



## Biotest Group





**Company Presentation**May, 2012



#### **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., and the disposal of the Microbiological Monitoring to Merck KGaA
   the remaining activities are being reported as Discontinued Operation.
- All comparative figures relate to the corresponding last year's period, unless stated otherwise.



#### **Biotest Group: Highlights Q1 2012**







- Biotest Q1 2012 Group Sales up by 1.1%; Increase largely attributable to an upfront payment by Abbott on a pro rata basis to the Biotherapeutics segment
- Q1 2012 EBIT increased by 14.3% despite difficult plasma protein market environment and unabsorbed costs in Boca Raton
- Bivigam<sup>TM</sup>: Approval expected in mid 2012
- New Strategic orientation of Biotest:
   the products are used in the treatment areas of
  - > Haematology,
  - Clinical immunology and
  - **▶** Intensive care medicine



### **Biotest Group**

- Headquarter in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 11 countries worldwide
- Employees (FTE)\*: 1,670\*\*
   Thereof 45% located outside Germany
- Founded in 1946, IPO in 1987, SDAX in 2007 (preference shares)
- Biotest shares:
  - 6,595,242 ordinary shares
  - 5,133,333 preference shares



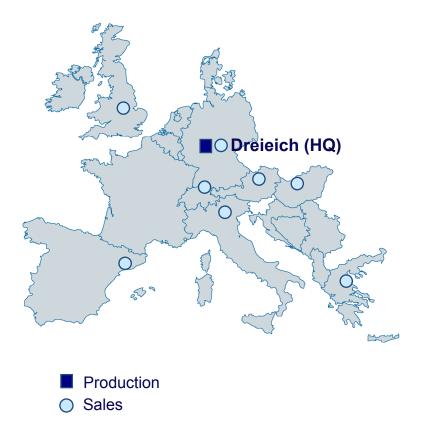
Headquarter, Dreieich

\*: as of March, 2012 \*\*: Continuing Operations



## **Biotest Group overview**

## **European production** and distribution sites



#### Additional sites:

USA: Florida (■ ○)

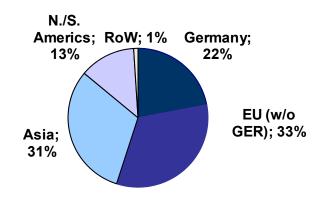
Brasil: Sao Paulo

Russia: Moscow

Distribution also via 69 distributors

in 68 countries

#### Sales by region (Q1 2012):





#### **Shareholder structure**

#### **Biotest AG**

Ordinary shares: 6.6 mio

with voting rights

OGEL GmbH\*: 50.03% KSK Biberach\*: ~24%

Free Float: ~26%

56.4% of total capital, and 100% of voting rights

Preference shares: 5.1 mio no voting rights, but higher dividend

Free Float: 100%

43.6% of total capital, 0% of voting rights

\* as of May 2012



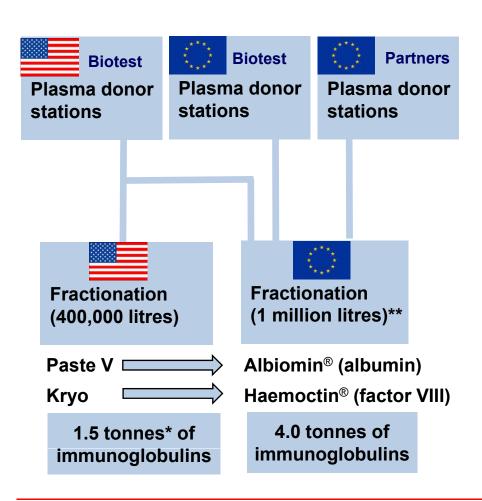
## **Biotest: History and milestones achived**

<b>1946:</b> Biotest- Serum Institut GmbH	facility at		<b>1987</b> : IPO		- Clinical testing of monoclonal antibodies	
1948: Test-Serum Anti-D	Dreieich    1968: First subsidiary outside Germany (Italy)   1971: Market launch of Intraglobin®		1991: Start of Microbiological Monitoring  2004: Start of modernized Plasma Proteins production	1	Acquisition of Nabi Preference share in SDAX  2010: Divestment of Medical Diagnostics  2011: Divestment of Microbiological Monitoring 2011: Biotest- Abbott Deal for BT 061	

1946



#### Plasma Proteins – Efficient production network



- Acquisition of Nabi Biologics in 2007 (USD 185 million)
- 22 plasma collection centres
- Exchange of intermediate products from US to Europe planned for 2012
- Network increases EBIT margin
- Capex for investments in production in Dreieich and Boca Raton 2008-2010: ~ USD 110 m

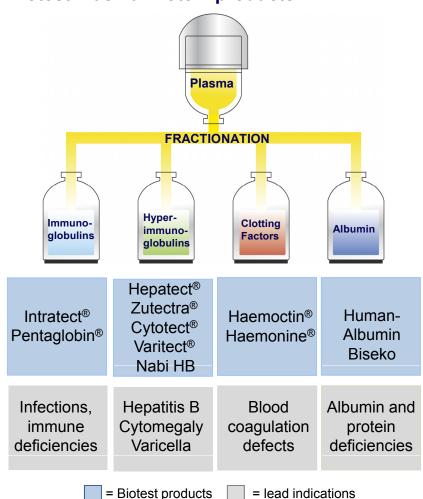
<sup>\*</sup> Approval will probably be granted Mid of 2012

<sup>\*\*</sup> Production in Dreieich and capacities at partners



#### Plasma Proteins business at a glance

#### **Biotest Plasma Protein products**



- Global market share IVIG: ~ 3%
- Intratect® market share in GER, AUT: > 17%, in UK, CH, I: > 10%
- World market leader with Cytotect<sup>®</sup> and Varitect<sup>®</sup>
- Leading position with Hepatect<sup>®</sup> in Europe and Nabi HB<sup>™</sup> in USA
- Biotest covers full value creation chain: plasma sourcing, production, distribution
  - vertical integration leads to rationalisation and higher productivity



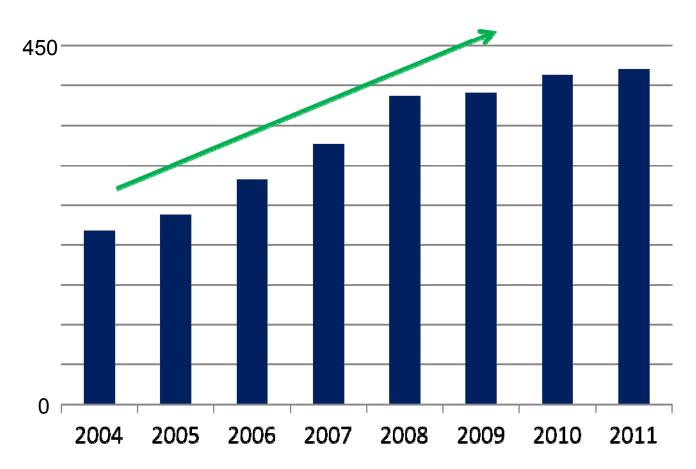


#### Financials Q1 2012



## Biotest has grown year by year

#### Revenues in € mio



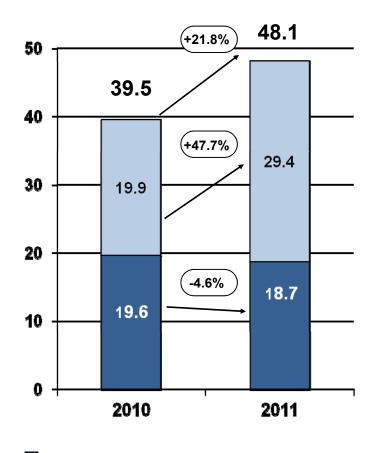


## Earnings increase from realised capital gains

## **EBIT** (€ million)

#### 77.3 80 67.7 +44.0% 60 35.7 24.8 40 -3.0% 41.6 42.9 20 0 2010 2011

#### **Earnings after tax** (€ million)

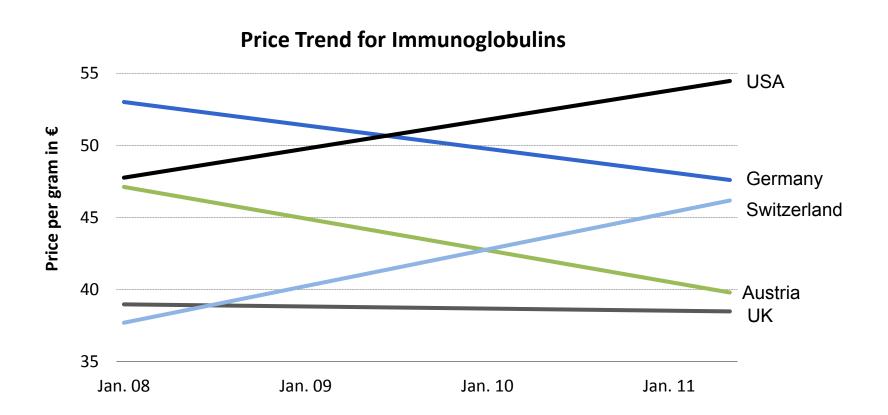


Discontinued Operation

Continuing Operations



## Immunoglobulins: Price gap between U.S. and Europe



Source: Biotest AG, UBS Investment Research
Trend curves based on prices obtained (A, UK, CH, D: prices for Biotest products, USA: average prices)
US prices converted to euros at constant exchange rates



#### **BPC Earnings reduced by one time expenses**



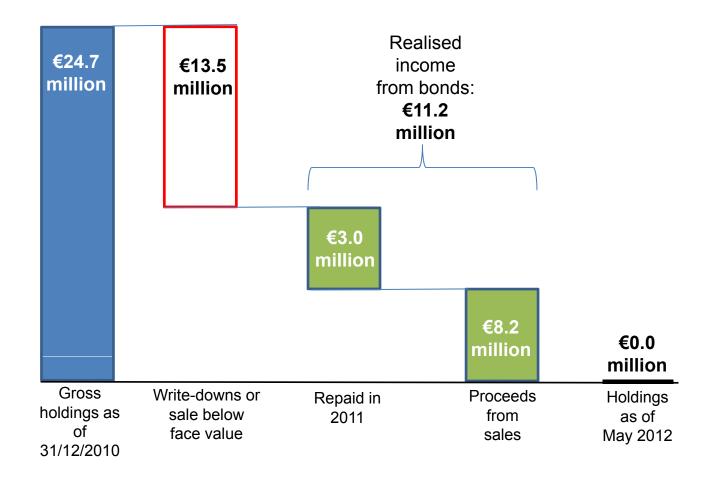


Delays and additional costs for the expansion of production at Biotest Pharmaceuticals Corp. (BPC) in Boca Raton in 2011

- Problems with automation and control technology required rework in the first half of 2011, leading to a longer idle period than planned
- Problems fixed, plant has been operating under stable conditions since August 2011
- Full capacity (1.5 tonnes of immunoglobulins per year) will be reached gradually
- Negative impact on earnings in 2011: approximately €10 million



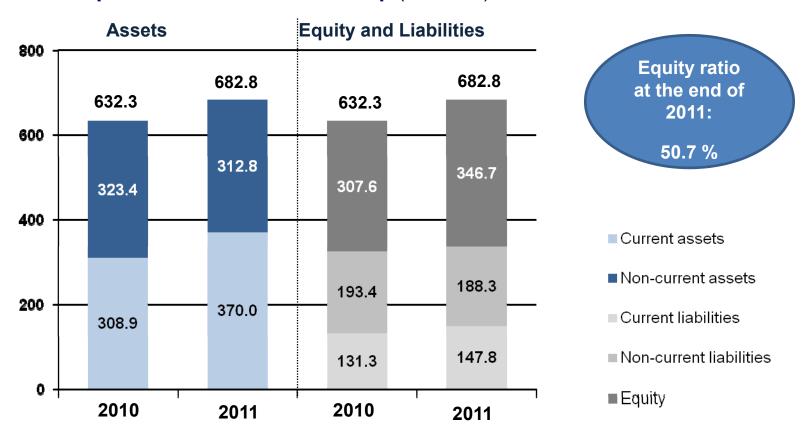
#### Greek bonds lose considerable value





#### Statement of financial position: net debt reduced by 60%

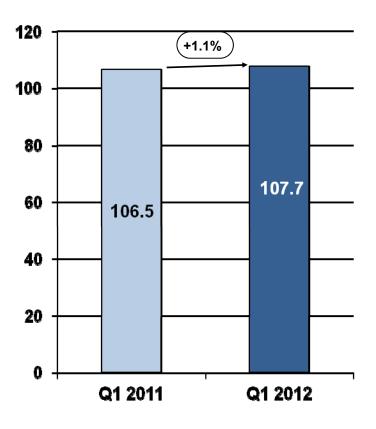
#### Financial position of the Biotest Group (€ million)





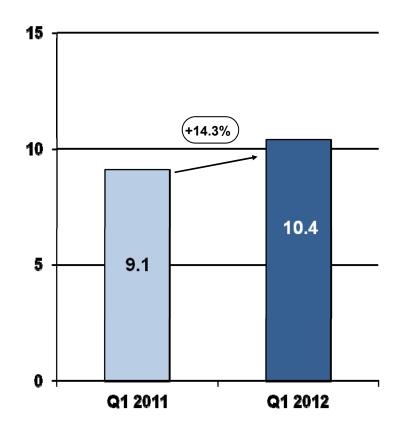
#### Biotest with a solid start in Q1 2012

#### Sales\*(€ million)

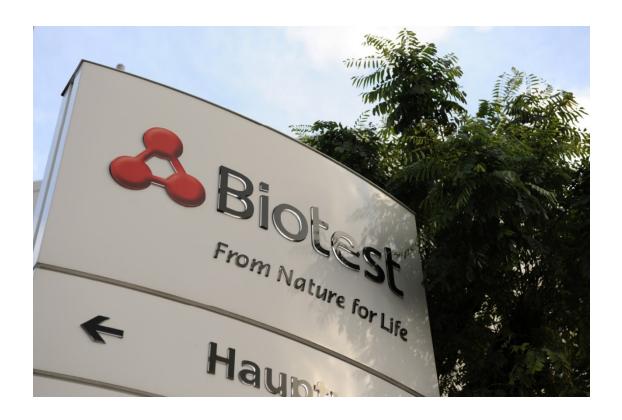


#### \* Continuing Operations

#### **EBIT\***(€ million)







### **Important strategic milestones**



## **Agreement with Abbott regarding BT-061**



- Contract with Abbott on the further development and marketing of the monoclonal antibody
- Abbott is one of the world's market leaders in biotechnological products for the treatment of immunological diseases
- Lead indications: rheumatoid arthritis and psoriasis
- Since 2011, tregalizumab is the official <u>International Nonproprietary Name</u> (INN) for BT-061



## Agreement is a milestone for Biotest



- Joint development of Tregalizumab from clinical phase III
- Upon marketing authorisation:
  - Joint marketing in Germany and four other European markets
  - Exclusive marketing by Abbott in other markets
- USD 85 million advance payment to Biotest
- Additional milestone payments of up to USD 400 million
- Royalties after marketing authorisation in Abbott's excluseve territories



## US authorisation of Bivigam<sup>™</sup> expected soon



- FDA authorisation for polyspecific immunoglobulin expected in summer 2012
- Bivigam<sup>TM</sup> is similar to Intratect<sup>®</sup> product authorised in other markets
- Authorisation will broaden the basis for US activities
- Around USD 100 million in annual sales expected in the medium term



## **Biotest AG**



## **New strategic orientation**



#### **Company focus**

Biotest is a **pharmaceutical company** that concentrates on the development, production and marketing of **biological medicinal products**.

Biotest's medicinal products are obtained either from human blood plasma or are manufactured using

biotechnological methods.

They are used in the treatment areas of haematology, clinical immunology and intensive care medicine.



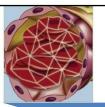
### **Treatment areas: products**



#### Haematology



# Clinical immunology



## Intensive care medicine

Haemoctin® Haemonine®

Bivigam™
Hepatect®
Nabi-HB®
Zutectra®
Fovepta®
Cytotect®
Varitect®

Intratect®

Pentaglobin® Humanalbumine Biseko® Cofact®



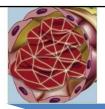
## Treatment areas: development projects



#### Haematology



Clinical immunology



Intensive care medicine

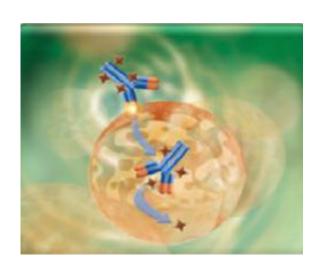
BT-062

Civacir®
Cytotect® 70 (BT-094)
Tregalizumab (BT-061)
BT-063

IgM concentrate Fibrinogen



# Haemathology development projects BT-062 – specific mechanism of action



#### **Active substance / mechanism:**

- Immunoconjugate consisting of antibody and highly active cytotoxic agent
- Antibody binds specifically to cancer cells
- Only then is the cytotoxic agent released

#### Advantages:

- Targeted attack on malignant cells
- Healthy tissue is largely spared
- Precise targeting enables the use of high doses of cytotoxic agent

#### Effective attack on tumour cells



#### Haematology development projects: BT-062 Clinical studies in the lead indication of multiple myeloma

#### Study 969

#### Focus:

- · Tolerability, safety
- Anti-tumour activity

#### Results / status:

- Good tolerability up to a dose of 160 mg/m<sup>2</sup>
- Clinical benefit in more than 50% of patients

#### **Study 975**

#### Focus:

- Increase in efficacy and tolerability through administration of the dose over several days
- Anti-tumour activity

#### Results / status:

- Good tolerability
- Evidence of efficacy confirmed

#### Study 983

#### Focus:

- Tolerability and safety in combination with approved standard therapy
- Anti-tumour activity

#### Status:

First patient expected in mid-2012



## BT-062 with potential in other types of cancer

- BT-062's binding site also extensively present in malignant cells of other types of cancer
- Applies for tumour cells and metastases, even in advanced disease

Type of cancer	Potential target patients*
Breast	45%
Pancreas	50%
Prostate	50%
Bladder	63%

Possible starting points for BT-062, which are now being examined



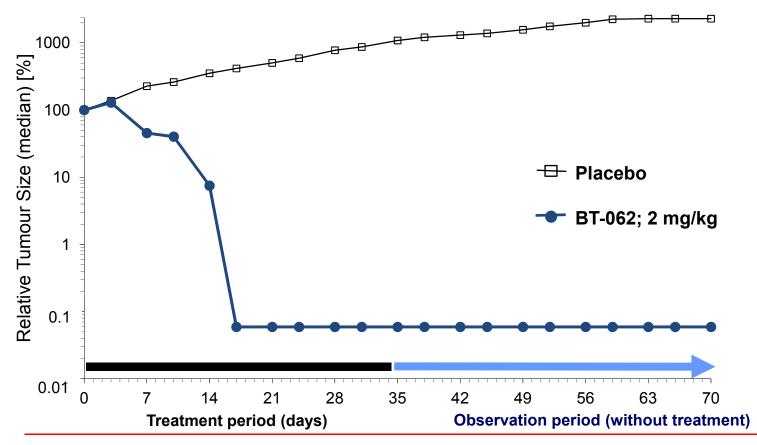
Focus on four indications

\* Percentage of patients with tumours that overexpress CD138



## **BT-062**: impressive activity against tumours

- Treatment of a tumour that was resistant to established therapies
- Complete tumour regression even below the maximum tolerated dose





## Clinical immunology development projects BT-061: Potential Indications Rheumatoid Arthritis/ Psoriasis

#### Study 979

- Scope:
  - Phase Ilb RA (BT-061 + MTX\*)
  - Multidose, subcutaneous up to 75 mg, 12 weeks treatment
- Patients: 176
- Patient recruitment in progress

#### Study 985

- Scope:
  - Phase I (Pharmacodynamics, Pharmacokinetics)
  - Single dose, subcutaneous up to 200 mg
- Patients: 36
- Clinical trial protocol submitted for approval

#### Study 986

- Scope:
  - Phase IIb RA (BT-061 + MTX\*), Multidose, subcutaneous six months treatment

- Patients: 350
- First patient expected in H1 2013

\*MTX = Methotraxate



#### Clinical immunology development projects

Intratect® 10%: Outpatient care of antibody deficiency syndrome

Cytotect® 70: Infection prophylaxis in the case of cytomegalovirus infection during pregnancy

Civacir <sup>™</sup>: Reinfection prophylaxis following hepatitis C-induced liver transplant

**Tregalizumab:** Monoclonal antibody rheumatoid arthritis and psoriasis

BT-063: Monoclonal antibody, systemic lupus erythematosus



#### Civacir: project with signficant potential



- Hepatitis C immunoglobulin for reinfection prophylaxis following hepatitis C-induced liver transplant
- High medical need:
  - Number of hepatitis C-induced liver transplants is high, and increasing
  - High reinfection risk in the transplanted liver
  - No viable alternatives
- Start of clinical development by BPC towards the end of 2012
- Orphan drug designation in Europe and the USA means exclusive marketing rights for seven or ten years if granted marketing authorisation



## Intensive care medicine development projects

**IgM concentrate:** IgM-enriched immunoglobulin for the

treatment of severe bacterial infections

**Fibrinogen:** Used in acute clotting disorders due to

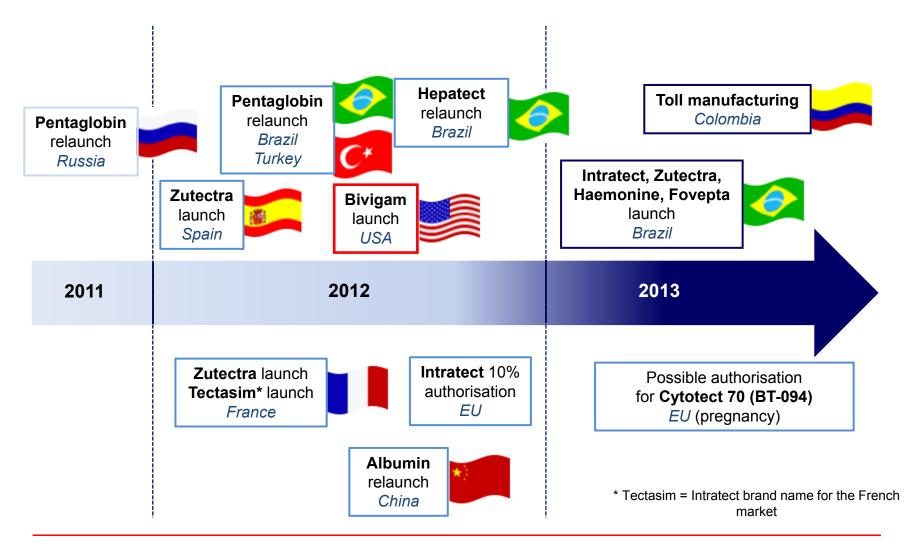
fibrinogen deficiency, infusion solution

prepared much more rapidly than

reference product



#### Internationalisation - new market entries



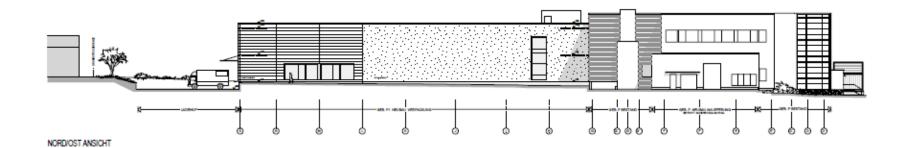


#### Investments in further growth

#### New bottling and packaging facility in Dreieich:

- Building extensions, process optimisation
- New filling line
- Increase in packaging units per year from 3 to 6 million
- Technical completion by 2013

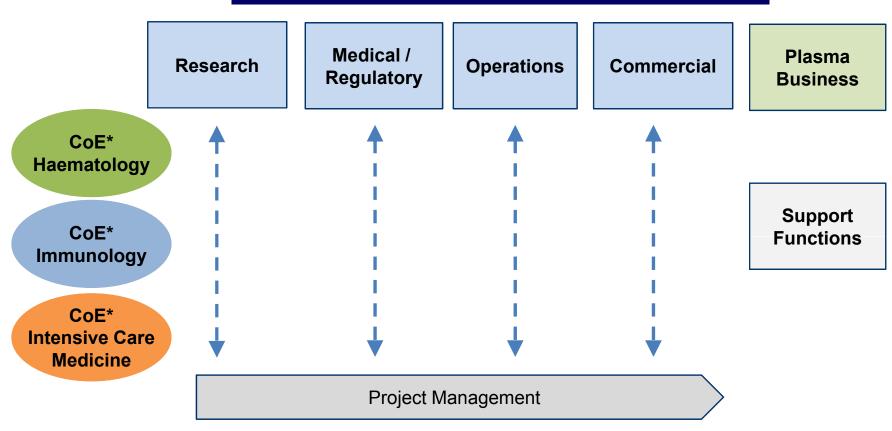
#### **Total investment: €30 million**





#### **New structure for increased effectiveness**

#### **Board of Management / Business Management**



\*CoE = Center of Excellence



#### **Guidance 2012**

**Sales:** Sales growth of 3-5 percent compared to 2011

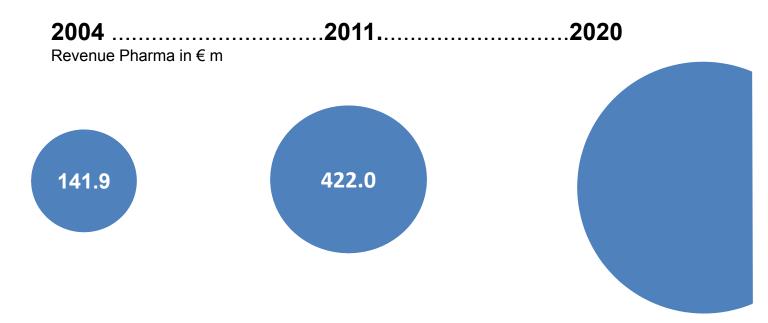
**EBIT:** Slight increase vs EBIT of 2011 (€ 41.6 m)

Still high ramp up costs in US

The 2012 guidance assumes that the market environment for our business in countries like Greece, Russia and several countries in the Middle East does not deteriorate due to financial or political reasons. Another precondition is the launch of Bivigam<sup>TM</sup> in the US in mid of 2012



## **Continuing strong growth**



#### **Growth driven by:**

- Futher strengthen R&D activities
- In-licensing of close to or marketed products
- Mergers & Acquisitions



#### **Contact and Financial Calendar 2012**

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**Financial Calendar 2012** 

Aug 13, 2012 Q2 Report 2012

Nov 13, 2012 Q3 Report 2012/

**Analyst conference**