

### **Biotest AG**

## **Analyst Conference Frankfurt/Main, 20 March 2007**





### **Professor Dr. Gregor Schulz, CEO:**

### **Building blocks of success**





### **Highlights 2006**

#### **Business**

- Strong growth: Pharmaceutical sales: +28%
- Orphan drug designation for Cytotect<sup>®</sup> in USA and Europe (cytomegalovirus infection during pregnancy)
- Approval of Hepatect<sup>®</sup> FH in six European countries
- Diagnostics: strategic refocusing, forming of two Global Business Units (immunology and microbiology) with different developments in 2006: immunology still flat, microbiology growing
- mAb on track, authorisation of PEI for clinical study of BT-061

### Successful financial re-engineering

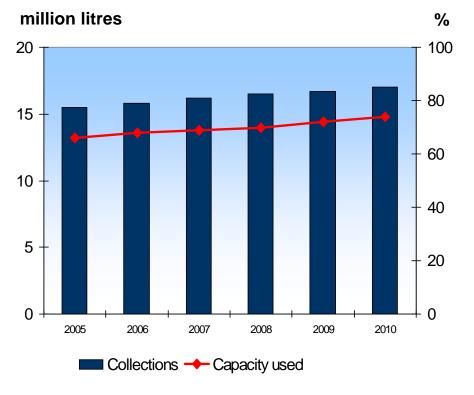
- New syndicated loan agreement with significantly better conditions
- Long term financing portion further increased



# Market environment – supply: tight collection levels limit growth of plasma markets

- Increase of plasma collection in developed world limited by regulatory hurdles
- It will take several years to significantly increase the number of collection centres
- Though plasma demand is growing at a rate of at least 5%, throughput levels cannot be immediately improved

## Collection levels in the developed world and fractionation capacity used by top 5 players



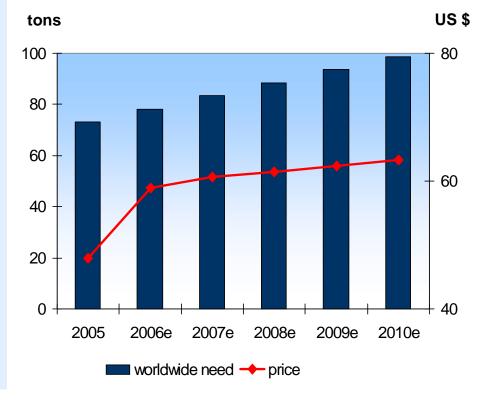
Source: Morgan Stanley



# Market environment – demand (1): IVIG markets – continuous upward trend

- Increase in demand for IVIG in Europe and the USA
- Pricing fundamentals remain favourable
- Prices in Europe approx. 15% below US level

## Global need of IVIG (in tons) and price (US\$ per gram) in North America



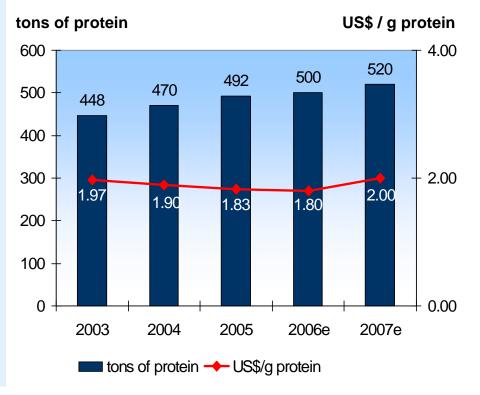
Source: APFA, Morgan Stanley, own estimates



# Market environment – demand (2): plasma-derived F VIII stable, Albumin recovers

- Stable demand for plasma-derived coagulation factors
- Biotest market share amounts to 7%
- Albumin continues to recover, prices slightly up – worldwide demand amounts to 500 tons of protein

#### **Development of the global Albumin market**



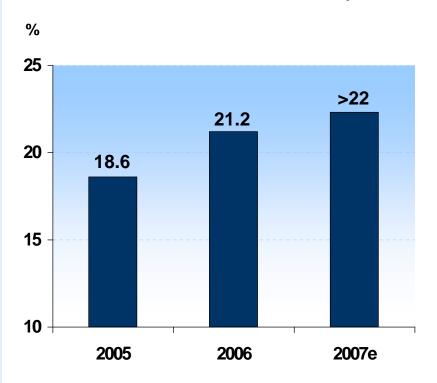
Source: MRB, own estimates



### Biotest plasma proteins - major achievements in financial year 2006

- Marked increase in sales in almost every product group
- Intratect already holds a market share of 21% in Germany and 6% in the UK
- Cytotect® is granted orphan drug status in the EU and the USA for treatment of cytomegalia in pregnancy
- Hepatect® FH, produced using new filter aid procedure, is granted approval in six European countries
- Biotest opens new plasmapheresis station in Merseburg near Halle
- Biotest takes action to double its chromatographic purification capacities

#### Market share of Intratect® in Germany





From Nature for Life

# Biotest plasma proteins strategy (I): upgrading product portfolio, entering new markets

- Expansion efforts directed at EU and US markets in the first instance
- Submission of European application (MR procedure) for approval of Haemoctin<sup>®</sup>, Albumin FH and Haemonine (MR procedure) in 2007
- Biotest will seek approval for Intratect<sup>®</sup> and Albumin FH in USA until 2010
- Phase III clinical trial for Intratect<sup>®</sup> in the USA expected to start in 2008 – Biotest has already started to buy US plasma
- Establishment of lean regulatory team in the USA by end of 2007

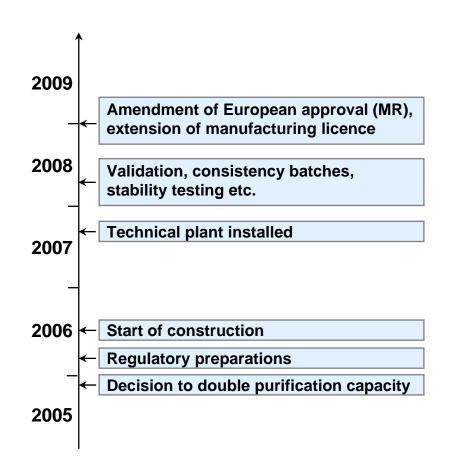




From Nature for Life

# Biotest plasma proteins strategy (II): ensuring human plasma supply, expanding capacities

- In 2006, the four donor centres operated by Biotest already supplied 30% of entire volume of plasma processed
- In Q2 2007, a donor centre in Cologne will launch operations, adding another 30,000 litres
- Further operations planned: Biotest centres shall contribute 40% in the long term, while remaining supply is secured by external contracts
- Chromatographic purification capacities, currently utilised at a rate of 100%, will be doubled by end of 2008





# Biotest plasma proteins strategy (III): development of new areas of indication and application

#### Intratect®

for treatment of fibromyalgia: clinical trial (Phase III) running, first results expected at end of 2008

### Cytotect<sup>®</sup>

for prophylactic treatment of connatal cytomegaloviral infections in pregnancy: clinical trial (Phase III) to start mid of 2007

#### Medical device

using plasma proteins as preservation solution during bypass surgery: launch of clinical trial in 2007, approval end of 2008



# Cytotect®: high unmet medical need, increasing awareness among the general public

From Nature for Life

- Cytomegalia is the most common congenital infection. A topic keenly discussed among physicians and by the general public
- Largest clinical trial ever launched by Biotest will extend over a period of 2 years
- In the meantime, Cytotect<sup>®</sup> is administered on a case for case basis
- In 2007, the initiative ICON was founded for prevention and therapy of cytomegalovirus infections during pregnancy
- ICON is supported by a renowned medical advisory board





# Study of the use of Cytotect® in pregnant women: design and development

From Nature for Life

- Clinical Phase III: open, prospective, randomised, controlled, multi-centre
- 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 > 20,000 pregnant women in order to have at least 50 evaluable cases in each group





## Orphan drug status adds to Cytotect® market potential

### **Europe (EMEA)**

### **USA (FDA)**

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



From Nature for Life

### Biotest diagnostics - major achievements in financial year 2006

- Strategic refocusing of the Diagnostic segment
- Redrafting of marketing agreement for TANGO®, hospitals will be supplied by **US** subsidiary of Biotest
- Recruiting of sales team in the USA successfully completed
- Biotest applied to FDA for approval of reagents for manual blood group typing
- Heipha maintains position as market leader in Germany and increases sales in other European countries
- Launch of new particle counter well received by the market

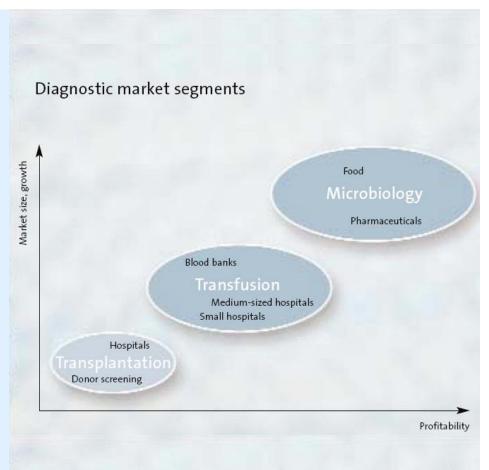




# Biotest diagnostic strategy – focusing on core markets, investing in sales & marketing

From Nature for Life

- Strategic focus on immunology and microbiology products
- Focus on markets and products with high approval and quality requirements
- Investments in marketing and sales in order to quickly increase market share
- By start of 2008, Biotest intends to operate as full service provider in the USA
- In microbiology, Biotest intends to gain more customers in food and cosmetics industry, alongside big pharma
- Investment in new ground-breaking technology combining PCR with innovative media technology





# Biotest biotherapeutics - major achievements in financial year 2006

From Nature for Life

- Launch of clinical trial of BT-061
- Cooperation and licence agreement with ImmunoGen secures exclusive rights to use TAP technology for BT-062
- Biotest enters into an agreement with CMC for production of GMP material for clinical testing of BT-062
- Clinical development of BT-062 outlined to FDA and Dana Faber Cancer Institute, Boston
- Humanisation of BT-063 is successfully concluded





# Biotest biotherapeutic strategy (1) – successful partnering along the value chain

From Nature for Life

- Technology transfer
- Time-to market significantly reduced
- Efficient large-scale manufacturing processes
- Marked decrease of costs of goods sold

Cell and mole- cular biology	Process development	preclinical studies	toxicology and pharmacology	GMP production	Analytics	Clinical development
AERES  BioReliance  Glycotype  Lonza	<ul><li>Lonza</li><li>ImmunoGen</li><li>Orpegen</li></ul>	AMC  Karolinska  Harvard Medical School  diverse universities	<ul><li>MDS</li><li>Notox</li><li>Charles River</li><li>EDI GmbH</li><li>LPT</li></ul>	CMC Biopharm  Rentschler  Lonza	Toplab  CAT  BioReliance  Lonza	Acromion  Congenics  Parexel



From Nature for Life

# Biotest biotherapeutic strategy (2) – focusing on high medical need, partly outlicensing from Phase III onwards

- Biotest concentrates on indications with high patient prevalence and high medical need
- Development of mAb including Phase
  If for own account
- Partnerships with big pharma companies planned for further development and co-marketing
- Upfront and milestone payments expected to cover our share of costs from Phase III onwards

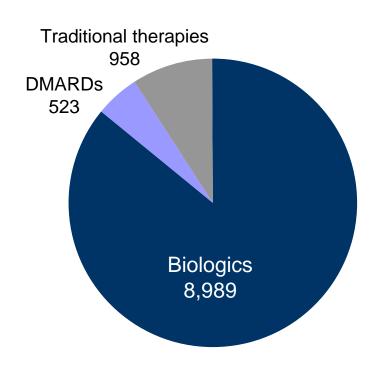




# BT-061: biologics currently available improve treatment of RA, but hardly any cases of remission

- 50% of patients stay on their drug for less than 2 years due to adverse events or loss of efficacy
- 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

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





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

## 2006

#### **Process development**

#### **Preclinical development**

#### **Clinical research**

#### 2006

- Completion of production, analytics and product release (by partner)
- Significant optimisation of yields
- Completion of pharmacological and toxicological studies / additional tests required due to TeGenero
- Approval by regulatory agency (PEI) to start clinical trial

#### 2007

- Completion of optimisation programme
- Proof of comparability and consistent quality of the clinical batches
- Production for further clinical studies
- Completion of the long-term toxicology study in animals
- Phase I in psoriasis
- Phase I/II in RA

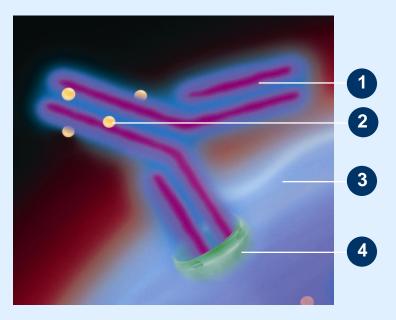
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# BT-062: significant potential for treatment of highly aggressive multiple myeloma (MM)

From Nature for Life

- MM remains an incurable malignancy with growing incidence
- High-level expression (50-200x higher compared to normal plasma cells) of target antigen
- High specificity of target: no expression on haematopoietic bone marrow precursor cells and B cells
- Immunotoxin with murine antibody 5-10x more effective than competitive agents
- Outstanding results confirmed by new generation of immunotoxin using humanised (chimerised) antibody.



- 1 mAb
- 2 cytotoxic agent
- 3 cancer cell
- 4 target antigen



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

#### **Clinical research Process development Preclinical development** Process transfer to Continuation of First discussions with contract manufacturer preclinical development potential clinical Cooperation with Further process investigators ImmunoGen started development 2006 Clinical batch Coordination with FDA Selection of clinical production Completion of centre (Dana Farber toxicological studies Cancer Institute, Boston) 2007 Final discussion of clinical protocol with FDA Application for orphan drug status



## **Expected development portfolio by end of 2007**

		pre-clinical	Phase I	Phase II	Phase III	Approval Phase
Plasma products - FH-Process						1 11400
• Hepatect® FH*						
• Albumin FH*	* Applicat	ion for extens	sion of			
• Haemoctin®*	European	approval				
• Haemonine®						
New Indications						
• Medical device (bypass surgery	)					
Cytotect® NF (pregnancy)						
• Intratect® (fibromyalgia)						
mAb						
• BT-061 (RA)						
BT-061 (psoriasis)						
BT-062 (multiple myeloma)						



### **Dr. Michael Ramroth, CFO:**

### A marked increase in sales and earnings





# Strong revenue growth in Pharmaceutical business, stable business in Diagnostics

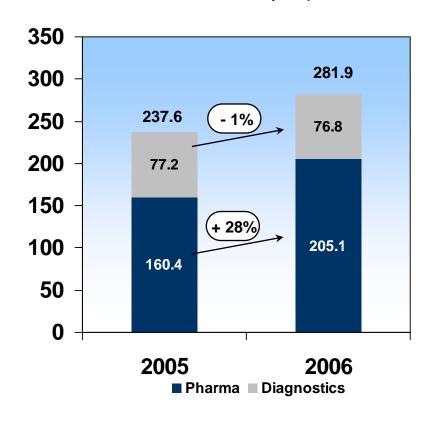
#### **Pharmaceuticals**

- Prices slightly improved
- Immunoglobulins: double-digit growth, Intratect® market share >21% in Germany
- Humanalbumin: sales increase by 90%
- Start of toll manufacturing business in 2006, sales > €10m

#### **Diagnostics**

- Shrinking business in transfusion and transplantation
- Growth in hygiene monitoring

#### Revenues in 2005 and 2006 (€ m)





## Pharmaceuticals: sales by product group (€m)

	2005	in %	2006	in %	Diff. in %
Hyperimmunoglobulins	42.1	27%	43.4	21%	3%
Intraglobin / Intratect	38.9	24%	52.0	25%	34%
Haemoctin / Factor IX	50.2	31%	55.4	27%	10%
Humanalbumin / Other	29.2	18%	54.3	27%	86%
	160.4	100%	205.1	100%	28%

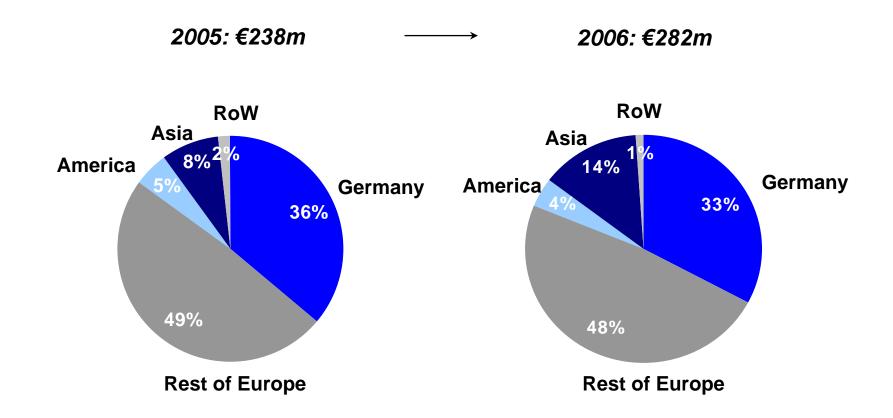


## **Diagnostics: sales by product group (€m)**

	2005 ii	2006	in %	Diff. in %
Transfusion	19.3 25	% 17.9	23%	-7%
Transplantation	12.8 179	<sup>%</sup> 11.7	15%	-9%
Infectious disease	<b>7.2</b> 9	7.3	10%	1%
Hycon	<b>27.6</b> 36	% 30.2	39%	9%
Merchandise	10.3 13	9.7	13%	-6%
	<b>77.2</b> 100	<b>76.8</b>	100%	-1%



# Sales by region: strong increase in Asia (especially Middle East)





### Earnings growth exceeds sales increase

#### **Profitability**

• Gross profit: + €30.4m

• R&D costs: + €9.2m

• EBIT: + €6.7m

• EBT: + €6.6m

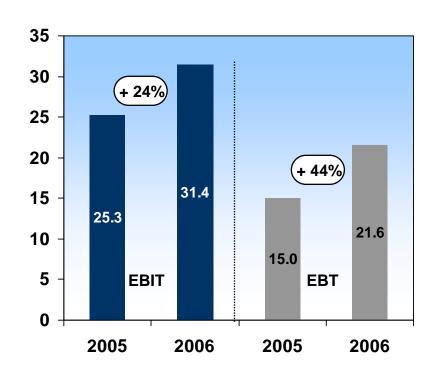
#### **Financial result**

- Financial expenses significantly reduced to €9.8m (2005: €11.4m)
- Reduced liabilities, lower interest rate due to the new syndicated loan agreement

#### **Earnings per share**

 EPS increased to €1.48 (2005: €1.13)

## EBIT and EBT of the Biotest Group in 2005 and 2006 (€ m)

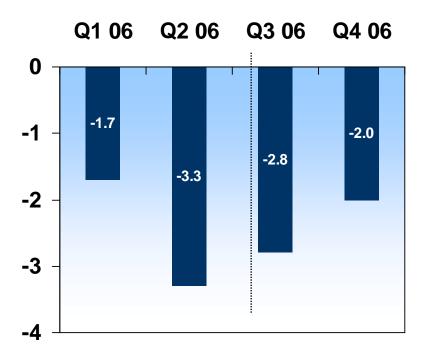




### Biotherapeutic segment: R&D expense amounts to €9.8m in 2006

- Development of new business segment on schedule
- R&D expenses are expected to increase by 30% in 2007 due to launch of clinical trials

## EBIT in the Biotherapeutic segment (€ m)





## **Biotest Group - income statement**

	2005	2005		5
	€m	%	€m	%
Revenues	237.6	100	281.9	100
Cost of goods sold	-126.1	-53	-140.0	-50
Gross margin	111.5	47	141.9	50
Other operating income	10.9	5	7.8	3
Distribution expense	-54.9	-23	-63.3	-22
Administrative expense	-19.5	-8	-22.8	-8
R&D expense	-16.9	-7	-26.1	-9
Other operating expenses	-5.8	-2	-6.1	-2
Operating profit (EBIT)	25.3	11	31.4	11
Financial result	-10.0	-4	-9.5	-3
Income from associated companies	-0.3	0	-0.3	0
Earnings before tax	15.0	6	21.6	8
Income tax	-3.8	-2	-4.3	-2
Profit after tax	11.2	5	17.3	6
Minority interest	-1.0	0	-1.3	0
Consolidated net profit	10.2	4	16.0	6



## Significant reduction of net debt and increase of EBITDA in 2006

- Significant reduction of net debt and increase of EBITDA in 2006
- Net debt:

31 Dec 04: €136m 31 Dec 05: €75m

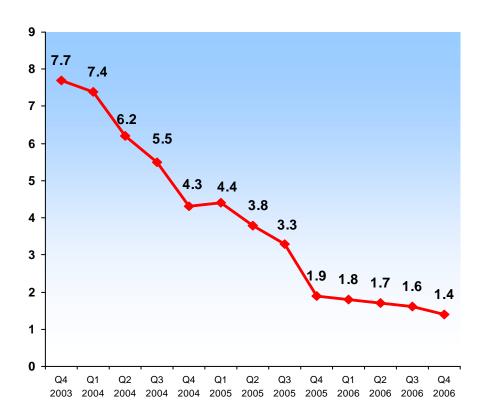
31 Dec 06: €66m

• EBITDA:

2004: €32m 2005: €40m 2006: €47m

Substantially improved ratio

#### **Net debt / EBITDA**





## **Biotest Group: balance sheet - assets**

	2005	2006		
Assets	€m	%	€m	%
Non-current assets				
Fixed assets	154.1	44	153.6	42
Other assets	0.3	0	0.0	0
Deferred tax assets	8.1	2	9.3	3
∑ Non-current assets	162.5	46	162.9	45
Current assets				
Inventories	108.4	31	104.8	29
Trade receivables	66.1	19	73.9	20
Income tax receivables	1.0	0	1.2	0
Cash and cash equivalents	7.6	2	8.9	3
Other current cssets	5.4	2	10.4	3
∑ Current assets	188.5	54	199.2	55
Total assets	351.0	100	362.1	100



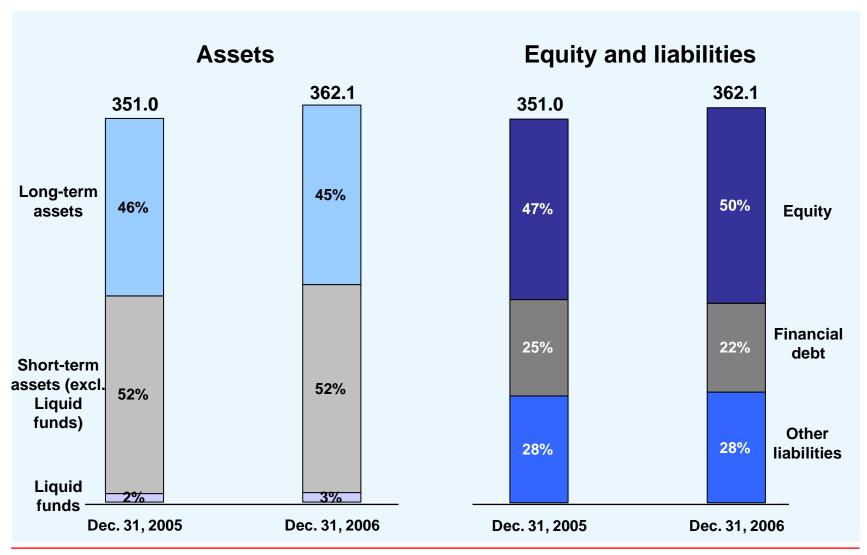
## **Biotest Group: balance sheet - equity and liabilities**

From Nature for Life

	2005			2006	5
Liabilities	€m	%		€m	%
Equity	164.8	47		179.3	50
Liabilities					
Non-current liabilities					
Pension provisions	42.4	12		43.1	12
Other provisions	4.3	1		3.5	1
Non-current financial liabilities	69.1	20		64.7	17
Other liabilities	0.3	0		0.0	0
Deferred tax liabilities	2.3	1		2.7	1
$\Sigma$ Non-current liabilities	118.4	34		114.0	31
Current liabilities					
Other provisions	8.1	2		10.9	3
Current Tax liabilities	2.8	1		4.7	1
Current financial liabilities	19.3	5		16.7	5
Trade payables	25.2	7		23.5	6
Other liabilities	12.4	4		13.0	4
$\Sigma$ Current liabilities	67.8	19		68.8	19
$\Sigma$ Liabilities	186.2	53		182.8	50
Total equity and liabilities	351.0	100		362.1	100



### **Balance sheet**





### Outlook 2007

#### **Forecast**

- Revenue expected to increase by 5 7%
- Profit will grow further despite higher R&D expense in Biotherapeutics

#### **Pharmaceuticals**

- Further revenue growth limited by capacity and short term plasma supply
- Increase of capacity of own plasma donation organisation
- Prices for plasma products will further stabilise and slightly improve in H1 2007

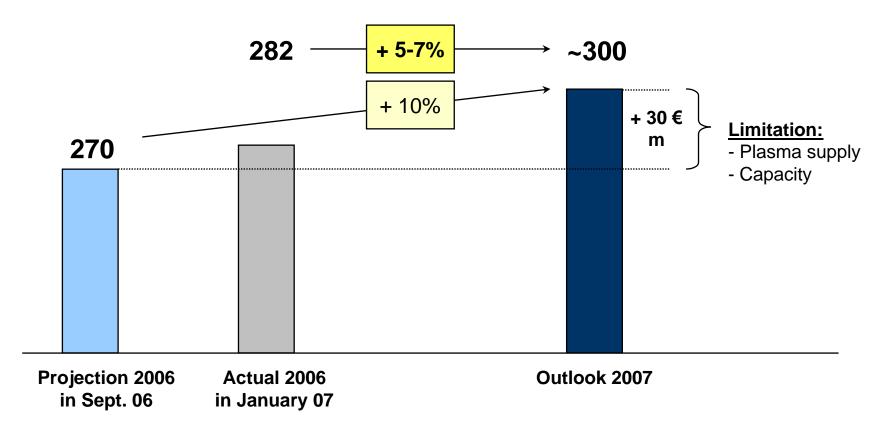
### **Diagnostics**

- Active search for new technologies and partners for immunological diagnostics
- Heipha will extend capacities to satisfy continuing rising demand



### Outlook unchanged: growth in revenue

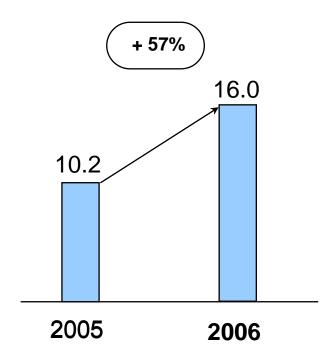
#### Revenue in €m



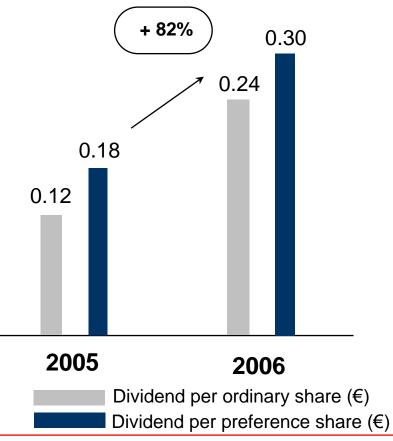


### **Proposed dividend increase**

Consolidated net profit (€ m)



### Sum of dividends





### **Disclaimer**

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