



## **Biotest Group**

Press and Analyst Conference FY 2013  
Frankfurt am Main, 25 March 2014

## 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: Highlights FY 2013



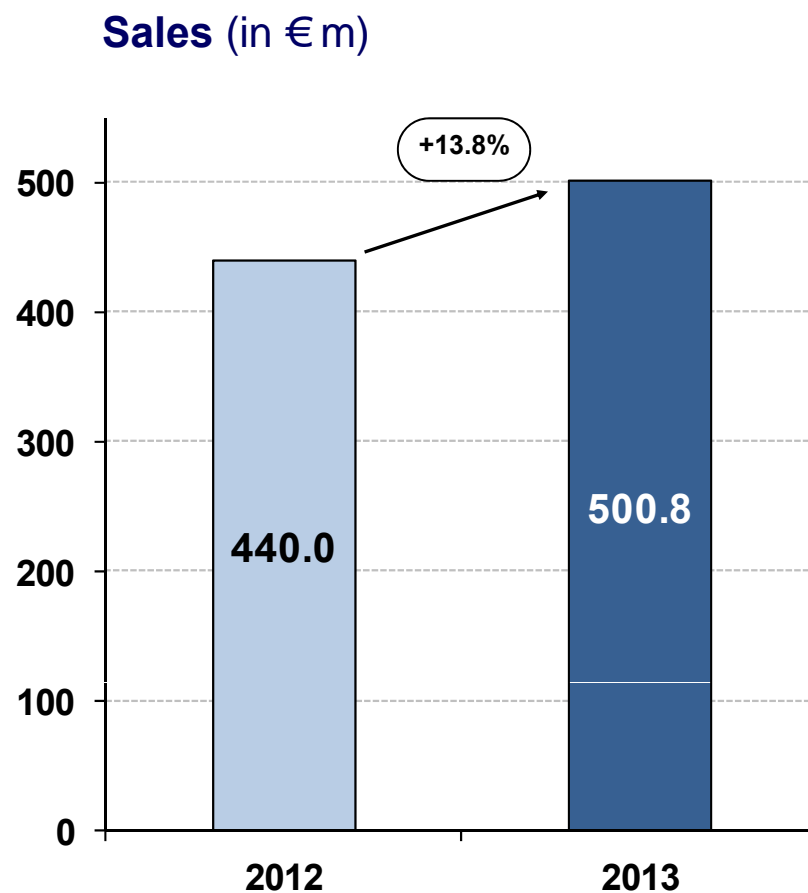
- FY 2013 group sales up by 13.8% to €500.8m  
Increase attributable to significant higher sales in the US and in Asia.
- FY 2013 EBIT increase by 20.4% to €53.8m
- Successful capital increase
- Successful placement of privately placed promissory note (Schuldschein) of €210m
- Start of "Biotest Next Level" – doubling of production capacities at headquarter in Dreieich



**Financials FY 2013**

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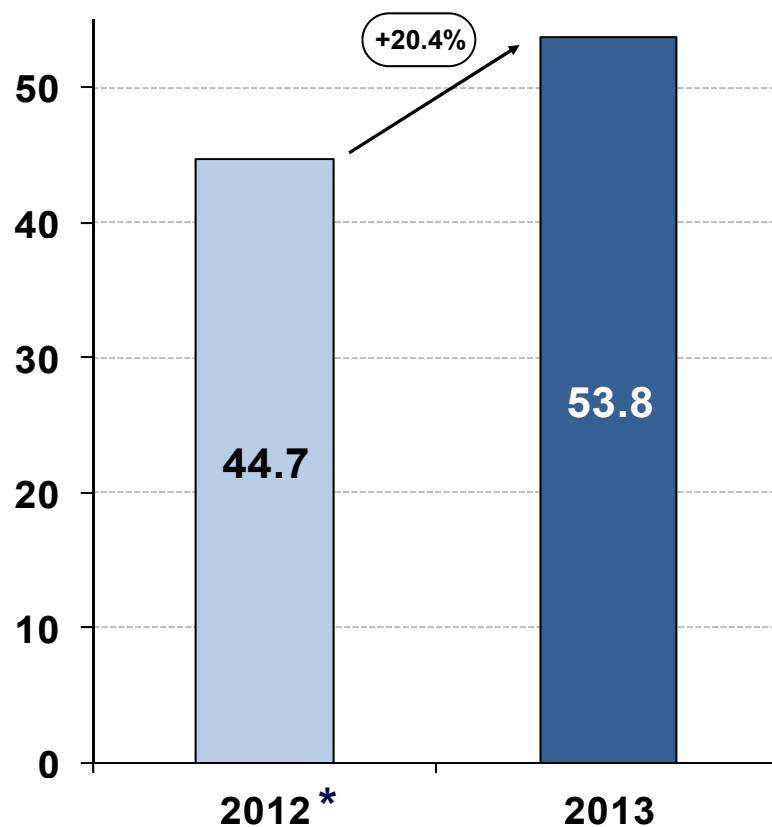
## Biotest with a significant sales growth



- FY 2013 sales at €500.8m, a growth of 13.8% vs. €440.0m in FY 2012
- Increase attributable to significant higher sales in the US and in Asia

## Biotest with a strong EBIT growth

EBIT (in € m)



- EBIT increase is largely due to higher sales in international markets
- Shift of products in markets with higher margin

\* Continuing Operations

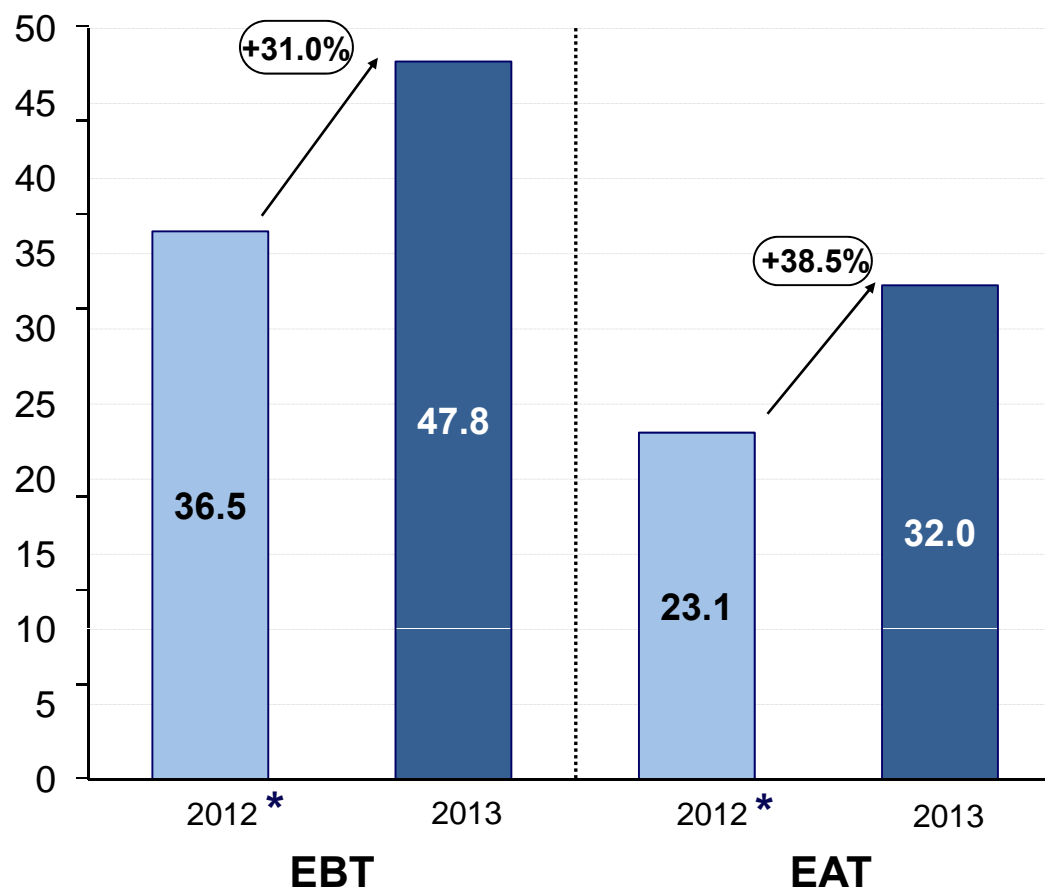
## FY 2013: EBIT Biotest Group (in € m)

	<b>FY 2013</b>	<b>FY 2012 *</b>	<b>Δ</b>
Therapy	32.1	26.3	+22.1 %
Plasma & Services	23.7	18.4	+28.8 %
Other Segments	-2.0	0.0	-
<b>Biotest Group</b>	<b>53.8</b>	<b>44.7</b>	<b>+ 20.4 %</b>

\* Continuing Operations

## Very strong increase in EBT and in EAT in 2013

**EBT and EAT (in € m)**



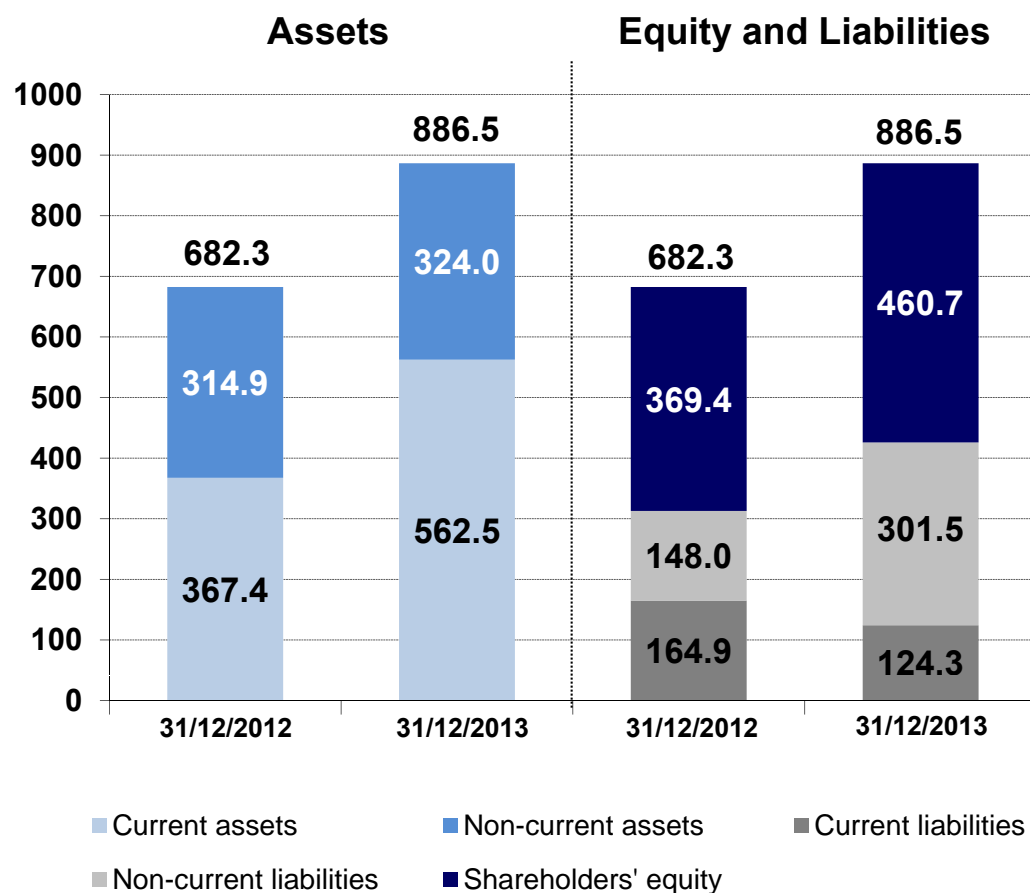
- Tax rate 33.1% in FY 2013 vs. 36.7% in FY 2012
- Tax rate back to normal level
- Financial result FY 2013 at -€ 7.0m vs. -€ 9.2m in 2012

\* Continuing Operations



# Strong balance sheet after restructuring of financing

Balance sheet of Biotest Group (in € m)



## Assets

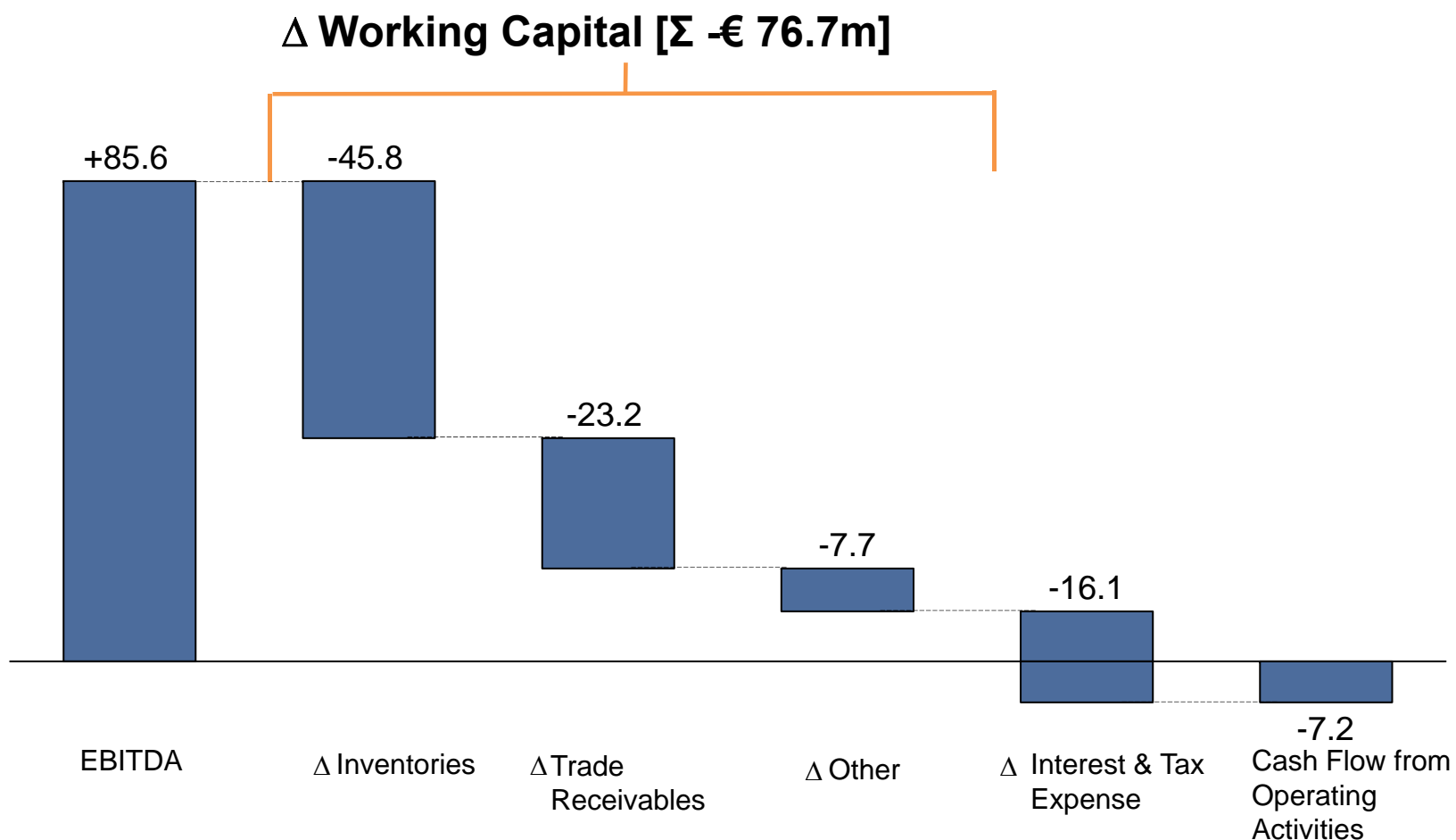
- Current assets: Cash increase of €147.2m
- Increase in inventories and receivables due to strong growth

## Equity and Liabilities

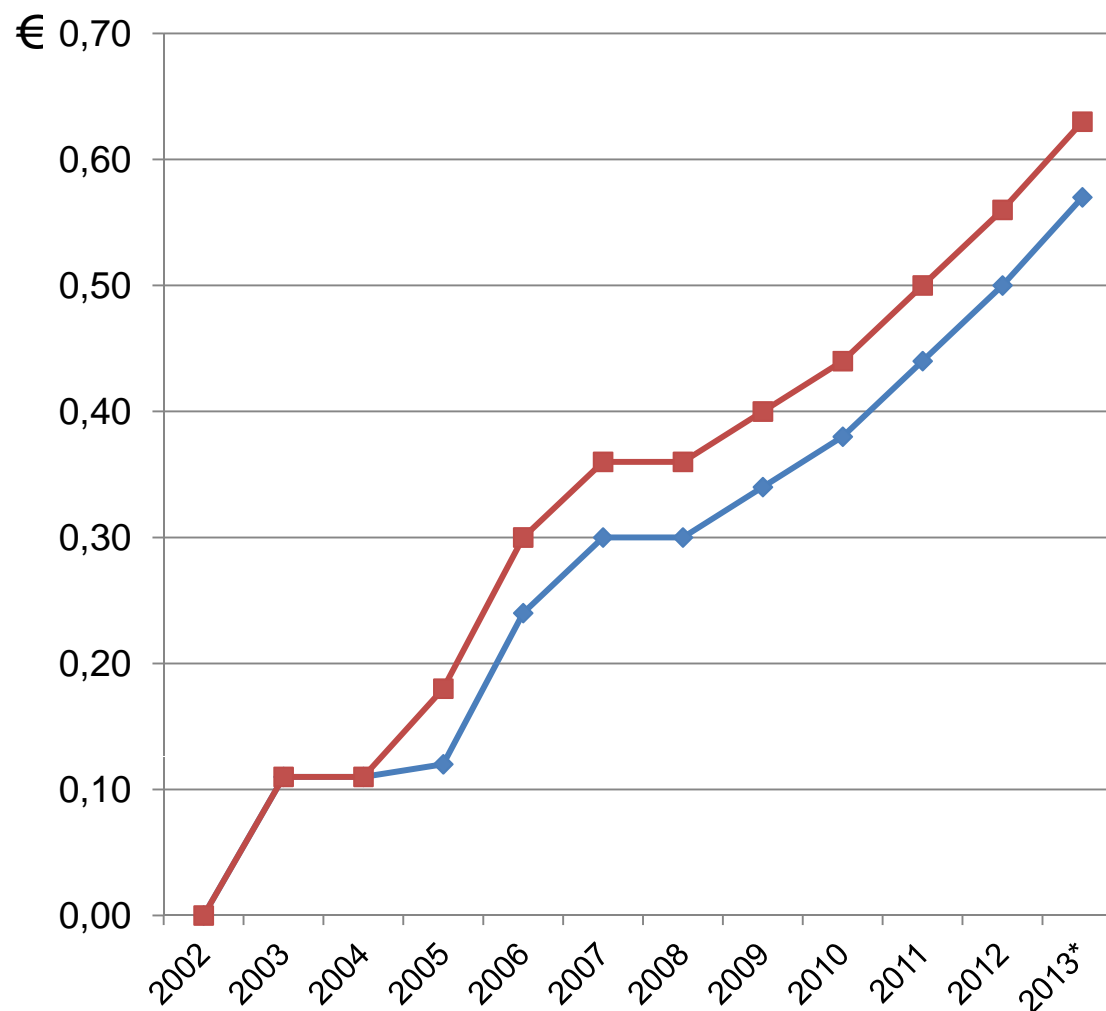
- Successful capital increase with gross proceeds as of €76.1m
- Successful placement of privately placed promissory note (Schuldschein) of €210m
- **Equity ratio** as of 31 Dec 2013: 52.0% (31 Dec 2012: 54.1%)

## Cash flow from operating activities

January – December 2013 (in € m)



## Development of dividend per share in €



◆ Ordinary share

■ Preference share

- Dividends for 2013\*:
  - €0.57 per ordinary share
  - €0.63 per preference share
- 5th consecutive dividend increase
- Total dividend payout:
  - 2003: € 0.0m
  - 2013: € 7.9m

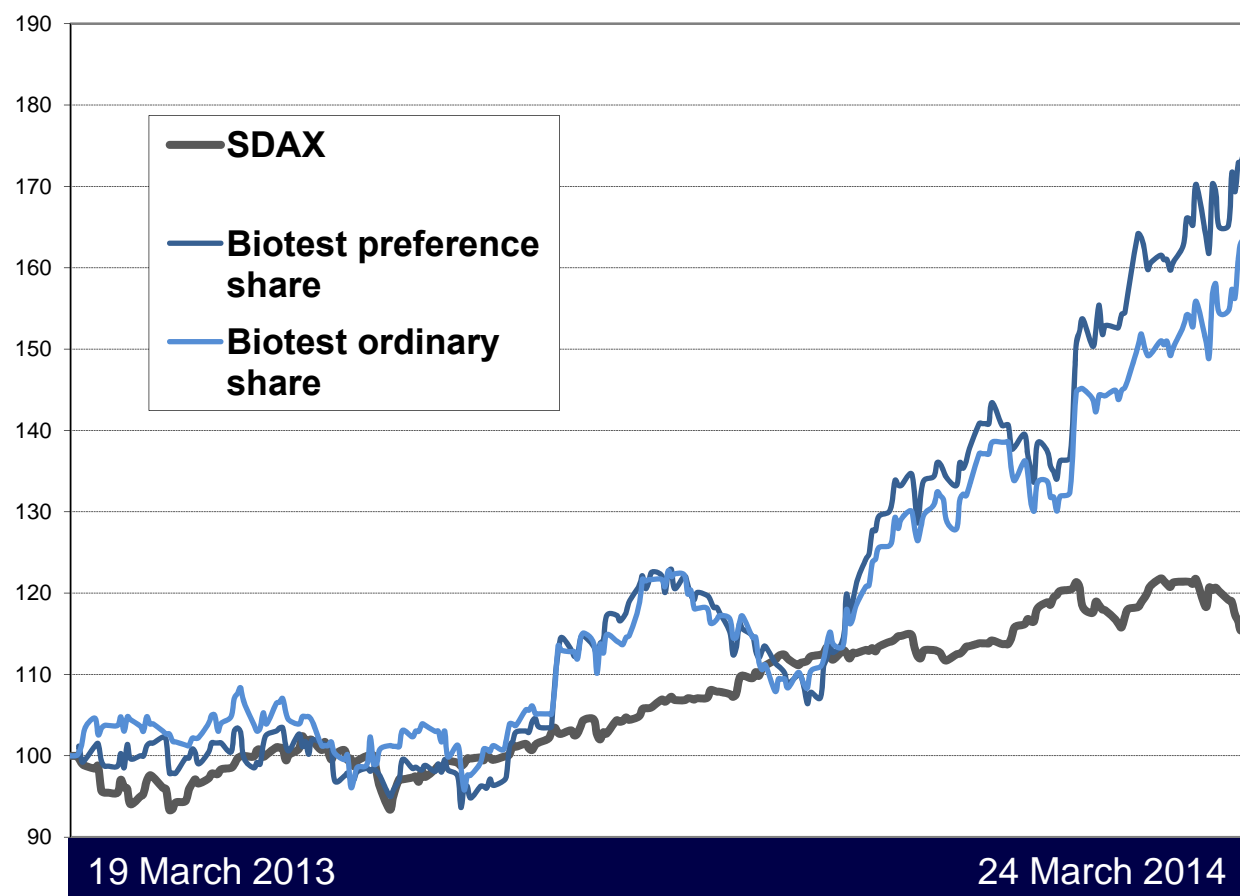
### EPS 2013

- Ord. share: € 2.54
- Pref. share: € 2.60

\* Proposal to Annual General Meeting on 7 May, 2014 in Frankfurt

## Biotest stock: attractive development

### Biotest AG share price performance vs. SDAX



Closing price on 19<sup>th</sup> of March 2013 = 100

Coverage of Biotest	Target price [€]
Commerzbank	u.r.*
Solventis	u.r.*
equinet	82.5
HSBC	83.0
Hauck & Aufhäuser	109.0
Main First	146.0

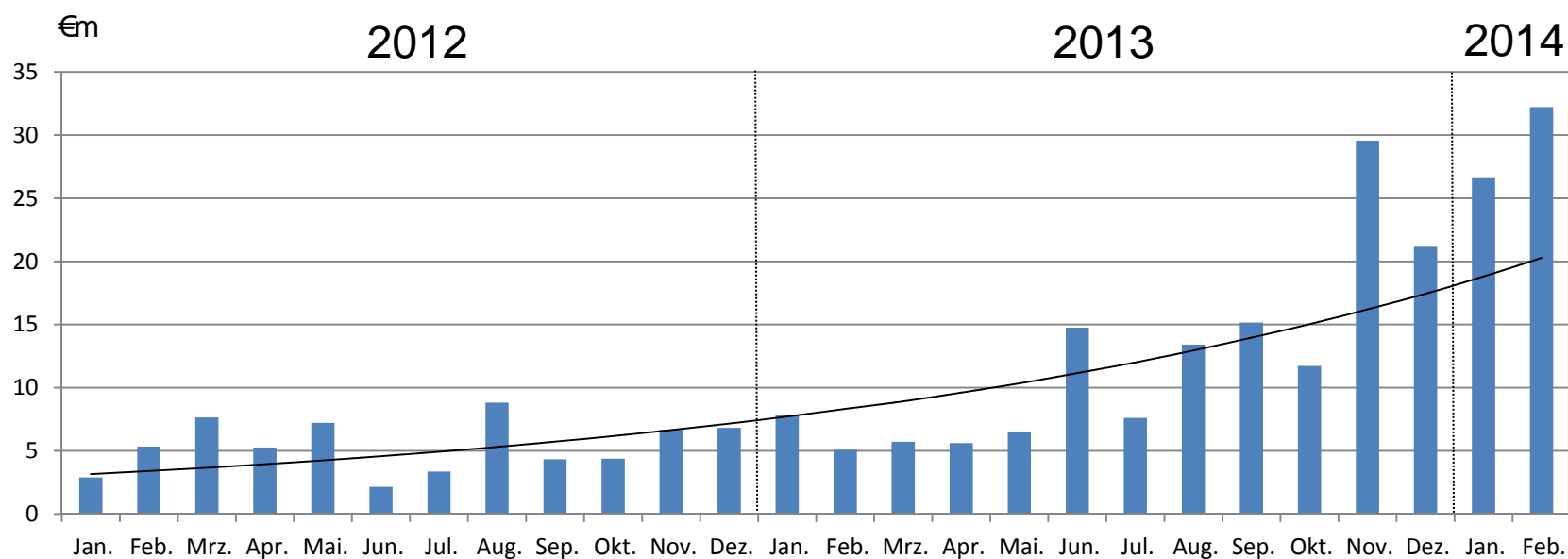
- Shareholder return<sup>\*\*</sup>:  
82% (ordinary shares)  
66% (preference shares)

\* under review

\*\* Performance 03/2013 – 03/2014 plus dividend for 2012 (as of 08 May 2013)

## Biotest stock: attractive target for large investment funds

### Monthly preference share turnover [Xetra in € m]



- Increased liquidity due to capital increase
- International investors (Allianz Global Investors, Flossbach von Storch, JO Hambro, BNP, Jupiter, Fidelity, Candriam Belgium, Fisher Funds, Danske Bank, UBS)
- Biotest has become an interesting target for larger, international funds

## Guidance 2014



**Sales:** In the financial year 2014 sales will grow in a range of 10%

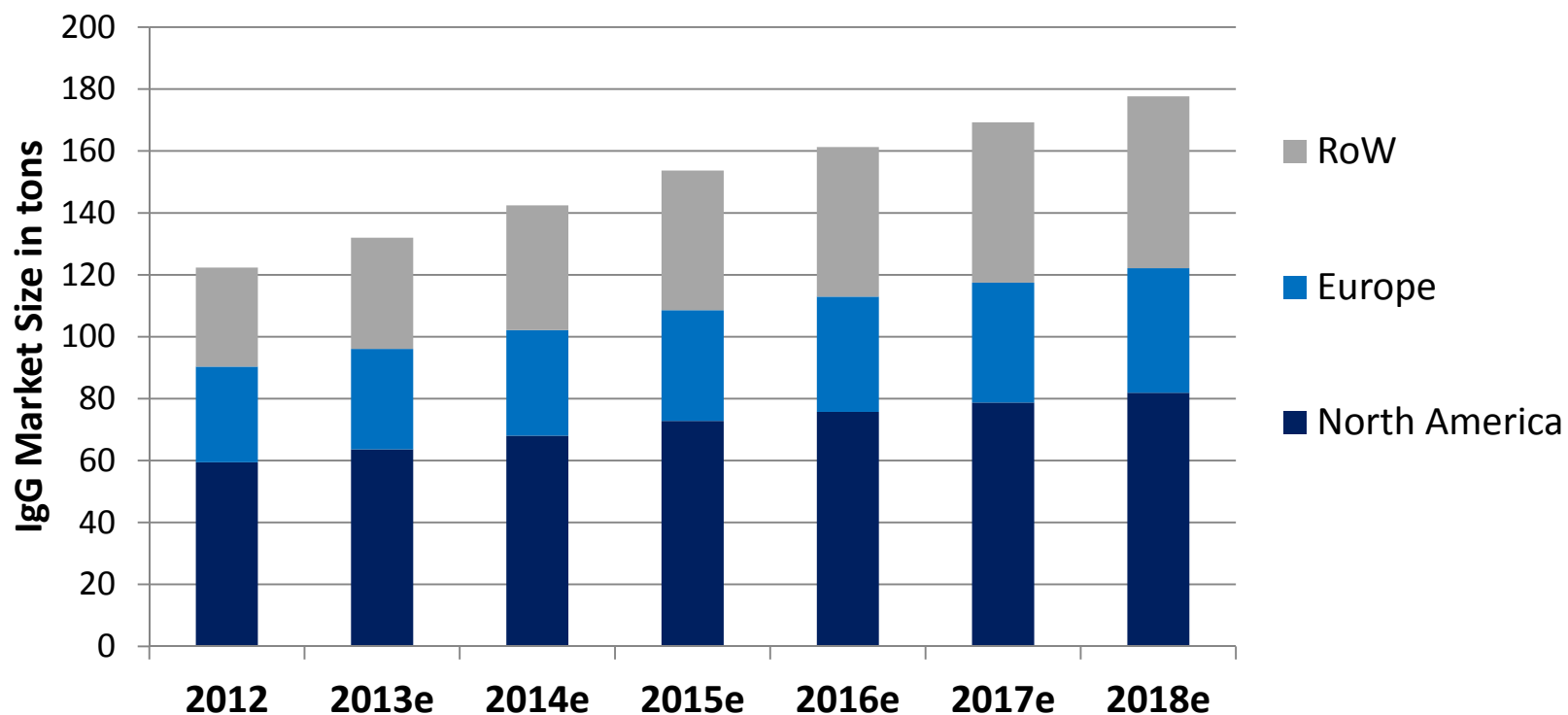
**EBIT:** We expect an EBIT increase of approximately 10%



## **Extension of international business**

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## Immunoglobulin (IgG) market development

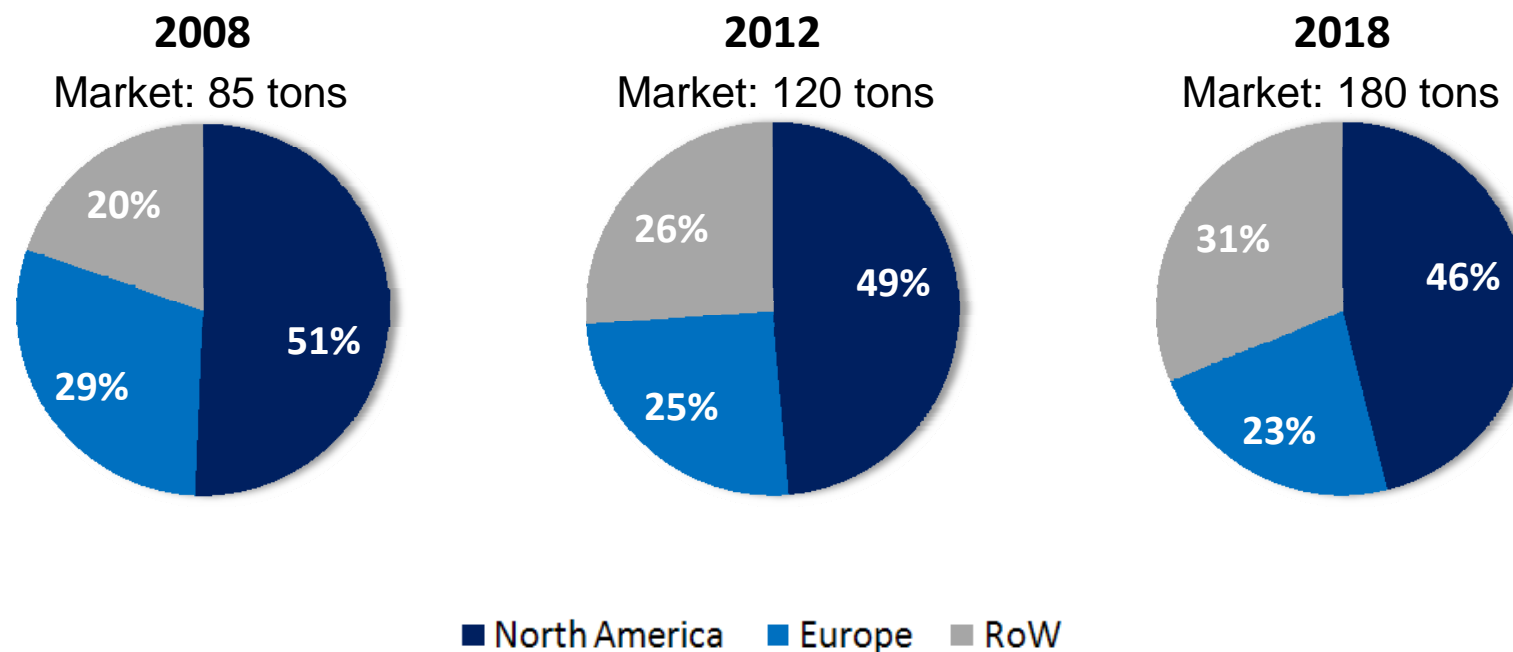


- The global IgG market is expected to grow to ~180 tons by 2018.

Sources: Biotest Market Research based on MRB (2013)



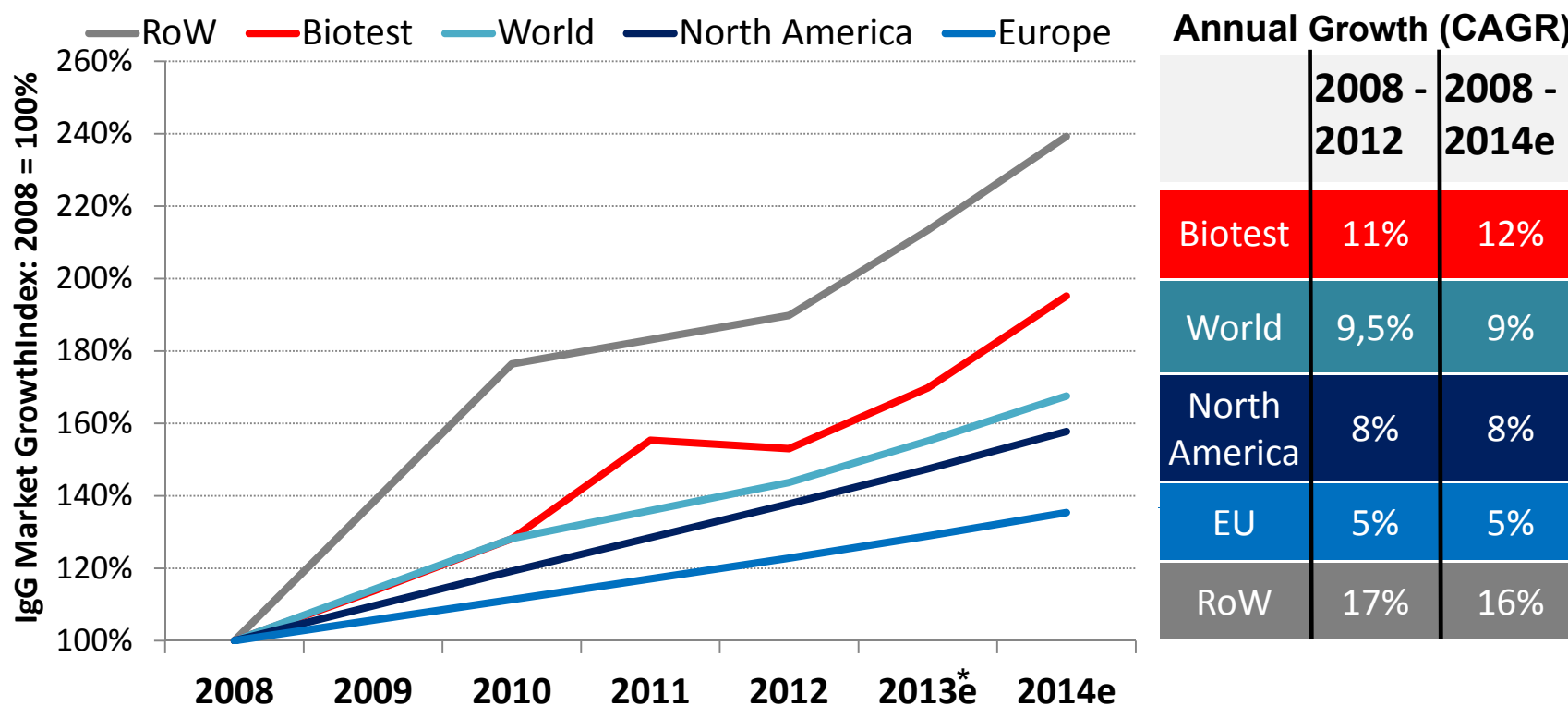
## Global Immunoglobulin market: geographic split



- The global IgG market is expected to grow to ~180 tons by 2018.
- The market share of RoW countries is expected to increase to 31%.

Sources: Biotest Market Research based on MRB (2013), Morgan Stanley Research (October 29, 2013), UBS Investment Research (March 29, 2013)

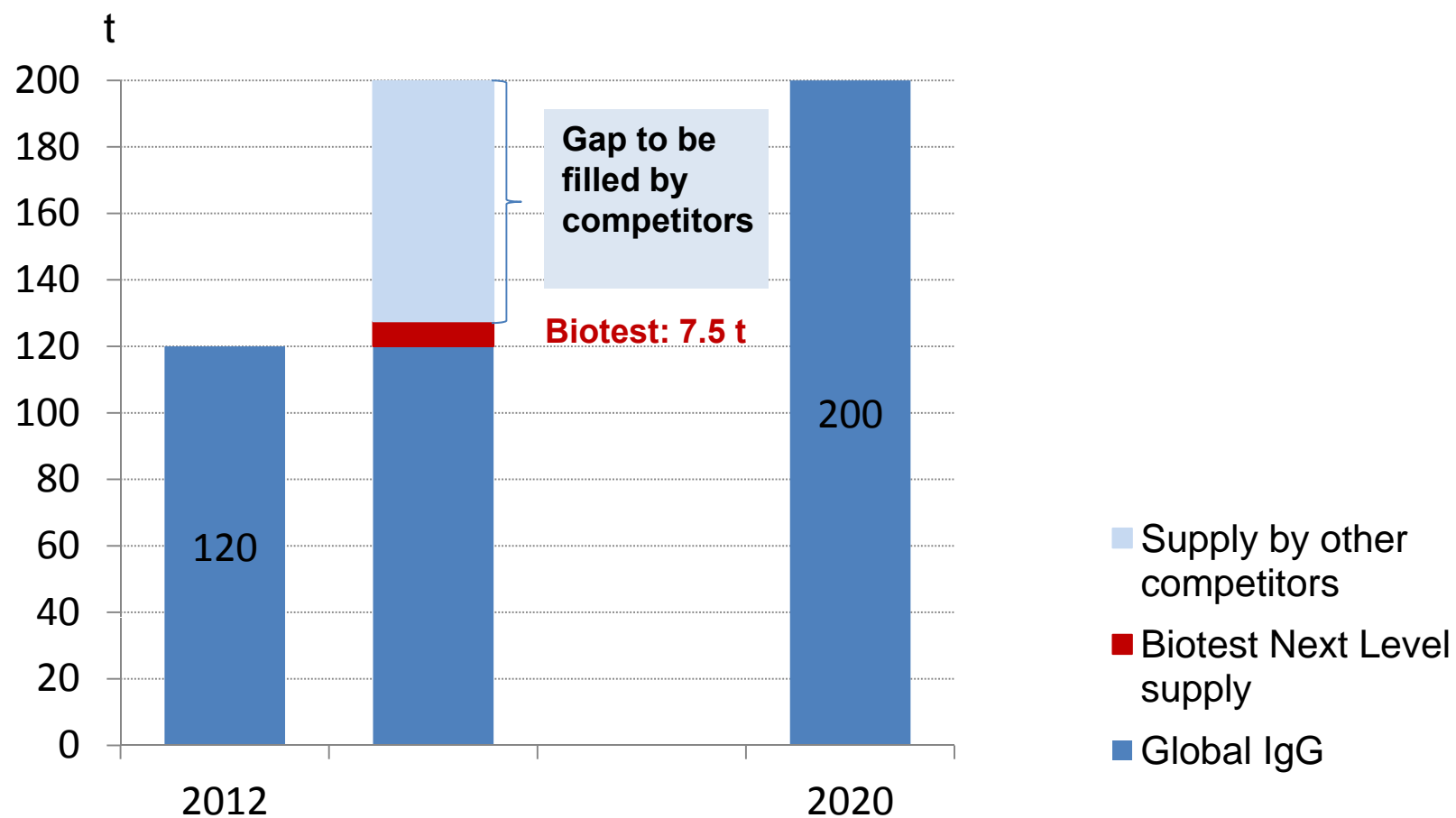
## Growth rates of Immunoglobulin markets



- With an annual growth rate of 11% between 2008 and 2012, Biotest grew faster than the IgG world market.

\* 2013 includes actual Biotest sales. All other markets were forecasted based on the 2012 figures. Sources: Biotest Market Research based on MRB (2013), Morgan Stanley Research (October 29, 2013), UBS Investment Research (March 29, 2013).

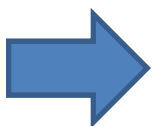
## No oversupply in Immunoglobulins expected



## BPC: Bivigam<sup>®</sup> in the US

### BPC (Biotest Pharmaceuticals Corp.):

- BPC has received marketing authorization of Bivigam<sup>®</sup> end of 2012
- Successful launch of Bivigam<sup>®</sup> in the US in February 2013
- Bivigam<sup>®</sup> is well accepted in the market
- Recall of two batches of Bivigam<sup>®</sup> in the US in February 2014 due to quality issues with a few glass vials
- Cost of recall for testing and re-labeling is included in 2013 result
- This has resulted in delay of delivery to distributors and customers in 1<sup>st</sup> quarter 2014
- Sales estimate for Bivigam<sup>®</sup> in US for 2014: approx. \$ 60m



**Sales potential Bivigam<sup>®</sup> from 2015 onwards of \$ 100m**

## China: moving into a growth market



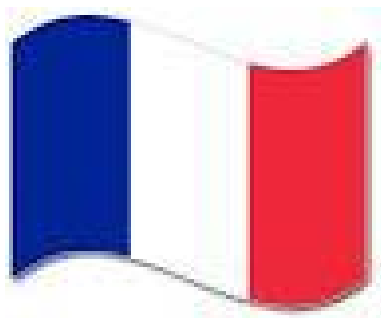
- China is world's third-largest pharmaceutical market
- Double-digit growth rates
- Albumin market in China (2012): 205 t  
Import into China 50%  
average selling price: \$ 4.6/g
- Distribution partnership with leading Chinese pharmaceutical company Wanbang (belongs to Fosun Pharma Group)
- Regulatory approval for Albiomin 20% expected in Q3 2014
- First sales of Albiomin expected end of 2014

## Brazil: approval of Biotest products



- Approval of Albiomin 20% in Brazil in November 2013
- Further Biotest products under regulatory evaluation (Zutectra<sup>®</sup>, Fovepta<sup>®</sup>, Intratect<sup>®</sup> and Pentaglobin<sup>®</sup>)
- Brazil is the largest market in South America for plasma proteins and has a strong growth potential

## France: new subsidiary established



- New subsidiary founded in France
- First sales in France
- Approval of Zutectra<sup>®</sup>
- Transfer of regulatory approval from former distributor for Tectasim (similar to Intratect) soon

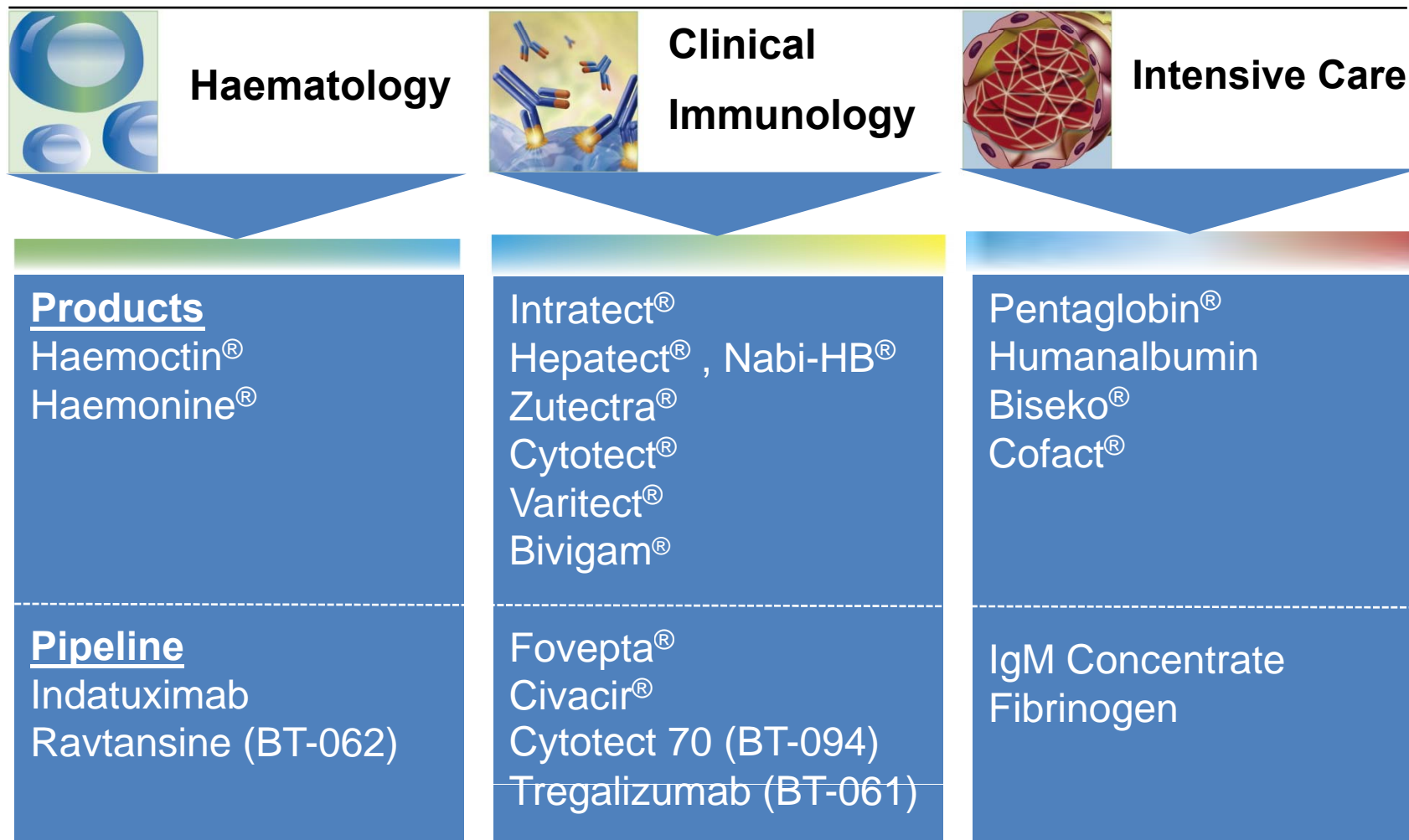


**Important projects**

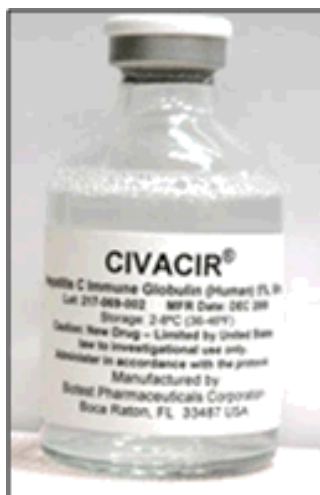
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## Three strategic areas of therapy: Products - Pipeline

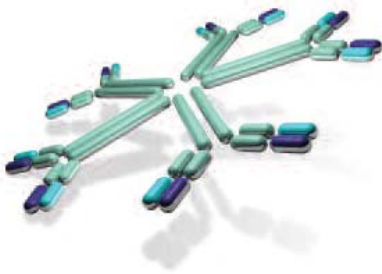


## Civacir® – Immunoglobulin with high potential



- Hepatitis C immunoglobulin for reinfection prophylaxis after liver transplantation
- "Orphan drug designation" in Europe and US:  
10- and 7-year exclusivity after authorisation (respectively)
- Very high medical demand:
  - Currently no reliable prophylaxis for the critical period immediately after transplantation is available
  - prevention of re-infection within first two month; in this time frame no virostatics can be used due to toxicity in combination with immunosuppressive therapy
  - In the EU and US alone, more than 5,000 liver transplants due to hepatitis C each year  
>> this corresponds to a market potential > € 200 m
- Clinical trial phase III in USA ongoing: inclusion of up to 91 patients planned in phase III trial in US; first patients successfully completed the study protocol
  - Scientific advice meetings with European Regulatory Authorities planned for Q2 2014

## IgM Concentrate: development on target



- IgM Concentrate for effective treatment of sepsis (severe bacterial infection)
- Unique mechanism of action
- Interim analysis of ongoing phase II trial: continuation of development clearly recommended\*
- Currently more than 100 patients have been included
- Study sites:
  - Germany: 16 active
  - Spain: 12 active
  - UK: planned 6
  - Belgium: 1 active

\*Recommendation by unblinded biostatistician

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## **Fibrinogen – start of clinical development**

- Severe bleeding is often associated with Fibrinogen deficiency
- Goal will be to enter the market with a "ready to use" formulation
- Phase I/II Study in patients with congenital Fibrinogen deficiency started Q1 2013
- First patients treated in Phase I/II study
- Sales potential: about € 100m/year

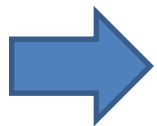
## Tregalizumab (BT-061)

**TREAT 2b**  
T cell REgulating Arthritis Trial 2b  
(TREAT 2b)

- Lead indications: Rheumatoid Arthritis (RA) and Psoriasis
- 6 months treatment with open label extension, prospective, placebo-controlled trial

### Regulatory issues of study

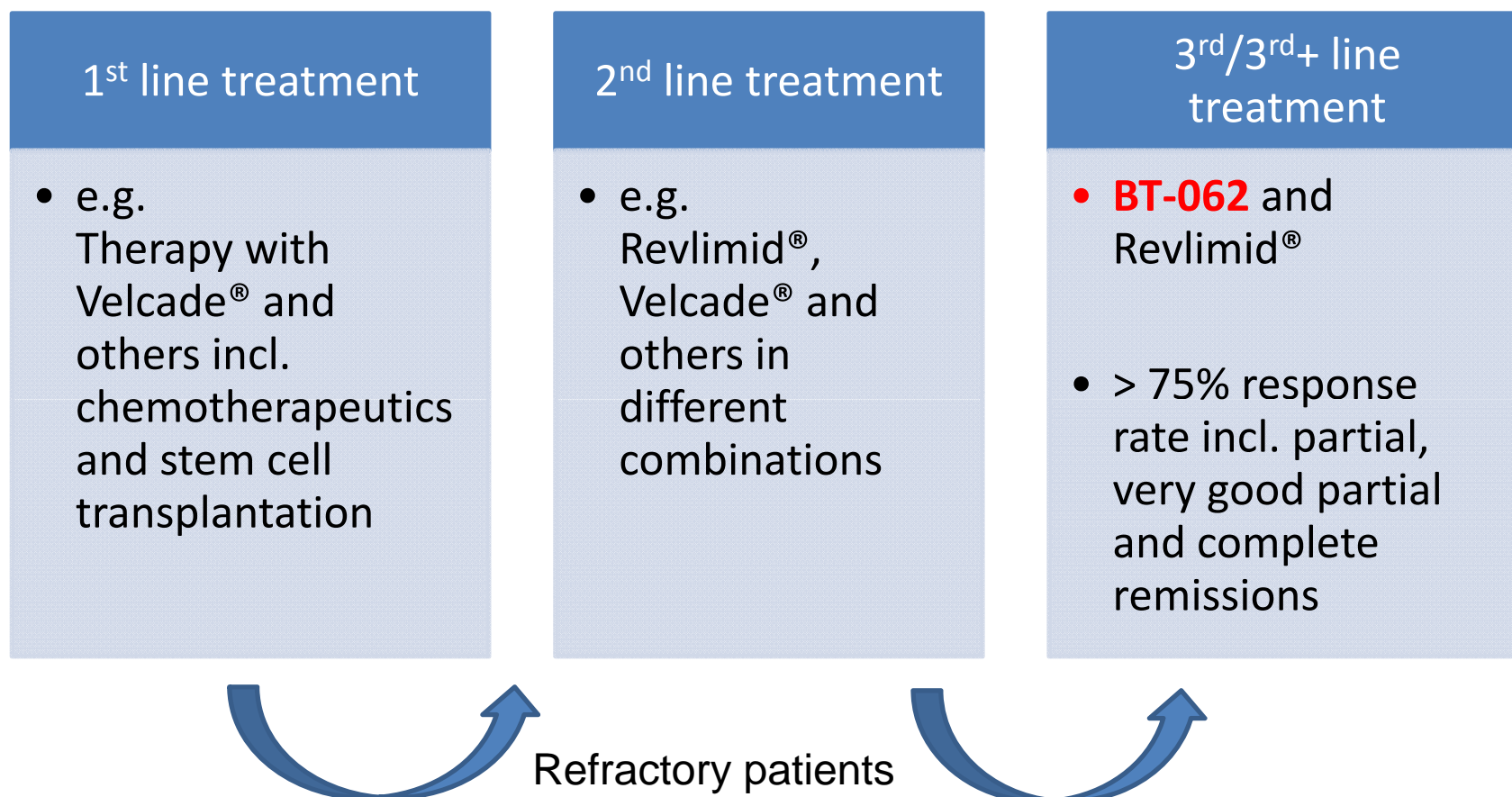
- *Full* approval in 13 countries (incl. US and Canada)
- more than 70 sites initiated and activated
- More than 300 patients have been screened so far
- More than 25% of total patient number (n=304) have been included in the study



**First results and data expected in H1 2015**

# Indatuximab Ravtansine (BT-062) in Multiple Myeloma

## Lines of treatment



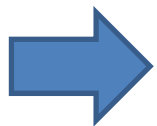
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## **Indatuximab Ravtansine (BT-062)**

### **Combination study 983: BT062 + Lenalidomide + Dexamethasone**

#### **Multiple Myeloma**

- Phase I /II ongoing
- BT-062 well tolerated in this combination regimen
- Patients were heavily pretreated; about 90% of patients had prior Lenalidomide exposure
- 100% of patients showed a clinical improvement; in more than 75% of evaluated patients complete, very good partial response or partial response have been observed
- Responses were even achieved in patients refractory to prior Lenalidomide and Dexamethasone therapy



**Study to be completed in H1 2015**

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## **Indatuximab Ravtansine (BT-062): solid tumor study 989**

### **Main study criteria**

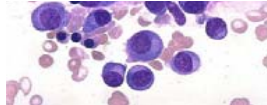


- Indications:** Triple negative breast cancer and advanced bladder cancer
- Objectives:** To evaluate pharmacokinetic, safety and anti-tumor activity of BT-062 in selected solid tumor indications
- Design:** Open-label, dose escalation, phase I/IIa study with repeated multiple doses of BT-062 (3 weekly doses in a 4 week cycle)
- Phase I:  
Dose escalation from 100 mg/m<sup>2</sup> up to maximum tolerated dose
  - Phase IIa:  
Treatment of 18 patients in each indication at selected dose level. In case of outstanding efficacy treatment of further 15 patients.
- Number of patients:** 40 to 80 patients depending on safety and efficacy obtained
- Country:** 15 sites in Germany (10) and Belgium (5)
- Regulatory status:** First patients screened: March 2014



## BT-062 – market potential worldwide markets

BT-062 is developed in indications with high unmet medical need.

Initial labels for BT-062

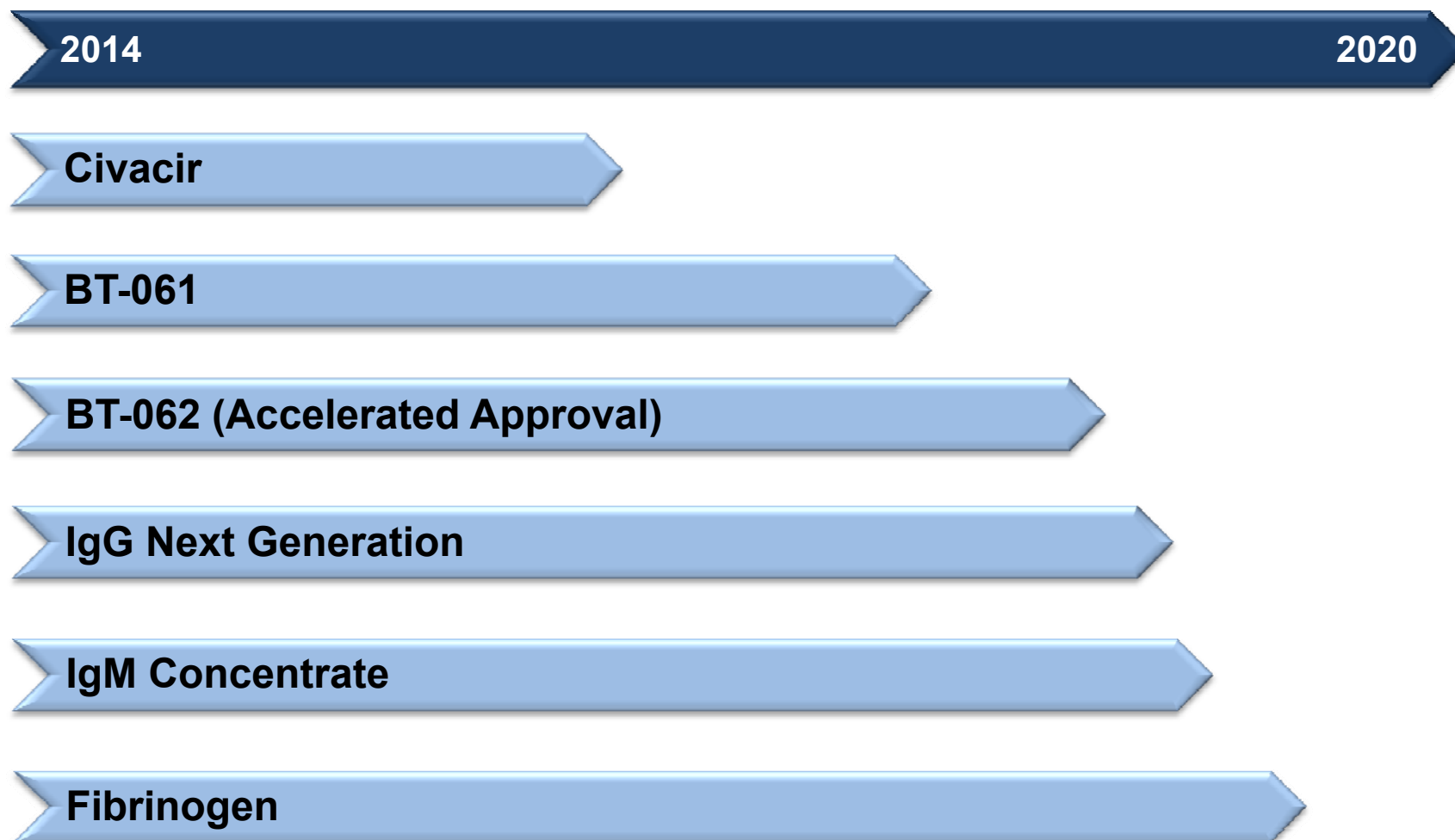
	Eligible Patients*	Market potential (Peak Net Sales)
<b>Multiple Myeloma (relapsed and refractory)</b> 	~80,000	~ € 950m
<b>Triple Negative Breast Cancer (metastatic setting, 2<sup>nd</sup>/1<sup>st</sup> line)</b> 	~50,000	~ € 300m
<b>Invasive Bladder Cancer (metastatic setting, 2<sup>nd</sup>/1<sup>st</sup> line)</b> 	~90,000	~ € 750m

Over a period of the next 10 years, high costs for clinical development and market introduction

→ Collaboration with strategic partner essential for raising full potential of BT-062

\* Number of patients who become eligible for drug treatment at particular stage - source: Decision Resources 2013 for 7 major markets and Biotest estimates

## New products at the horizon



## **New Biotest investments in Dreieich until 2018**



## Biotest investments in further growth

Expansion of global capacity to:

**Plasma fractionation:**

**3 million litres/year**

currently: 1.5 m litres/year

**Immunoglobulins:**

**13 t/year**

currently: 5.5 t/year

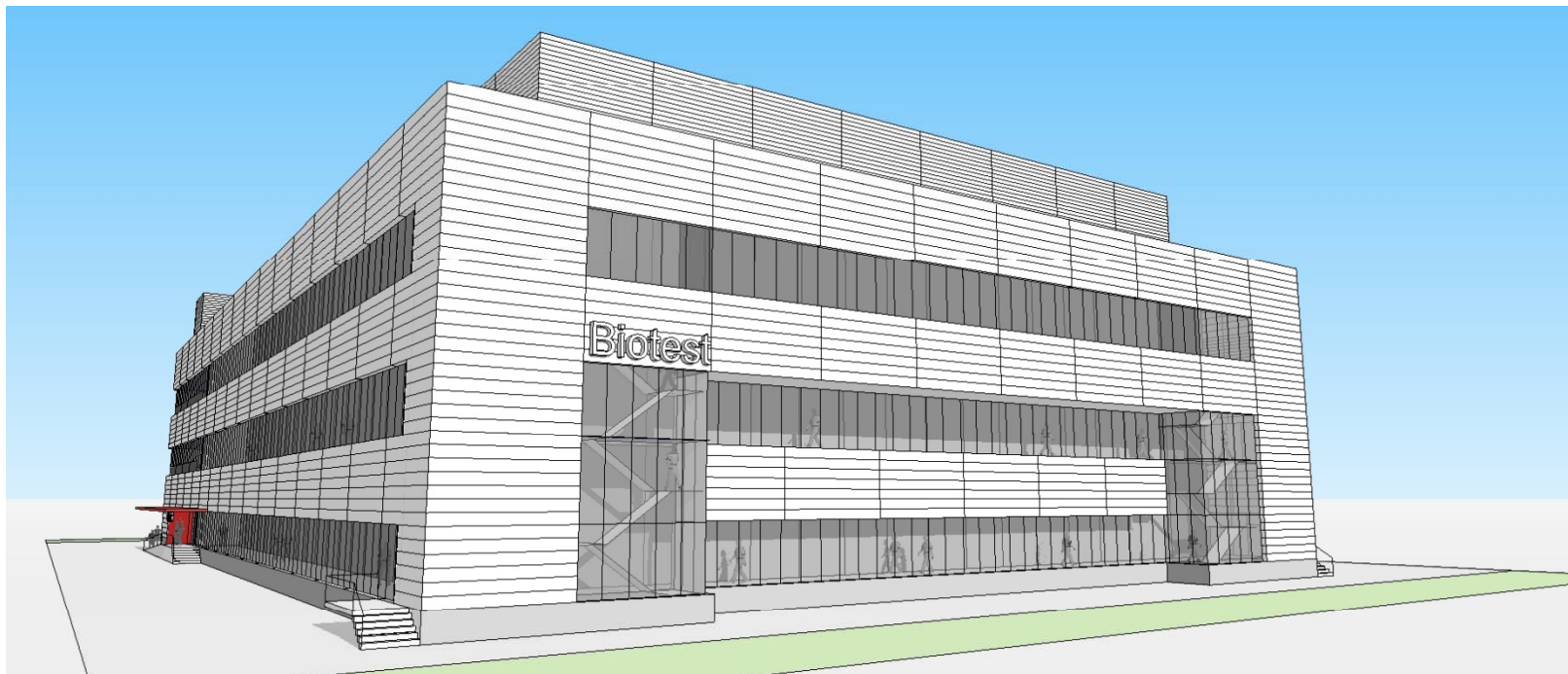
**Albumin:**

**75 t/year**

currently: 42 t/year

- Capacity expansion programme in Dreieich
- Construction of new production plants at head quarter in Dreieich
- Duration: 2013 to 2018
- Investment: €200 - 250m
- More than 300 additional jobs

## First layout impression: production building



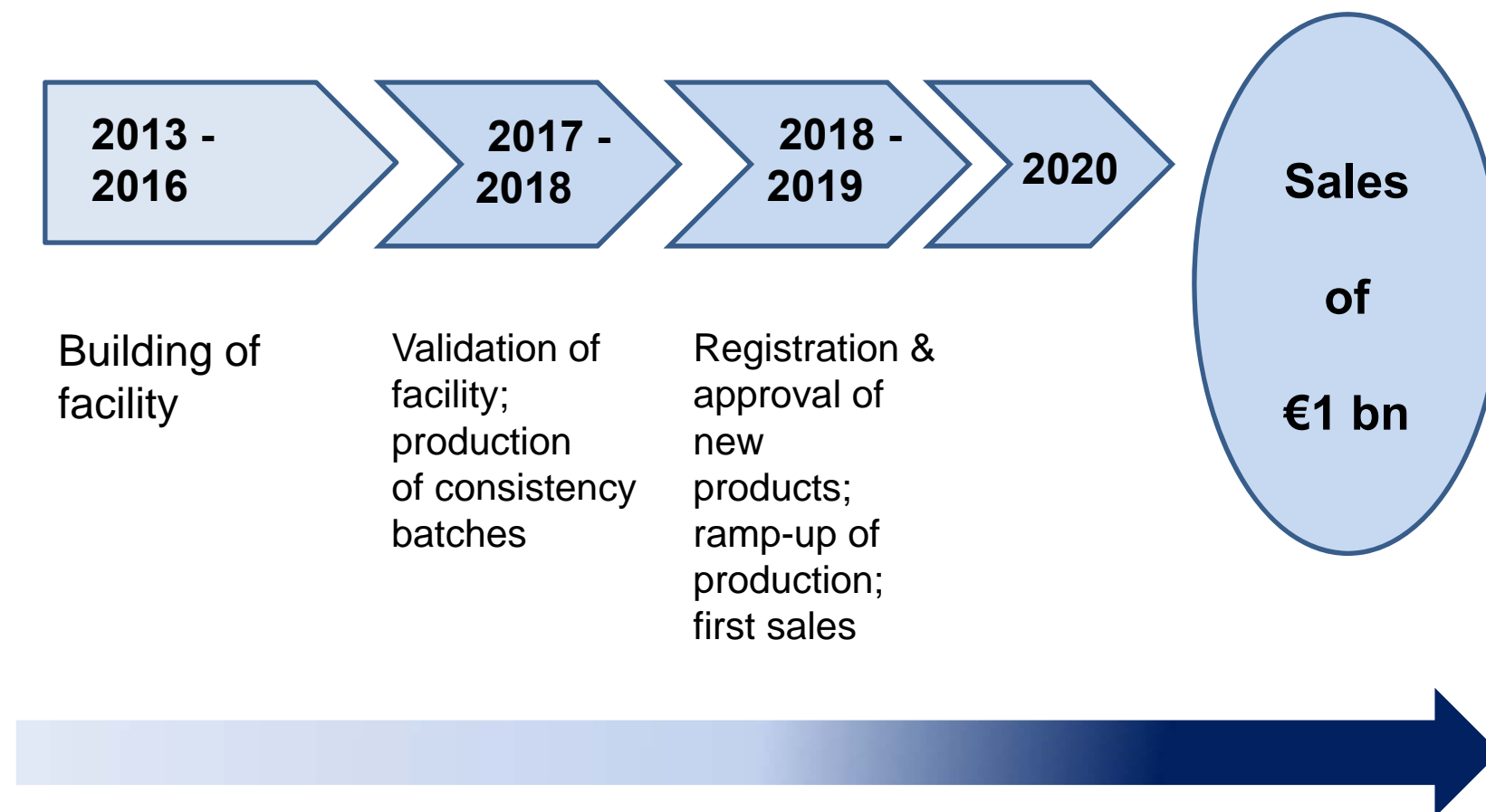


## Current activities: parking structure

Park deck will be finalised in April 2014 to ensure availability of property needed for production area.



## Timeline



## Contact and Financial Calendar 2014

### Investor Relations Biotest AG:

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Head of Investor Relations

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E-Mail: [investor\\_relations@biotest.de](mailto:investor_relations@biotest.de)

### Financial Calendar 2014

<b>7 May 2014</b>	<b>Annual General Meeting</b>
	<b>Q1 Report 2014</b>
<b>12 Aug 2014</b>	<b>Q2 Report 2014</b>
<b>12 Nov 2014</b>	<b>Q3 Report 2014</b>