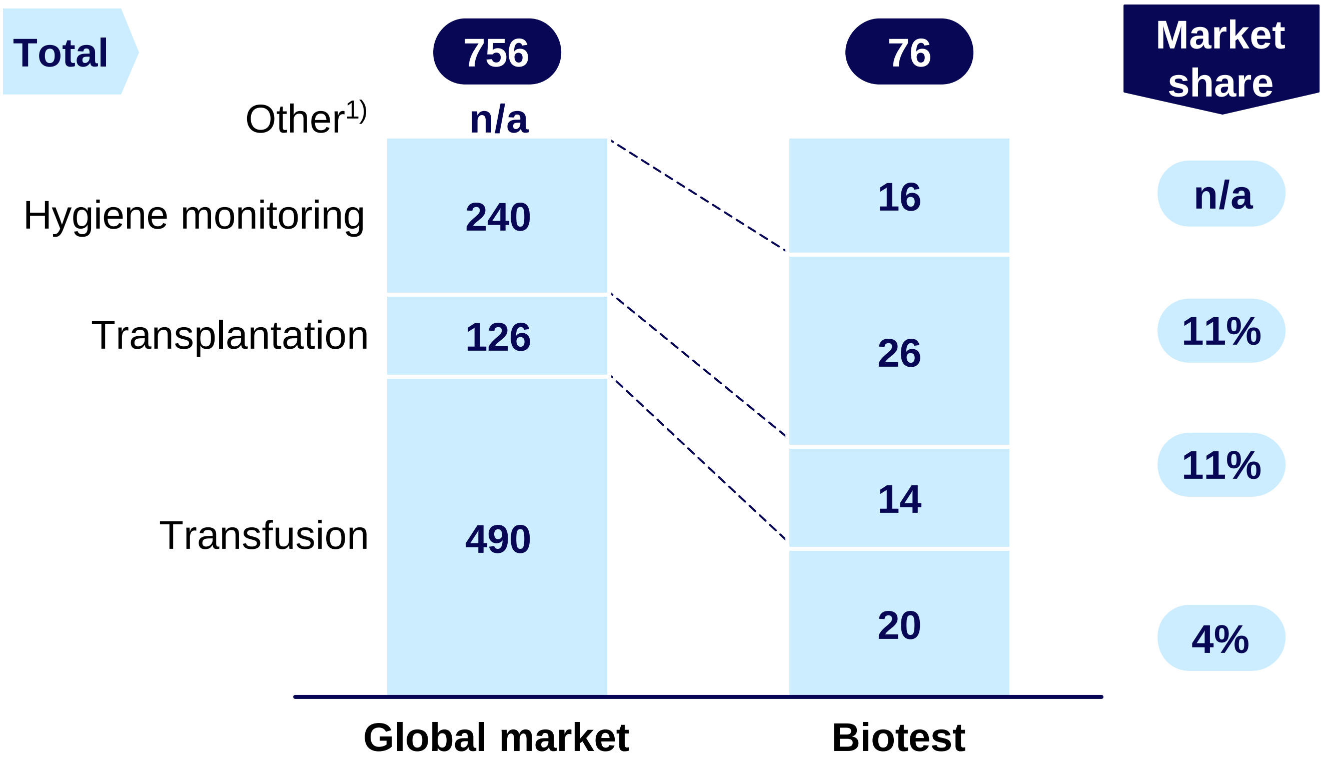
Source: MRB

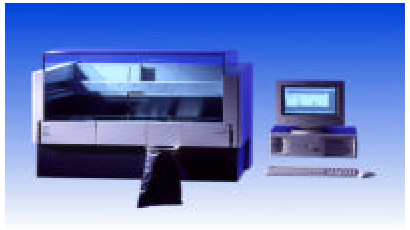
1) Rest of world
2) w/o recombinant factors USD 1,9 m

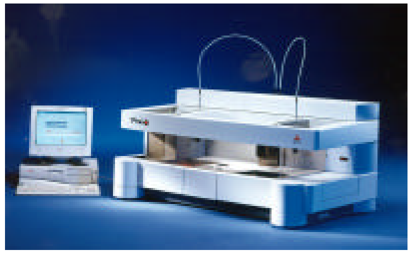
Diagnostic division - markets and competitors

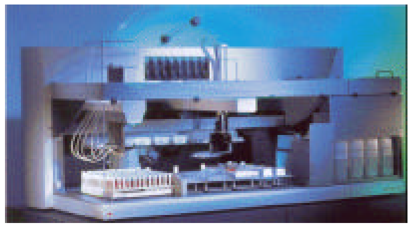
Transfusion and hygiene monitoring are largest markets, Biotest is strong in its hygiene business with 11% market share

Global market diagnostics, Biotest sales diagnostics 2003 [EUR m]









1) Infectious disease, other

Market for transplantation diagnostics stable, Biotest focuses on stabilizing its market position – growth by partnering possible

Strategy Diagnostics

PRODUCT GROUP	STRATEGIC FOCUS FOR BIOTEST
Transplantation	• **Stabilize market position** and **increase profitability** by - Concentration of R&D activities to completion and redesign molecular typing products - Adding new parameters to portfolio also used in HLA labs - Providing user oriented automation and solutions • Develop **long-term strategy** for **blood typing** • **Initiate growth** by **partnering**