





#### **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 comparative figures relate to the corresponding last year's period, unless stated otherwise.



## Biotest Group: Q1-Q3 2014 at a glance



- Biotest Q1-Q3 2014 sales up by 11.5% to €409.9 m. Increase largely attributable to an increase in volume and sales in international markets w/o US
- Q1-Q3 2014 EBIT decrease by 11.5% to €35.3 m
- Civacir® prevents re-infection in liver transplantation as shown in clinical phase III trial
- Biotest "Next Level" project is on track
- Recruitment of patients for study "Treat 2b" (BT-061) completed in record time



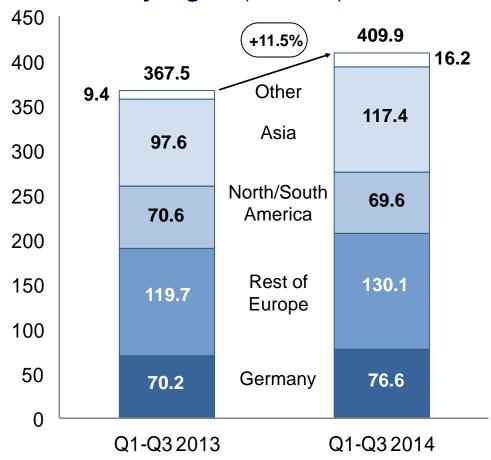


# Financials Q1-Q3 2014



## Sales growth much stronger than expected

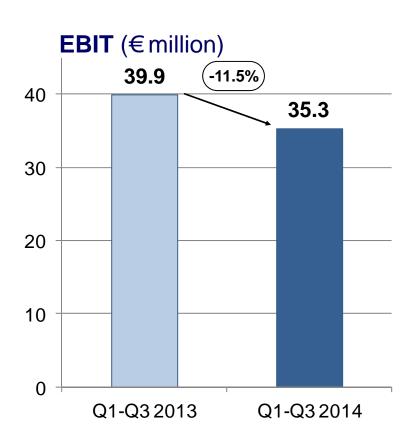
#### Sales by region (€ million)





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#### **EBIT** decrease



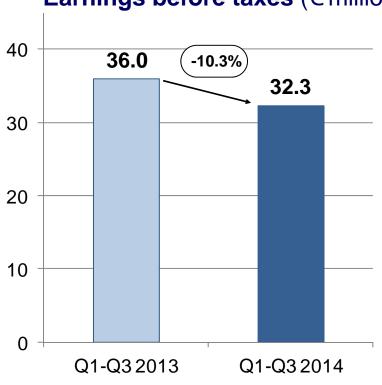
- Increased costs for clinical trail material of € 4.0 m for BT-061 and Civacir<sup>®</sup> due to good progress in clinical studies
- Unabsorbed costs in US due to slow down of production
- Additional costs for the expansion plan
   "Biotest Next Level" of €2,2 m



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## **Earnings decrease**

#### **Earnings before taxes** (€ million)

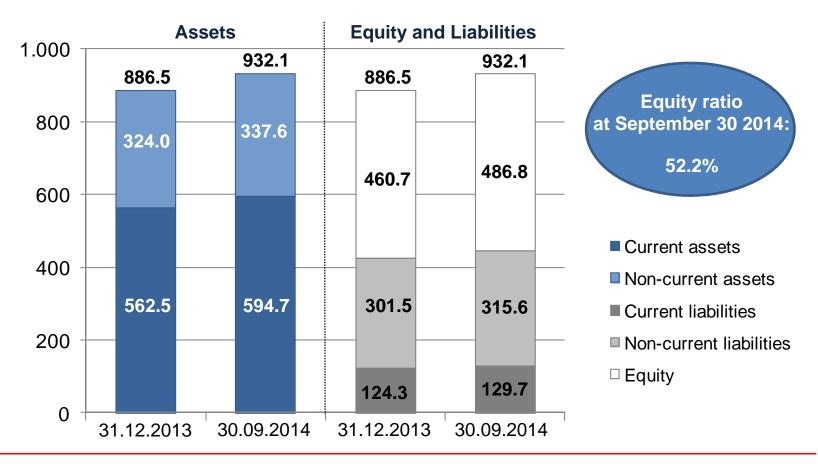


- Positive exchange rates effect
- Increased interest payments due to usage of additional credit lines



#### Financial position: strong equity base

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





# "Biotest Next Level": First projects initiated or already completed





"Biotest Next Level": Biotest's plan to more than double the production capacity until 2020

#### Already completed:

- Expansion of filling and packaging facilities
- First expansion of albumin production
- New multi-storey car park

#### **Construction advanced:**

- Plasma goods receipt area
- Virological test laboratory



# "Biotest Next Level": Production expansion advancing



- Basic engineering completed in Summer 2014
- Building application filed on 25 July 2014 and granted on 12 November 2014
- Due to high energy efficacy
  Biotest was able to secure a
   €85 m loan of the KfW\*
  banking group with a ten
  years term and very
  favourable conditions



# Biotest's new outstanding day care offer



#### Day care almost completed:

- Day care building in walking distance to headquarter building
- For 80 children age < 3 years and > 3 years
- Opening hours 6 a.m. 6 p.m.
- Open during holidays except for the period between Christmas and New Year

#### **Next steps:**

Roofing ceremony on 14 November 2014





# **Biotest's Target Markets**



#### **Biotest situation in the US**



BPC headquarters in Florida

- Experienced management in marketing
   & sales in the US
- Additional distribution channels established
- Number of plasma collection centres in the US will increase to 18 by the end of 2014
- Opening of three new plasma collection centres in 2015
- Plasma sales to third parties increased including high margin hyperimmune plasma sales



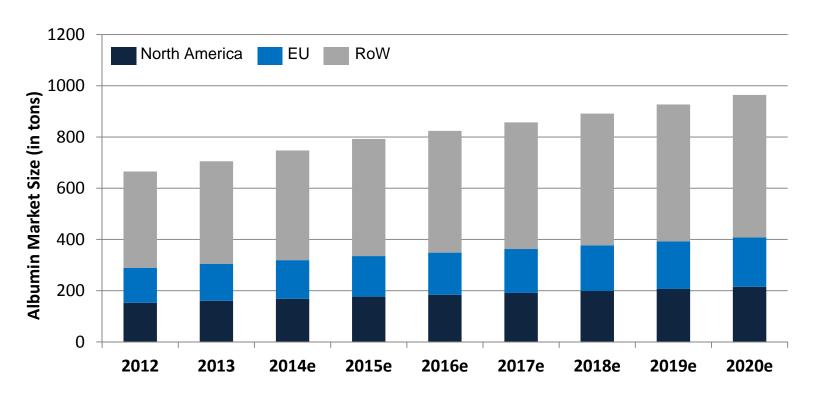
# Marketing authorisation Albiomin 20% granted in China



- Marketing authorisation for Albiomin 20% granted by CFDA\* on 21 October 2014;
   first sales expected at beginning of 2015
- Attractive Albumin market of 205 t p.a., thereof 60% import
- Distribution partner Wanbang; subsidiary of Fosum Pharma, one of the leading pharmaceutical companies in China



#### Global Albumin Market Forecast

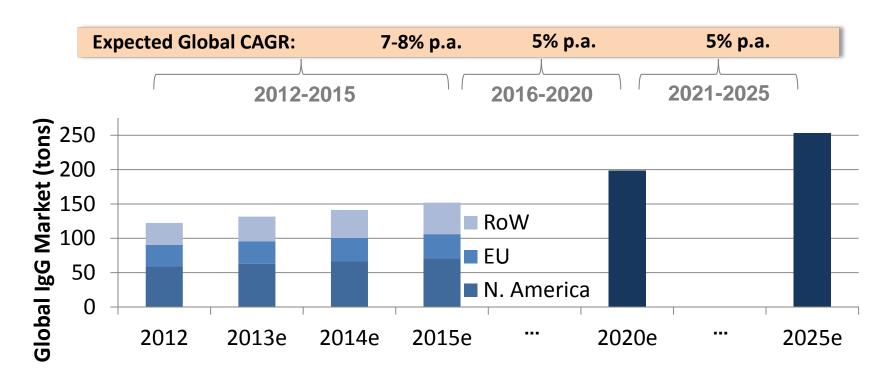


- The global Albumin market is expected to grow to ~965 t by 2020
- This is equivalent to an annual growth expectation between 4% and 6% p.a. in the period between 2013 and 2020

Sources: Biotest Market Research based on MRB (2013), IMS (2013)



# Global market trend immunoglobulin (SC/IVIG)



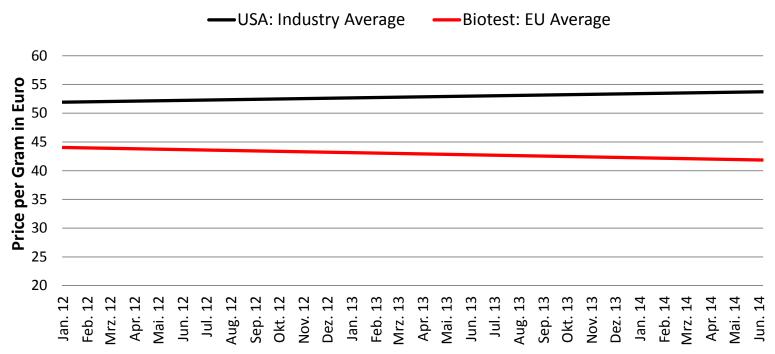
- In the midterm, up to 2015 the following regional growth rates are expected: EU: 4-5%, USA: 4-6%, RoW: 12-13% CAGR
- The global Immunoglobulin market is expected to grow with an average growth rate of ~5-6% p.a. in the period between 2012 and 2025.

Sources: Biotest Market Research based on MRB (2013) etc.



## IVIG Price Trends (Jan. 2012 – June 2014)

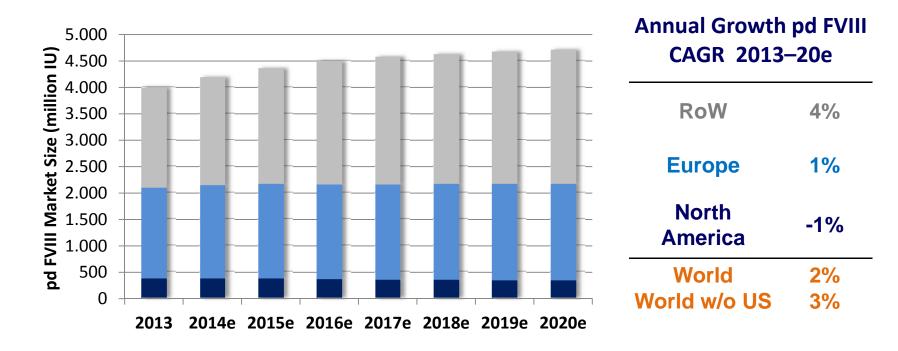
#### Trend Curves of IVIG Prices: Biotest (EU) vs. US Industry Average



Source: Biotest AG, Centres for Medicare and Medicaid Services (CMS). The chart above shows the linear trend curves of the reported per gram prices. EU average includes Austria, Germany, Hungary, Italy, Spain, Switzerland, UK. A constant exchange rate (30 June 2014) was applied to US prices.



#### **Global plasmatic FVIII Market Forecast**



- The global market for plasmatic FVIII preparations is expected to grow with an average growth rate of 2% p.a. until 2020
- Volume growth will mainly take place in emerging markets, a decline is expected for the US

Source: Biotest Market Research

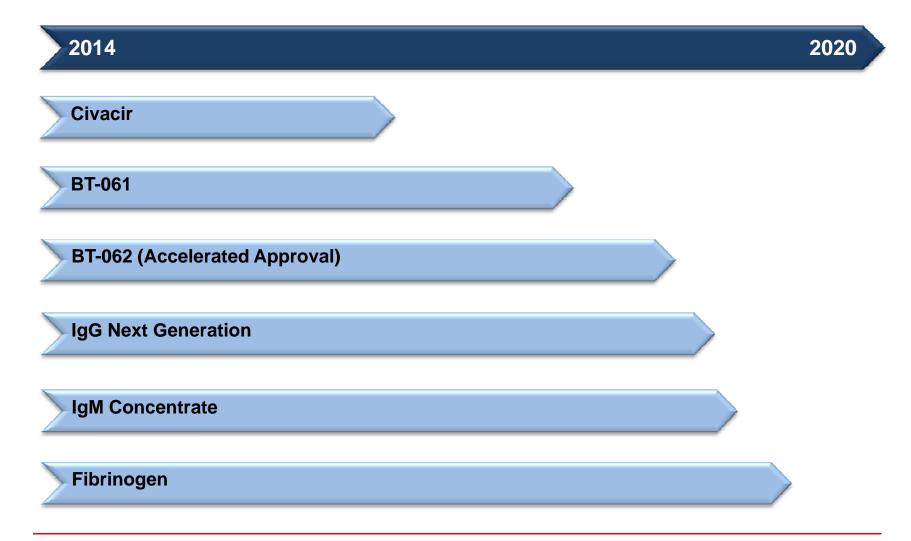




# **R&D** projects on track



# New products at the horizon



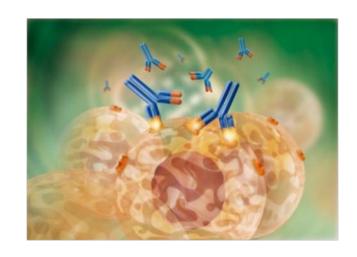


# **Tregalizumab (BT-061)**

- Tregalizumab targets a broad spectrum of autoimmune diseases
- Rheumatoid arthritis (RA) is one of the lead indications
- Psoriasis has been developed in first phase II studies
  - Currently on hold upon AbbVie request until after opt-in
- Very good tolerability/safety is a competitive advantage for diseases that require life-long treatment

#### **Current status**

- Production of clinical material for phase III started in 2014 at BPC with improved process
- Yield approximately doubled
- Phase IIb in RA ongoing





# Tregalizumab (BT-061) Treat 2b study:

#### Patient recruitment completed

Treat 2b: phase IIb trial in RA started in autumn 2013



- Largest clinical trial in Biotest history:
  - > 300 patients
  - 86 study centres in 14 countries, including USA, Canada and Europe
- Recruitment completed in September 2014 (321 patients randomized)
- Treatment of last patients will be completed end of February 2015
- Top line data (24 weeks treatment) expected in Q2 2015

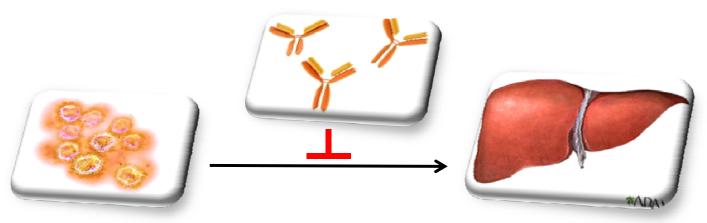


Q3 2015: AbbVie decision point on opt-in and start of Phase III



# Civacir® investigational drug product

- Intravenous Hepatitis C Immunoglobulin (10% concentration)
- For the prevention of HCV\* recurrence in patients undergoing liver transplantation
- Utilizes a short duration of new antivirals to reduce viral load just prior to transplantation
- Civacir® antibodies neutralise any remaining HCV and protect the transplanted liver

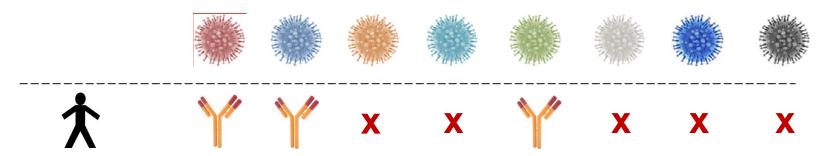


\*HCV = Hepatitis C virus

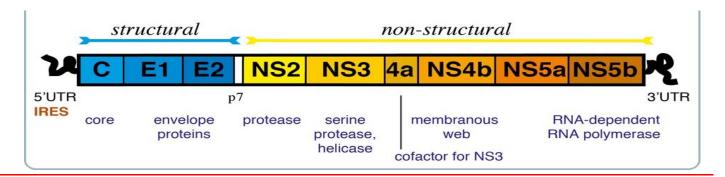


# **Composition of Civacir®**

 HCV mutates faster than HIV and an individual can be infected by several HCV mutant populations

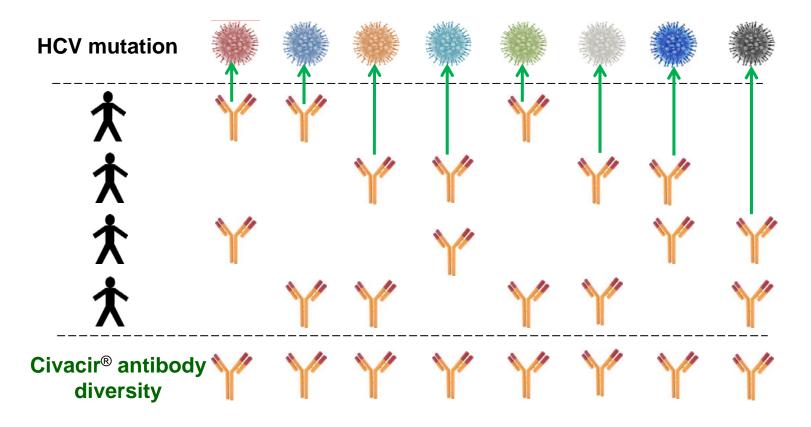


- Antibodies can be made against all HCV proteins; structural and non-structural
- Antibody diversity is limited by genetics in any one infected individual, leaving gaps in patient's ability to neutralize HCV





# Civacir® has antibody diversity isolated from hundreds of HCV donors with high titres of neutralising antibodies



Civacir® therefore provides a spectrum of antibody protection to neutralise HCV and protect the new liver from infection

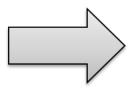


# New virostatics offers only limited protection from viral recurrence after transplantation

Sofosbuvir+Ribavirin treatment (up to 48 wks)



<u>64</u> patients randomized



41 patientsnon-detectable virusat transplantation

26 patients (63%) SVR\*





15 patients (37%) re-infection

Even with pre-treatment with Sofosbuvir or other virostatics viral recurrence rate in transplanted patients is still ~40 %

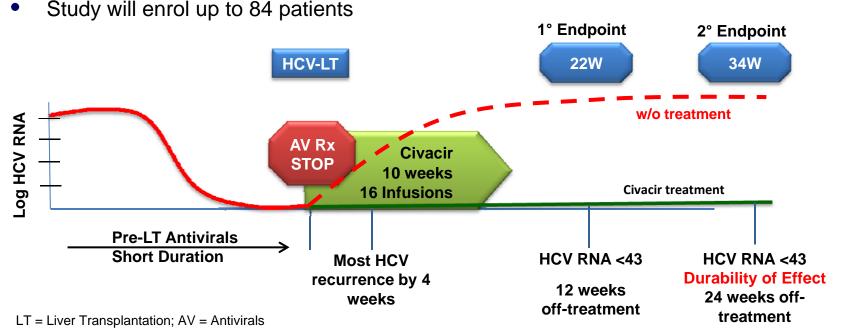
\*SVR = sustained viral response; source: Curry et al, AASLD 2013



# Ongoing US Civacir® trial (study 988)

- Evaluation of efficacy, safety & pharmacokinetics of Civacir<sup>®</sup> in liver transplant recipients
- 24 centres in North America, expansion to Europe in preparation
- Leading hepatologists involved in study
- Enrolling patients infected with HCV genotypes 1 6



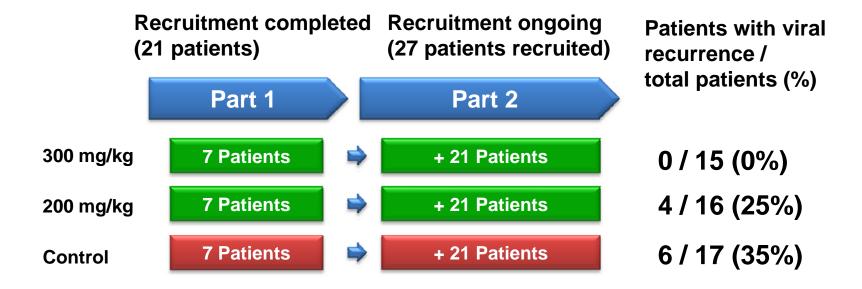




#### 988 Study: Interim Analysis (AASLD 2014 N. Terrault et al.)

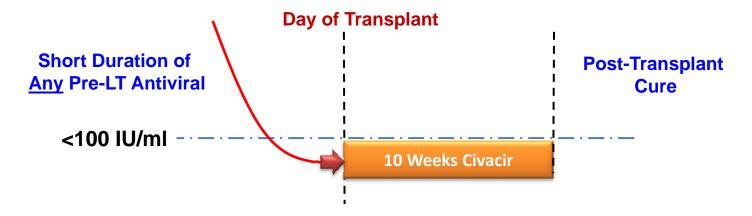
#### **Primary Objective**

Determine proportion of Civacir® treated subjects with unquantifiable HCV RNA(<43IU/ml) at 22 weeks post liver transplant (LT) compared to the control group





# The goal for Civacir®



- Civacir® is a save and effective treatment option for patients with undetectable to <100 IU / ml viral load at transplantation</li>
- Transplantation is feasible as soon as antiviral reduces the viral load to <100 IU / ml:</li>
  - → High flexibility in time point of transplantation
  - → No lengthy pre-treatment with antivirals required

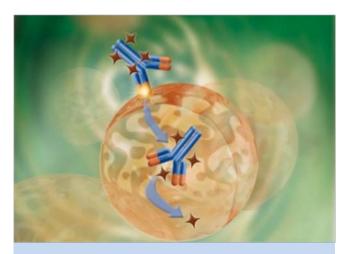


The Hepatitis C virus is eradicated, the transplanted liver is protected and the patient is cured

LT = Liver Transplantation



# Haematology: Indatuximab Ravtansine (BT-062)



#### Targeted mechanism of action:

- Antibody docks on cancer cell and toxin is then released:
- Targets cancer cells while healthy cells are very largely spared

- Clinical development in the lead indication multiple myeloma is continuing
- Sales potential in multiple myeloma of € 950 m; in triple negative breast cancer and bladder cancer € 1,100 m
- Very convincing data from this phase II study (combination with Lenalidomide) will be presented at the ASH\* conference on 6-9 December 2014



# **ASH abstract: Indatuximab Ravtansine (BT-062)**



#### American Society of Hematology

Helping hematologists conquer blood diseases worldwide

- BT-062 is well tolerated with LenDEX (Lenalidomide/Dexamethason)
- Very good responses in patients with relapsed and / or refractory multiple myeloma and patients who do not respond to standard therapy
- Overall response rate (ORR) is 78% including:
  - > 8% complete remissions
  - 28% very good partial remissions
  - 42% partial remissions
- Further data will be presented at the 56. ASH conference on 6-9 December 2014 in San Francisco, USA (Kevin R. Kelly, et al.)

\* ASH = American Society of Haematology



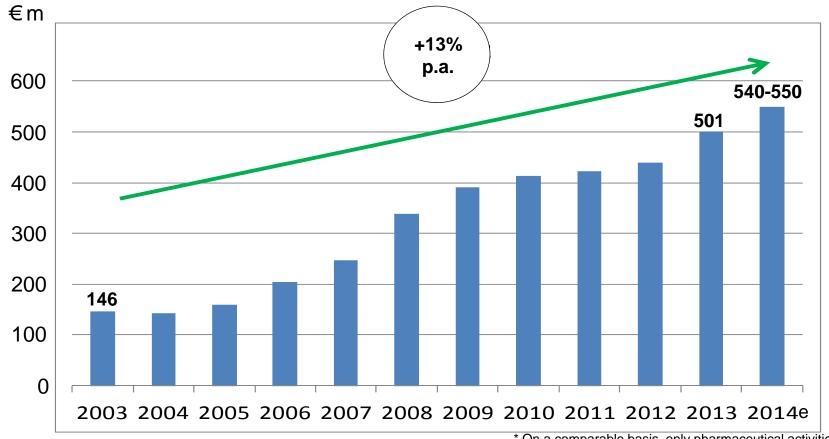


# Review Biotest Group Performance 2003 - 2014



## Continued and accelerated growth

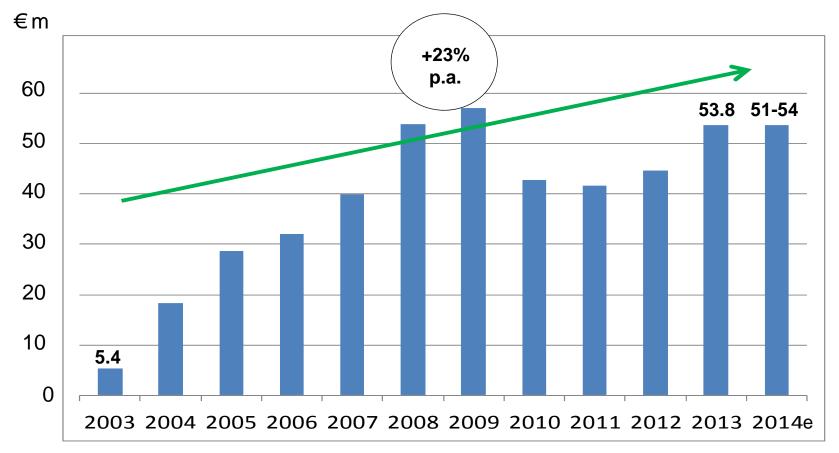
#### Biotest Group: Sales 2003–2014e (€million)\*





# **Impressive EBIT development**

#### Biotest Group: EBIT 2003–2014e (€million)\*



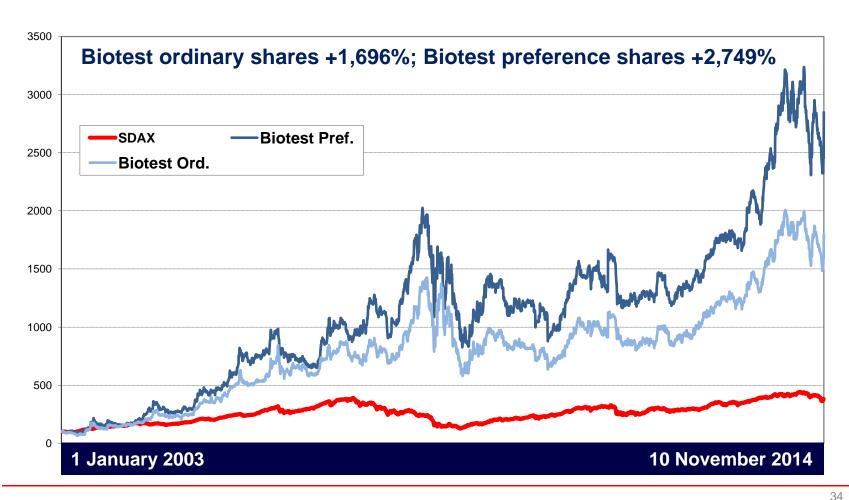
<sup>\*</sup> On a comparable basis, only pharmaceutical activities

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# Biotest stock greatly outperforms the benchmark

**Biotest share price performance** (closing price 1 January 2003 = 100)





#### Vision – our road to 2020



- Consistent focus on biological drugs for the therapeutic areas of haematology, immunology and intensive care medicine
- Continuous investment in the development of new therapeutic options
- Worldwide operations with a strong base in Europe and the US
- 2020 sales > € 1bn



#### **Contact and Financial Calendar 2015**

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#### **Financial Calendar 2015**

24 Mar 2015 FY Report 2014

07 May 2015 3M Report 2015

11 Aug 2015 6M Report 2015

10 Nov 2015 9M Report 2015