

## **Biotest Group: Creating Value. Living Values**



**Analyst Conference – Q1-Q3 2010**  
**Frankfurt/Main, November 8, 2010**

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## 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. These activities are being reported as Discontinued Operations. With the exception of the statement of financial position, the previous year's figures have been adjusted accordingly.

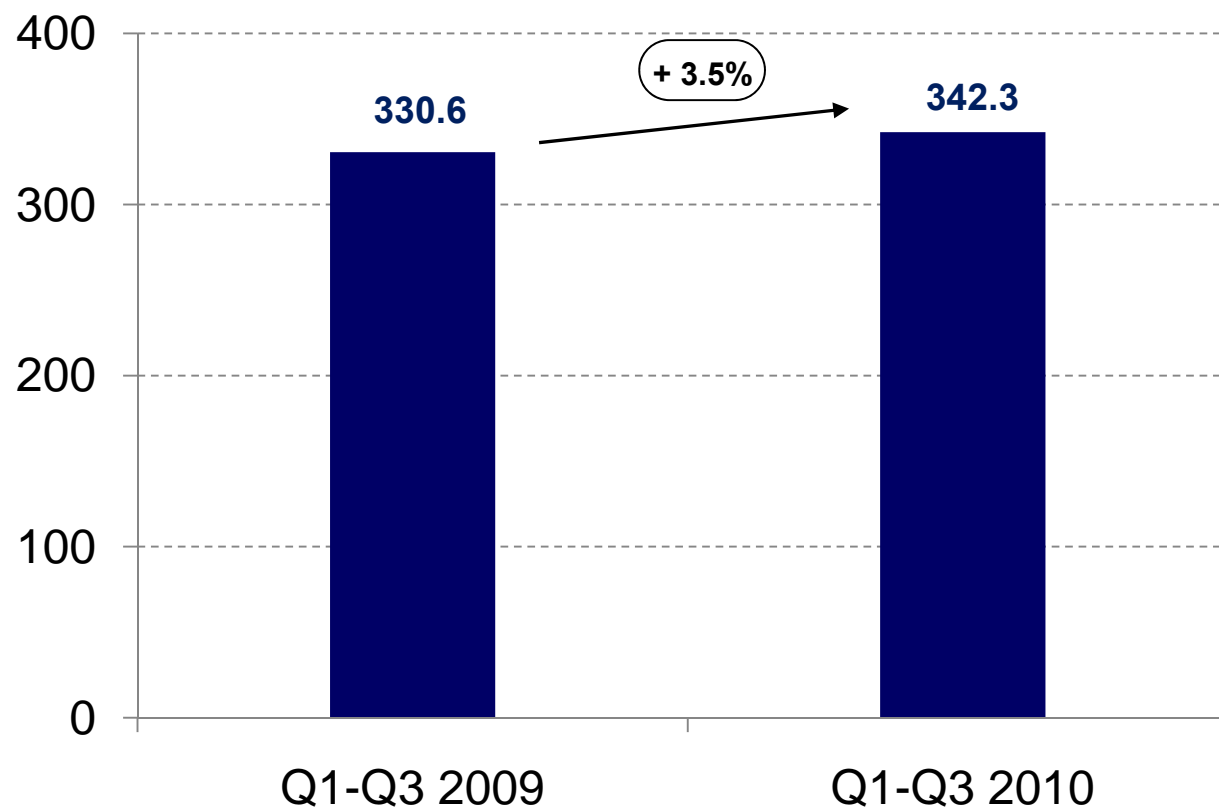
All comparative figures relate to the corresponding last year's period, unless stated otherwise.



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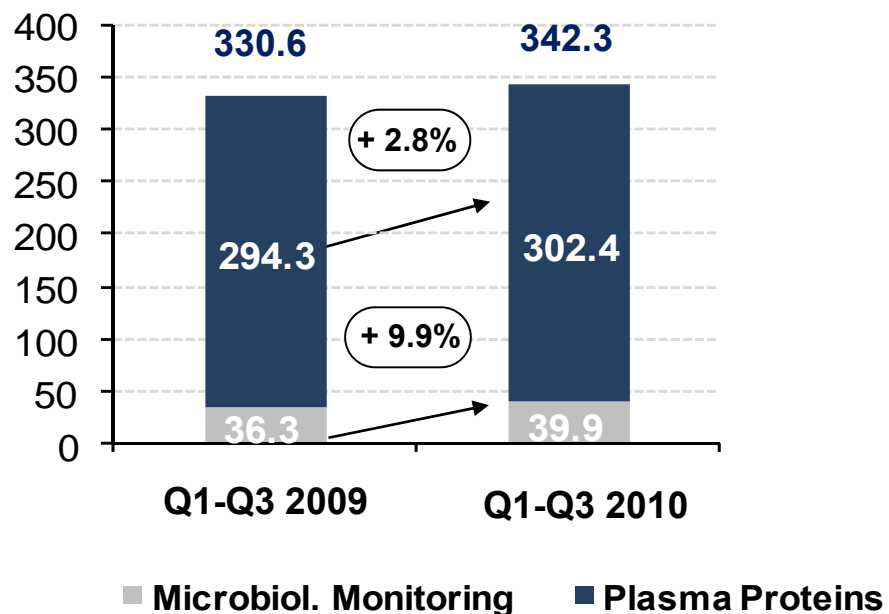
## **Financials Q1-Q3 2010**

## Biotest Group: small sales growth (€ m)



## Small sales growth despite difficult environment

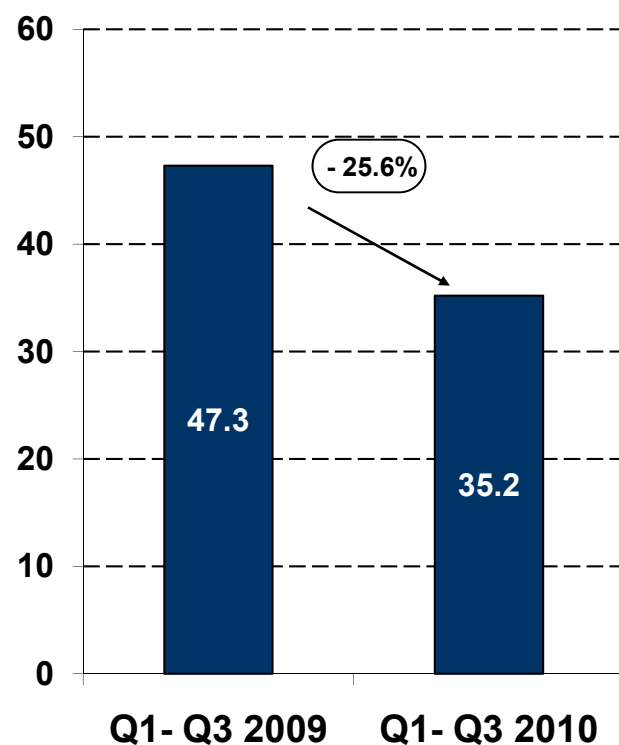
### Sales of Plasma Proteins & Microbiological Monitoring (€ m)



- Sales in Q1 – Q3 of 2010 were up by 3.5% to €342.3 m vs. Q1 – Q3 2009
- Plasma Proteins  
Volume: + €15.8 m  
Price: - €7.7 m

## Despite sales growth, EBIT decreased

### EBIT (in € m)



- Despite 3.5% sales growth, EBIT almost 26% lower than 2009
- Continuing price pressure for immunoglobulins and clotting factors
- Increase in volume could not compensate negative price effect
- Unfavorable product mix: more products sold with less attractive margins: plasma, clotting factors
- Positive, but non recurring: € 2.7 m insurance payment for BPC
- R&D expenses € 6 m higher than in 2009:  
Plasma Proteins: + € 2.8 m  
Biotherapeutics: + € 3.2 m

## Q1 – Q3 2010: EBIT Biotest Group (€ m)

	Q1 – Q3 2009	Q1 – Q3 2010	Δ
Plasma Proteins	63.7	53.6	- 16 %
Biotherapeutics	- 13.2	- 16.3	- 23 %
Microbiology	3.9	4.9	+ 26 %
Corporate	- 7.1	- 7.0	+ 2 %
<b>Biotest Group</b>	<b>47.3</b>	<b>35.2</b>	<b>- 26 %</b>

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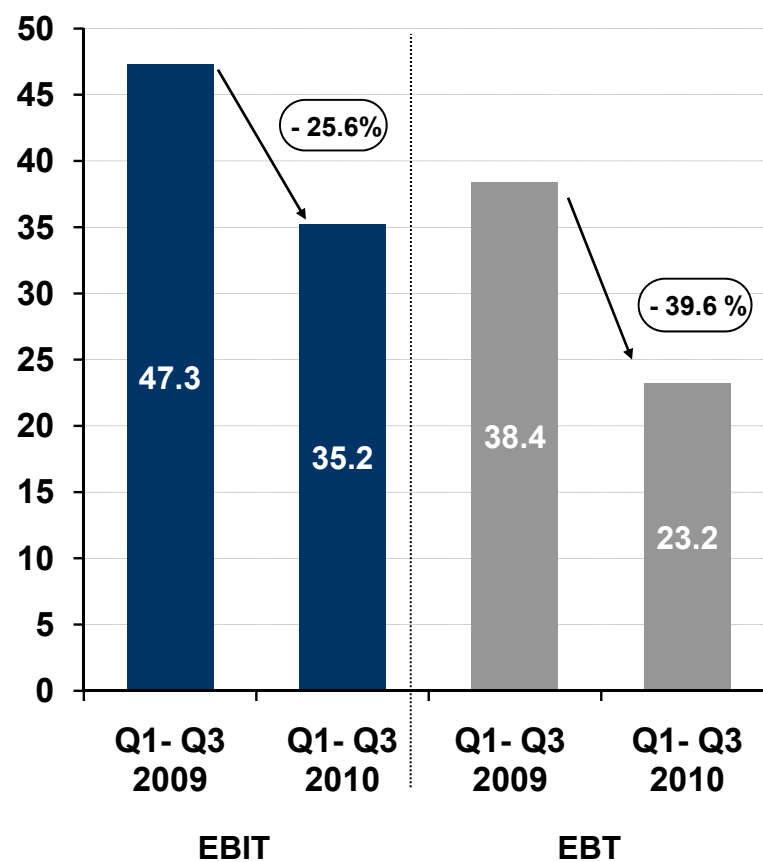
## Situation Greece

- The Greek parliament passed a bill to pay the outstanding accounts receivables of the pharmaceutical industry with zero-coupon bonds with a maturity of up to three years
- Biotest decided to participate in the program with an amount of € 24.7 m
- In September Biotest agreed with each hospital individually to accept the payment with bonds by exchanging the trade receivables towards the hospitals into claims against the state
- Since the bonds will carry no interest, Biotest discounted the nominal value with comparable interest rates. Financial result: - € 4.8 m
- Consequence: substantially lower EBT (€ 23.2 m vs. € 38.4 m last year) and EAT (€15.4 m vs. € 26.9 m last year)
- This loss is a one time effect in Q3 2010 and will be reversed until the bonds mature (1-3 years)



## Sharp decrease in EBIT and EBT (earnings before tax) in Q1-Q3 2010

EBIT and EBT (in € m)

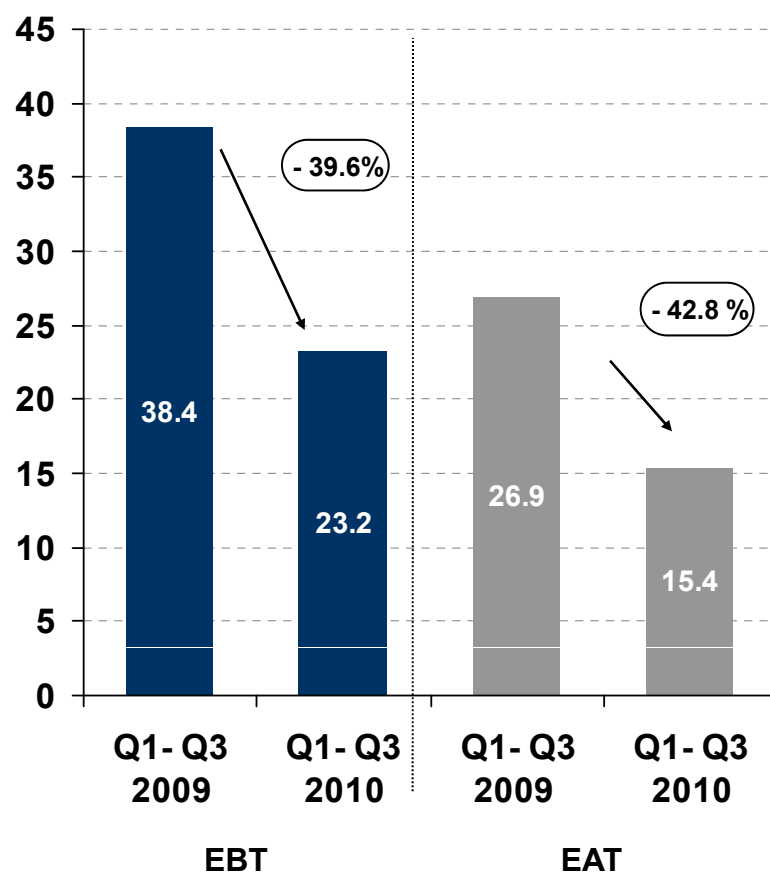


### Financial result:

<b>Q1-Q3 2009:</b>	<b>- € 8.9 m</b>
Discount on Greek zero coupon bond	- € 4.8 m
Lower interest expenses	+ € 1.7 m
<b>Q1-Q3 2010:</b>	<b>- € 12.0 m</b>

## High tax rate, low EAT (earnings after tax)

**EBT and EAT (in € m)**



### Tax Rate:

**Tax rate Q1-Q3 2009: 29.9%**

Tax audit payment



Losses in Greek due to bond discount ( €4.8 m):



Low tax rate: 25%

Earnings in the US due to insurance payment ( €2.7 m):



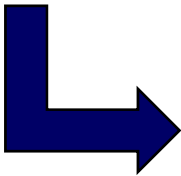
High tax rate: 34%

**Tax rate Q1-Q3 2010: 33.5%**

## Sharp decrease in profits in Q1-Q3 2010

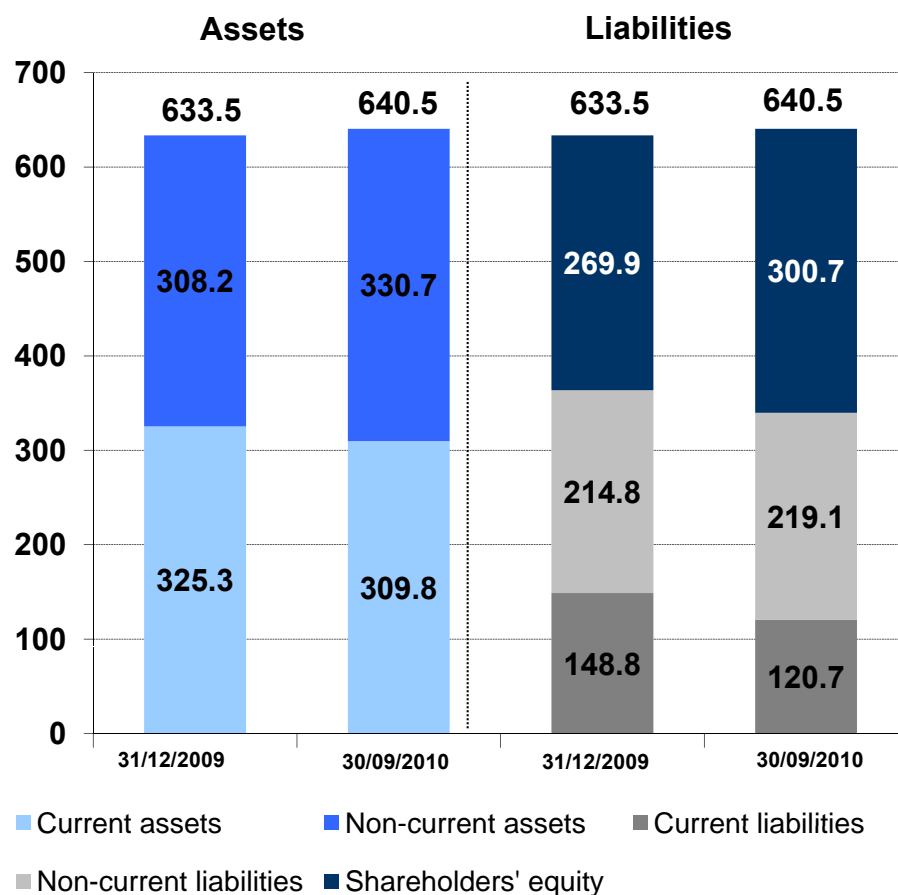
	Q1-Q3 2010		Q1-Q3 2009		△
(€ m)		in %		in %	
<b>Sales</b>	<b>342.3</b>		<b>330.6</b>		+ 4%
Gross Margin	141.3	41%	159.1	48%	-680 bps
<b>EBIT</b>	<b>35.2</b>	10.3%	<b>47.3</b>	14.3%	-26%
Financial result	-12.0		-8.9		-35%
<b>EBT</b>	<b>23.2</b>	6.8%	<b>38.4</b>	11.6%	-40%
Income tax	-7.8	[34%]	-11.5	[30%]	-360 bps
<b>EAT</b>	<b>15.4</b>	4.5%	<b>26.9</b>	8.0%	-43%

## Greece: balance sheet impact

	Income Statement (€ m)	Balance Sheet (€ m)
Switch from payment claim (trade receivables) to claim against State of Greece to get zero coupon bonds		Trade receivables: - 24.7
		Financial investm.: + 19.9
Discount on bonds due to no interests during maturity	Financial results: - 4.8	
		
		Retained earnings (equity): - 3.6
		Tax liability: - 1.2

## Strong balance sheet

### Balance sheet of the Biotest Group (in € m)



### Assets

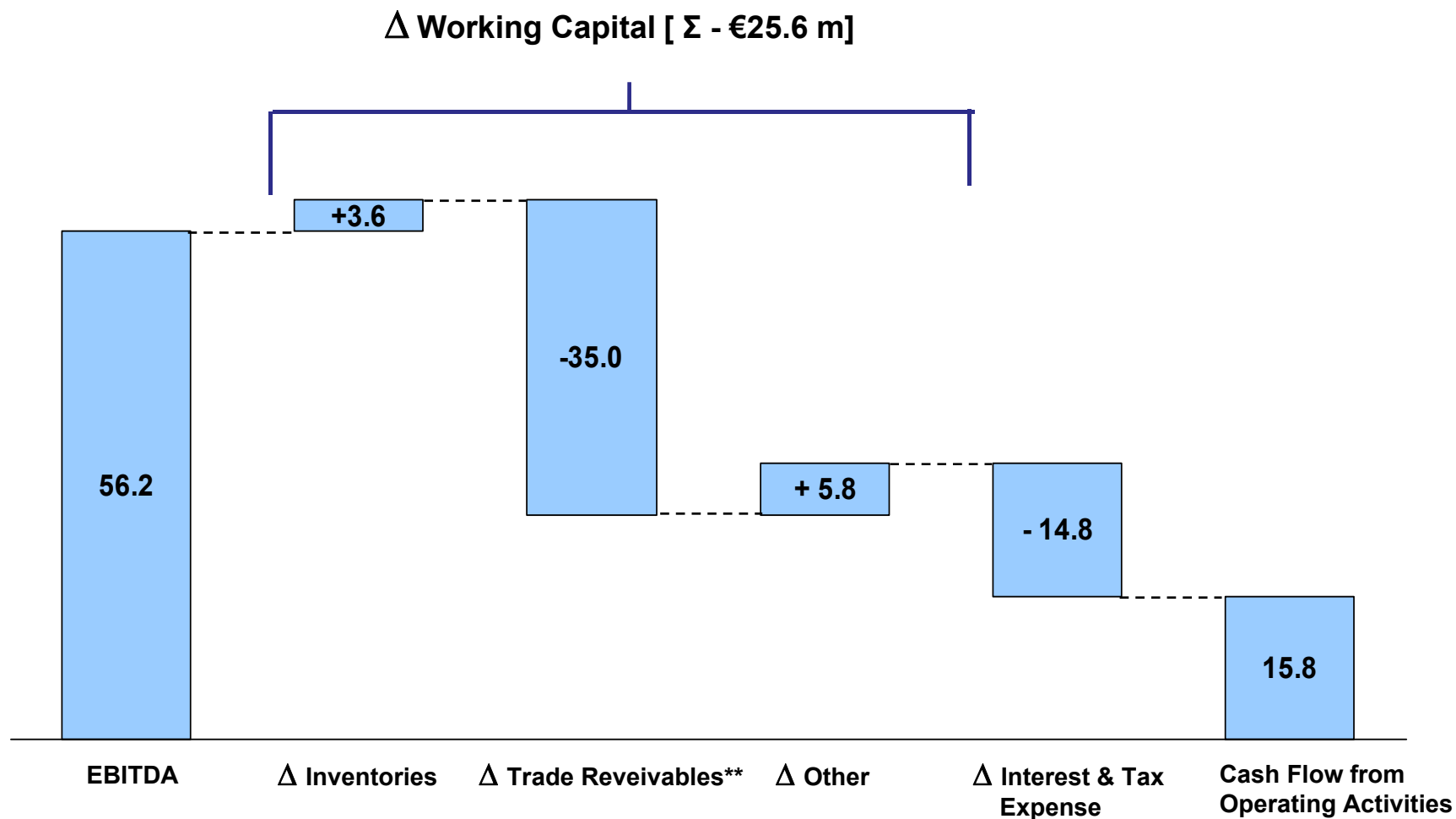
- Lower inventories due to strong Q3 Sales
- Higher Trade receivables due to higher sales volumes despite switch in Greek assets

### Liabilities

- Decrease in current financial liabilities
- Equity ratio as of 30 Sept. 2010: 47% ( 31 Dec. 2009: 43%)

## Cash Flow from Operating Activities in € m\*

Q1 – Q3 : January – September 2010



\* Continued Operations \*\* reduction of €24.7 m Greek trade receivables without cash impact

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## Current IVIG supply situation

- After a higher rate of thromboembolic side effects:
  - Licence of a competitive IVIG product (5% and 10%) had been suspended in the EU
  - Products had been withdrawn in Europe as well as in the US
- Coagulation activating factors may have triggered such side effects\* – they are definitively removed in production process for Intratect®
- Since 2<sup>nd</sup> week of October 2010 customers of the competitor are looking for another supplier.
- Biotest was and is able to deliver Intratect® instead of the withdrawn product – we made the first deliveries and see more orders from new customers
- Up to now IVIG inventories in the market are sufficient to substitute the withdrawn volumes. With lower inventories we may see less price pressure midterm

\* according to Biotest's assessment

## Outlook

We confirm our guidance given in July 2010:

**Sales:** Sales will grow compared to 2009  
with a low single digit percentage

**EBIT:** € 45 m (+/- 10%)



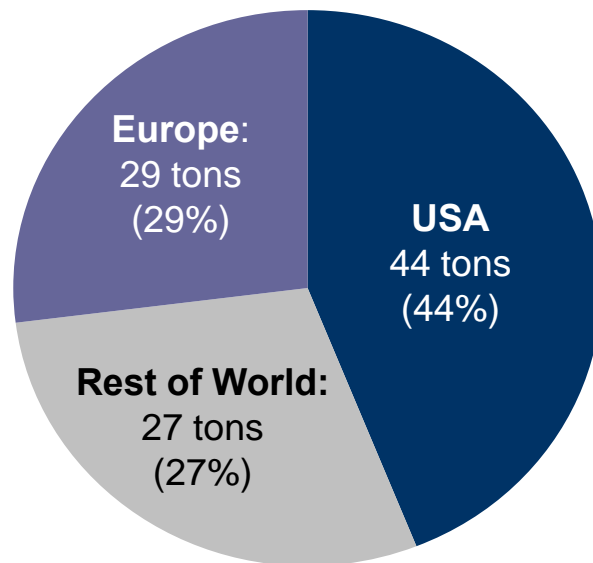


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## **Plasma Proteins**

## Current market environment and pricing situation for polyspecific immunoglobulins

**IVIG world market 2010e:**  
volume (in tons) and  
regional distribution (in %)



- Total volume IVIG world market as of 2010: ~ 100 tons
  - USA by far the most important market for IVIG worldwide
- ➔ Therefore, Biotest's strategic goal: launch of Bivigam in the US

Sources: MRB, UBS, Biotest Market Research

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## **Bivigam™ (IVIG) FDA filing in US**

- On November 3, 2010 BPC filed the licence application for the newly developed polyspecific IVIG with the FDA
- FDA filing occurred later than planned because we voluntarily generated data showing that Bivigam™ does not contain thrombogenic factors
- Brand name: Bivigam™, ready for use 10% liquid solution
- Without sugar, instead glycin as stabilizer

Filing of strategic importance to Biotest  
**Market potential ~ 100 m USD**

## IVIG market – Growth Rate and Price Trends

### Growth Rate 1st HY 2009 vs. 1st HY 2010

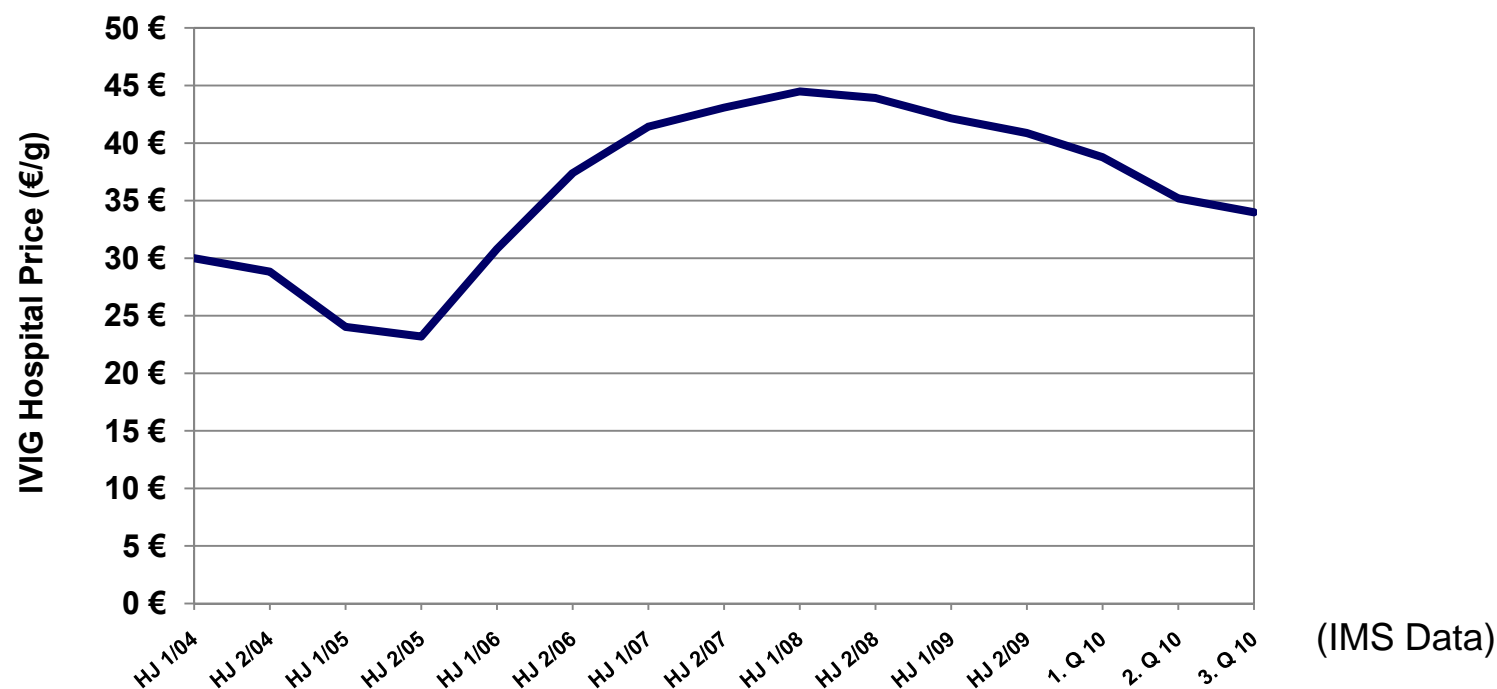
The consumption in the Biotest key markets was growing by 6 - 7% in volume (Germany, Austria, Greece, Switzerland, Italy, UK)

**However, in many countries decreasing prices**

### Price Trend:

- |                |   |             |
|----------------|---|-------------|
| • Austria:     | ↓ | ~ - 5 - 10% |
| • Greece:      | → |             |
| • Hungary:     | → |             |
| • Italy:       | ↘ | ~ - 4%      |
| • Switzerland: | ↘ | ~ - 3%      |
| • UK:          | → |             |

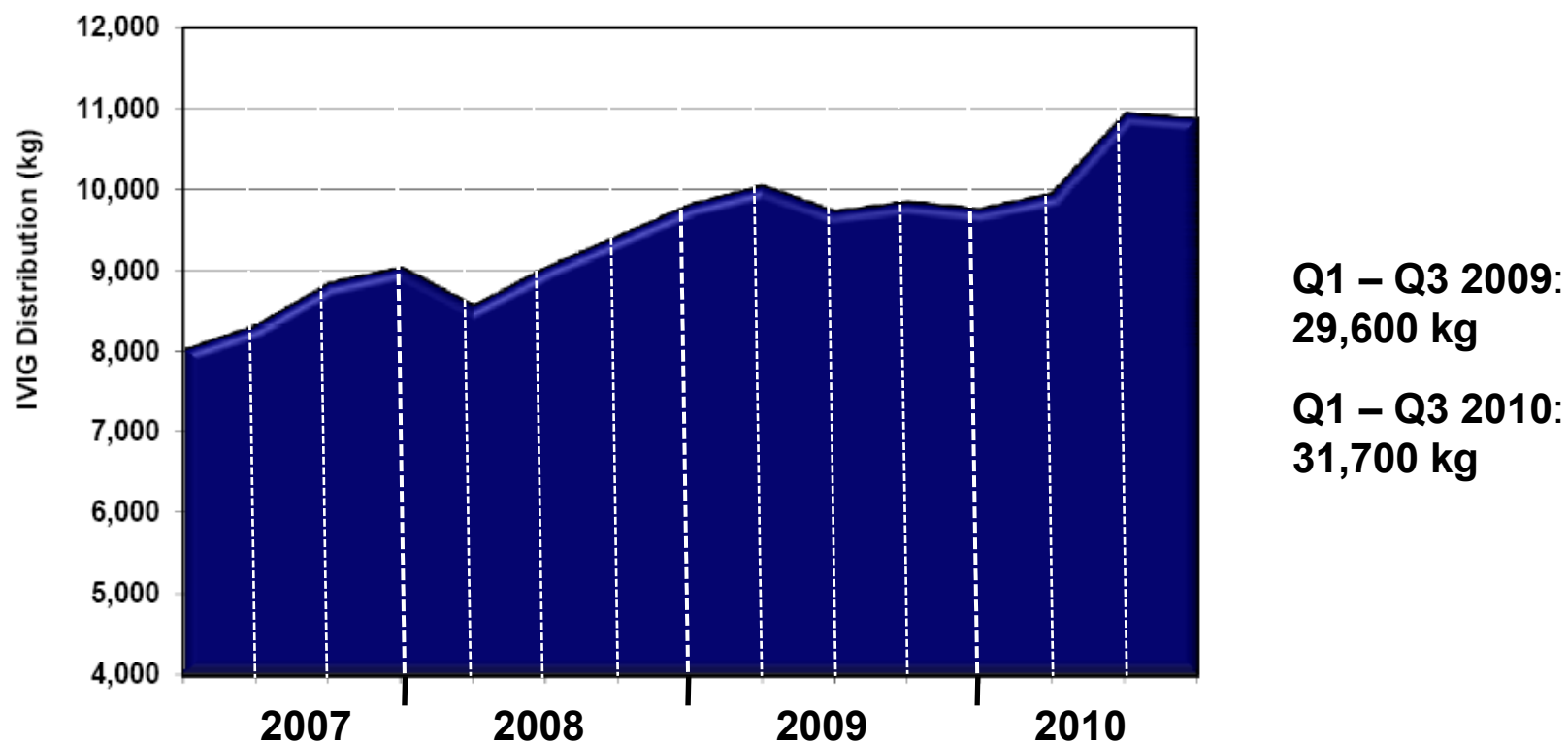
## Price trend IVIG – Germany



Biotest expectations:

Prices are stable in Q4/2010 and slightly increasing in 2011

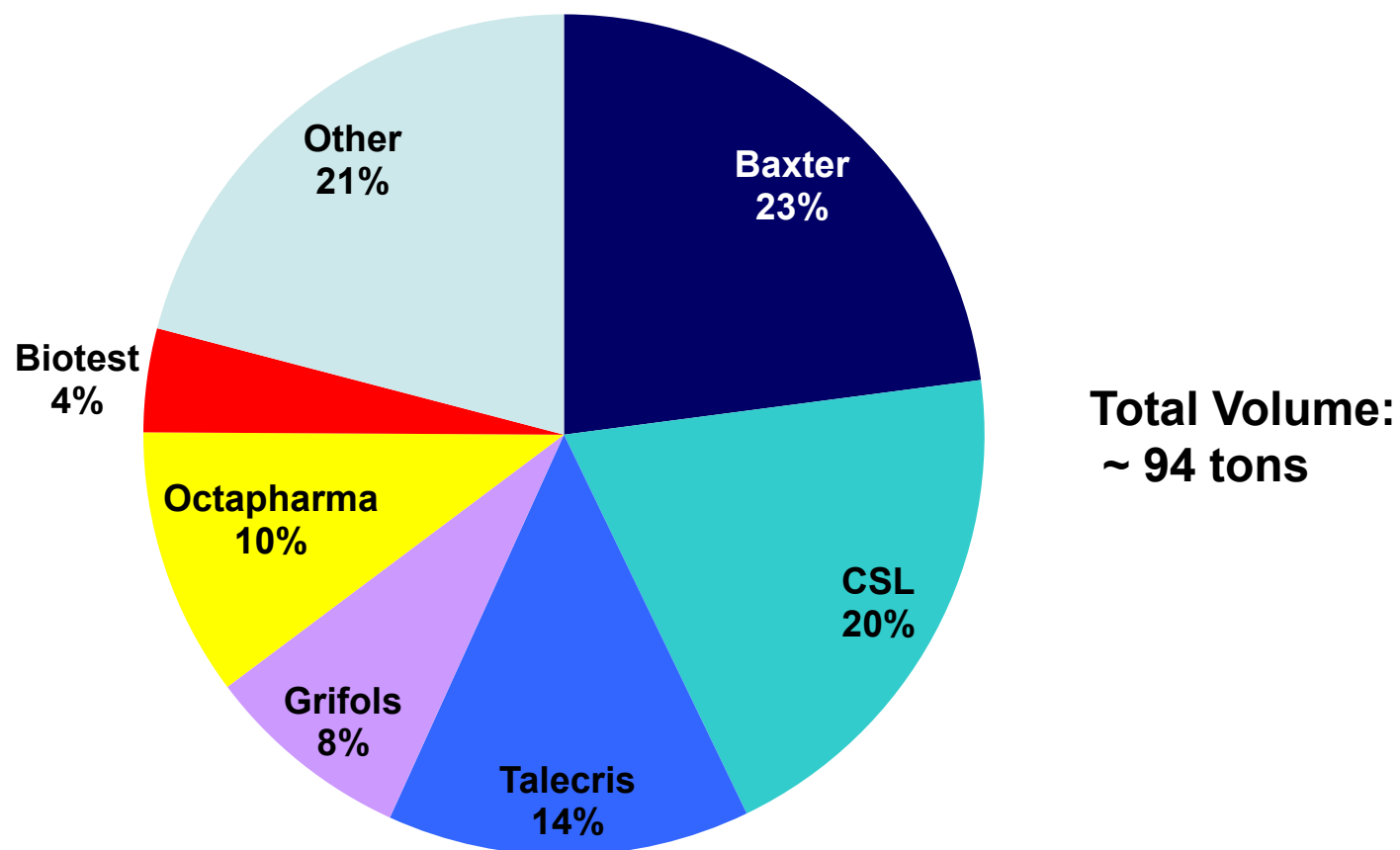
## US IVIG market development, 2007 – Q3 2010 distribution according to PPTA



- Quarter over quarter growth was negative in Q3 2010 (-0.6%), but cumulated distribution (Jan. – Sept.) was 7.0% up on previous year

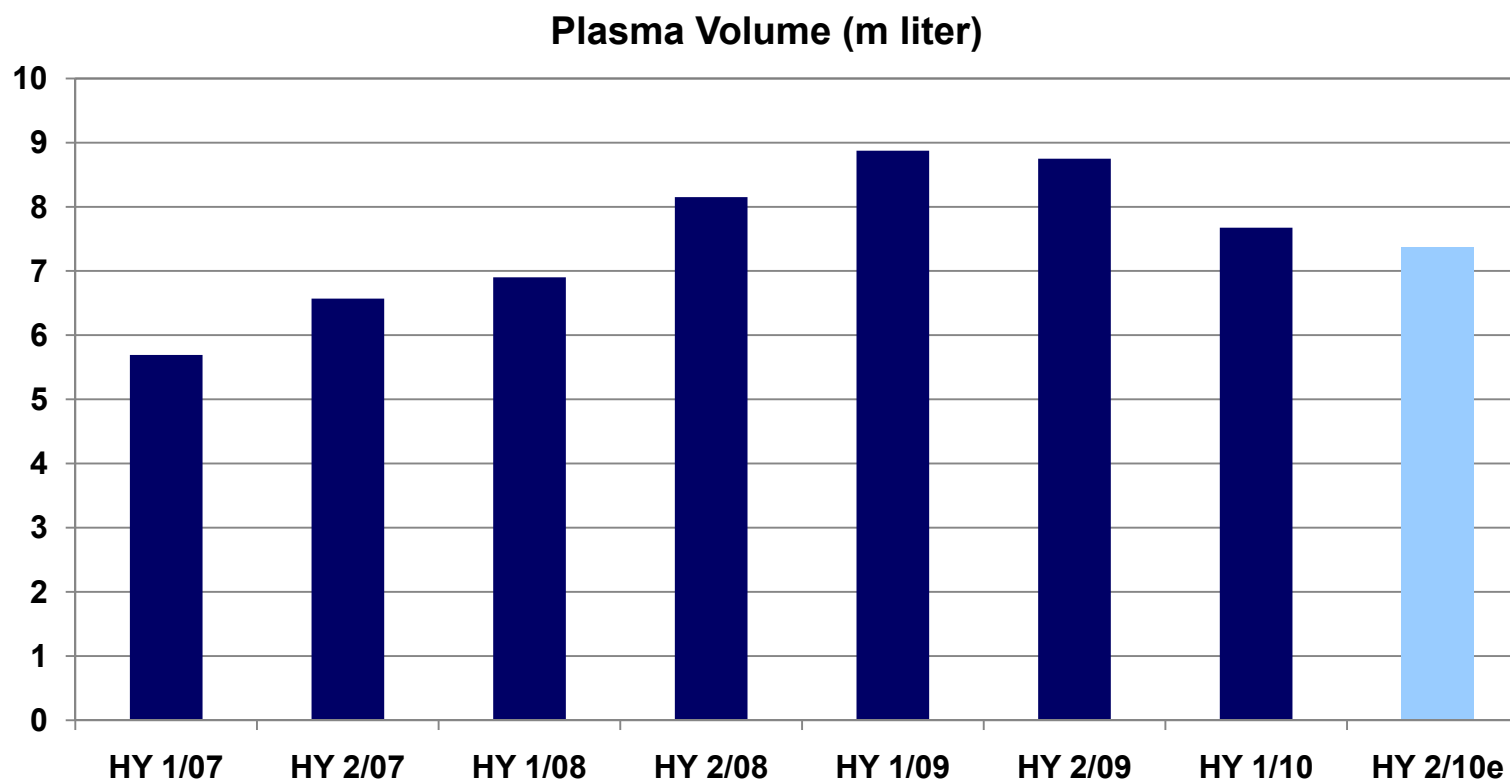
Source: PPTA data as reported by Jan-Aug 2010: UBS September 23, 2010; Jul 06 - Dec 09: Morgan Stanley; Volume September 2009: estimate on basis of graph

## Worldwide IVIG market, estimate 2009



Source: Own estimate based on MRB – 'The Worldwide Plasma Market 2008' & Citigroup Investment Research, 10 November 2009

## Biannual volumes of US Source Plasma



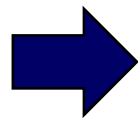
Source: PPTA; HY2 2010e: Biotest AG



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## **Biotest's expectations on IVIG volumes and prices in 2011**

- **Demand for IVIG will continue to rise** despite budget restrictions of social security systems
- In 2011 **volumes of IVIG offered** to be sold will be 12 – 15 tons **lower** than in 2010:
  - Volume of plasma being collected in the US will be 2 – 2.5 m liters lower than in 2009 due to reduced plasma collection
  - Octapharma will need some time to return to the market



Biotest expects that **prices will go up again in Europe and RoW earlier than previously projected**. We estimate that this will rather happen end of Q2 in 2011 than end of 2011

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## Major progress in development of Plasma Proteins (I)

### Zutectra®



Launched in Germany, UK, Austria, Italy, Ireland

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### Bivigam™



BLA submitted (Nov 3, 2010)  
Launch planned for Q4/2011

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### Fovepta®

(s.c. Hepatitis hyperimmunoglobulin for neonates)

Phase III trial completed

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### Cytotect 70



More than 6000 pregnant women screened  
32 seroconverted women included

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## Major progress in development of Plasma Proteins (II)

### IgM Concentrate



Phase I trial completed  
Phase II trial under preparation

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### Intratect 10%

Phase III trial started  
First patient expected to be included  
Nov 2010

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### Civacir<sup>®</sup>



Product characteristics optimized  
to increase potency of the product

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### Fibrinogen

New development started  
Indication: acute bleeding disorders

## CapEx ensuring further growth of Plasma Proteins

Bivigam Production in Florida:  
Expansion completed in Dec. 2010



Total spending: approx. US\$ 40 m

Expansion of filling and packaging  
facility in Dreieich: start: Dec. 2010



Total spending: approx. € 25 m






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**Biotherapeutics**

## Clinical development BT-061

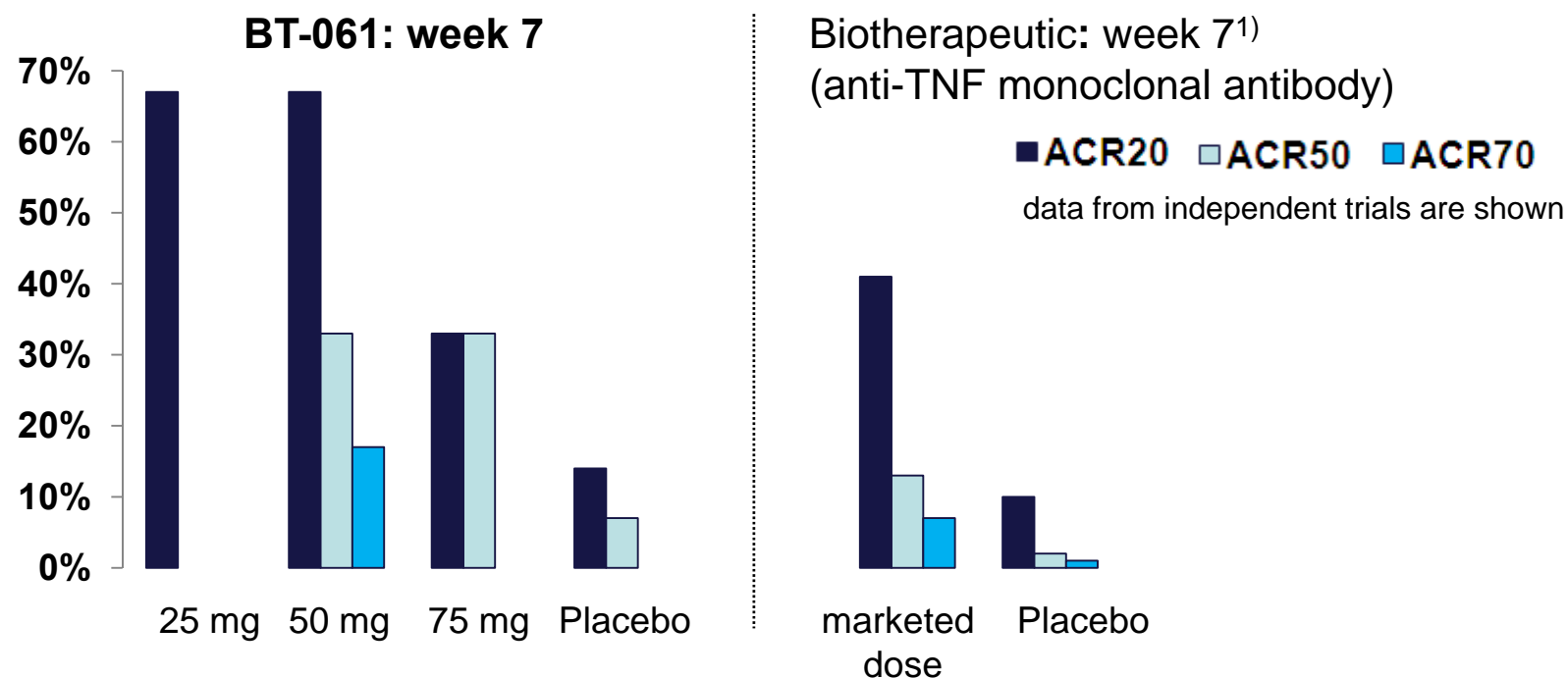
### Overview

Study no.	Indication	Design	Subjects planned	Status
961	Healthy volunteers	single dose <i>iv and sc up to 180 mg</i>	57	Completed 
967	Phase I/IIa: Psoriasis	single dose, placebo controlled <i>iv and sc</i>	56	Completed 
973	Phase II: Psoriasis	multiple dose, placebo controlled <i>iv and sc; focus on sc</i>	48	Recruitment ongoing
962	Phase IIa: Rheumatoid Arthritis	multiple dose, placebo controlled <i>iv and sc</i>	96	Completed 
971	Phase II: Rheumatoid Arthritis	BT-061 + MTX multiple dose, placebo controlled <i>iv and sc</i>	110	Recruitment completed
979	Phase II: Rheumatoid Arthritis	BT-061 + MTX multiple dose, placebo controlled; <i>sc</i>	176	Submitted

## Repeated treatment of RA patients with BT-061(monotherapy)

Study 962: Benchmarking against gold standard of biologic therapy (TNF-Antagonist)

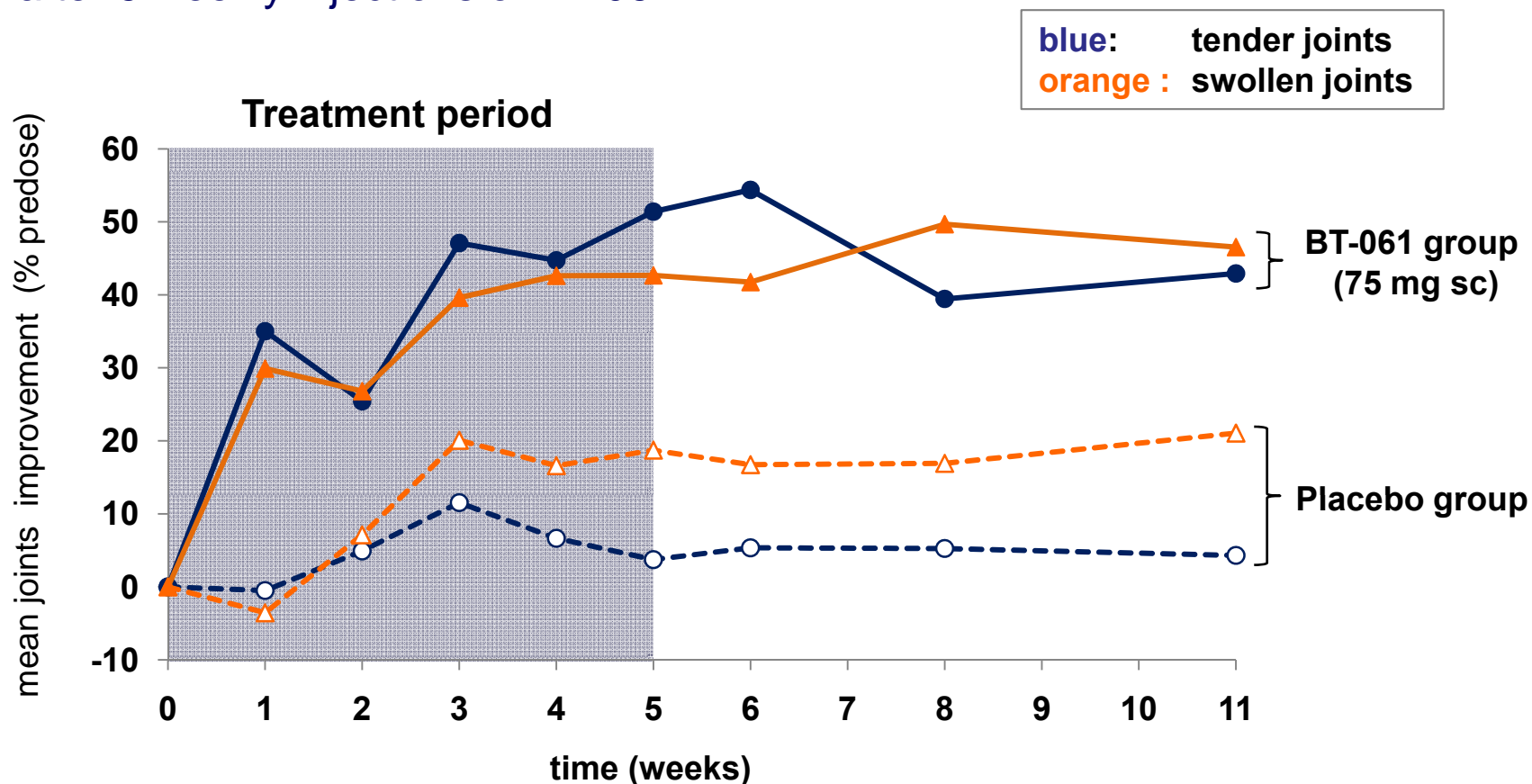
### ACR responses at week 7 (primary endpoint), monotherapy



- 1) Phase III trial results of anti-TNF monotherapy in DMARD non-responders at week 7 (results estimated from graphs)  
Please note: data from independent trials are not directly comparable as patient characteristics, route of administration, dose levels and treatment frequency are different

## Rheumatoid Arthritis Phase IIa Study (No. 962)

Mean improvement of tender and swollen joints  
after 6 weekly injections of BT-061

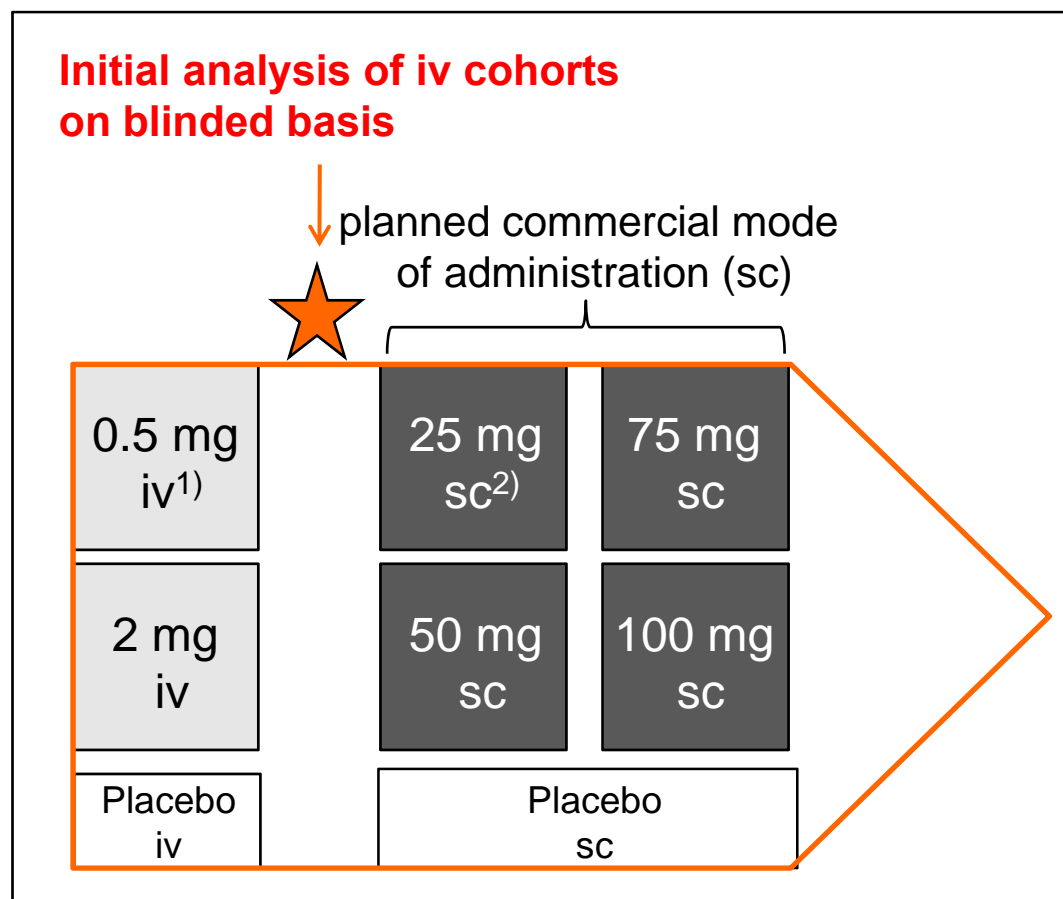


Improvement of joints lasts at least 6 weeks after end of treatment



## Psoriasis Phase II Study (No. 973) Trial Design

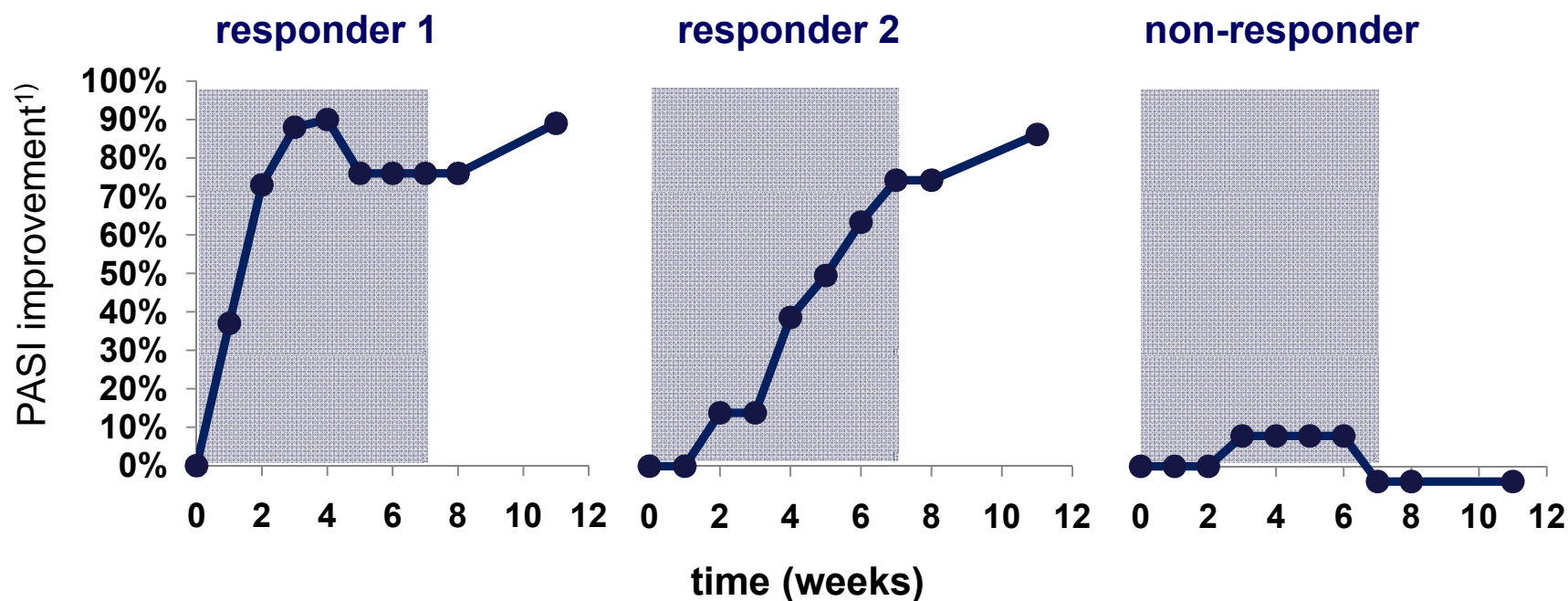
- **Indication:**  
moderate to severe chronic plaque psoriasis
- **Therapeutic regimen:**  
multiple dosing (8 weekly injections of BT-061 or placebo)
- **Follow-up period:**  
8 weeks
- In previous single dose trial (study 971): clinical benefit of up to 90 days



1) iv intravenous infusion  
2) sc subcutaneous injection

## Psoriasis Phase II Study (No. 973) Preliminary Results: Improvement of clinical symptoms - characteristic time courses

Responders and non-responders based on blinded data



■ treatment period: 8 weekly injections of BT-061 (0.5 or 2 mg) or placebo

1) PASI (average redness thickness and lesions by the Psoriasis Area and Severity Index) measures the redness, scaliness of the lesions, weighted area of involvement.

## Current clinical data support targeted product positioning

### Rheumatoid Arthritis

#### Phase IIa (No. 962)

Monotherapy

- study completed
- competitive efficacy
- good tolerability

#### Phase II (No. 971)

Combination therapy with MTX (No. 971)

- treatment completed
- follow-up phase ongoing

### Psoriasis

#### Phase I/IIa (No. 967)

- up to ~ 90% improvement of clinical symptoms (PASI)
- long duration of therapeutic effect after single administration (up to 90 days)
- good tolerability

#### Phase II (No. 973)

- multiple dosing
- first promising results obtained
- recruitment in sc cohorts ongoing



**Potential to position BT-061 via  
efficacy, safety, convenient administration  
(self-administration, 1 ml subcutaneously)**

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## **BT-061: Highlights**

### **Clinical Development**

- Encouraging results in both lead indications obtained

### **Partnership**

- Negotiations with international pharmaceutical companies about co-development / co-marketing intensified after completion of additional clinical trials
- Focus on companies with strong experience in Rheumatoid Arthritis

### **Further Indications**

- Positive preclinical results with BT-061 in the indication Multiple Sclerosis obtained
- Further development in this indication supported by the German Federal Ministry of Education and Research in the framework of the "Neu<sup>2</sup> Konsortium"<sup>1)</sup>

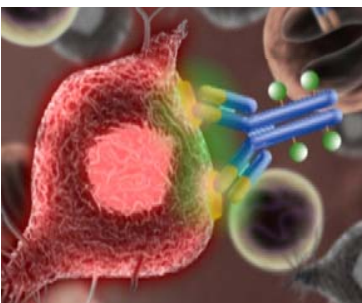
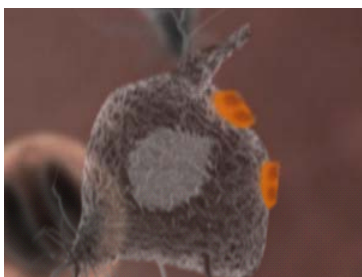
1) Neu<sup>2</sup> "Neue Wirkstoffe für neurologische Erkrankungen"

## Complex partnering discussions

<b>Regions + Scope</b>	<b>Challenges</b>
<p><b>Europe:</b> Co-development Co-marketing / Co-promotion</p> <p><b>USA:</b> Exclusive licence for partner for development and marketing</p> <p><b>Asia:</b> Exclusive licence for partner for development and marketing</p>	<ul style="list-style-type: none"><li>• Co-development:<ul style="list-style-type: none"><li>- goal, priorities</li><li>- time line</li><li>- decision rules</li><li>- deadlock procedures</li><li>- cost split</li><li>- transfer + exchange of results/new developments</li></ul></li><li>• Co-marketing / Co-promotion:<ul style="list-style-type: none"><li>- countries, scope</li><li>- definition of costs</li><li>- profit sharing</li><li>- conflict of interest</li></ul></li><li>• Upfront-, Milestone payments, Royalties</li></ul>

**Our goal: not a fast deal but an optimized structure and transaction**

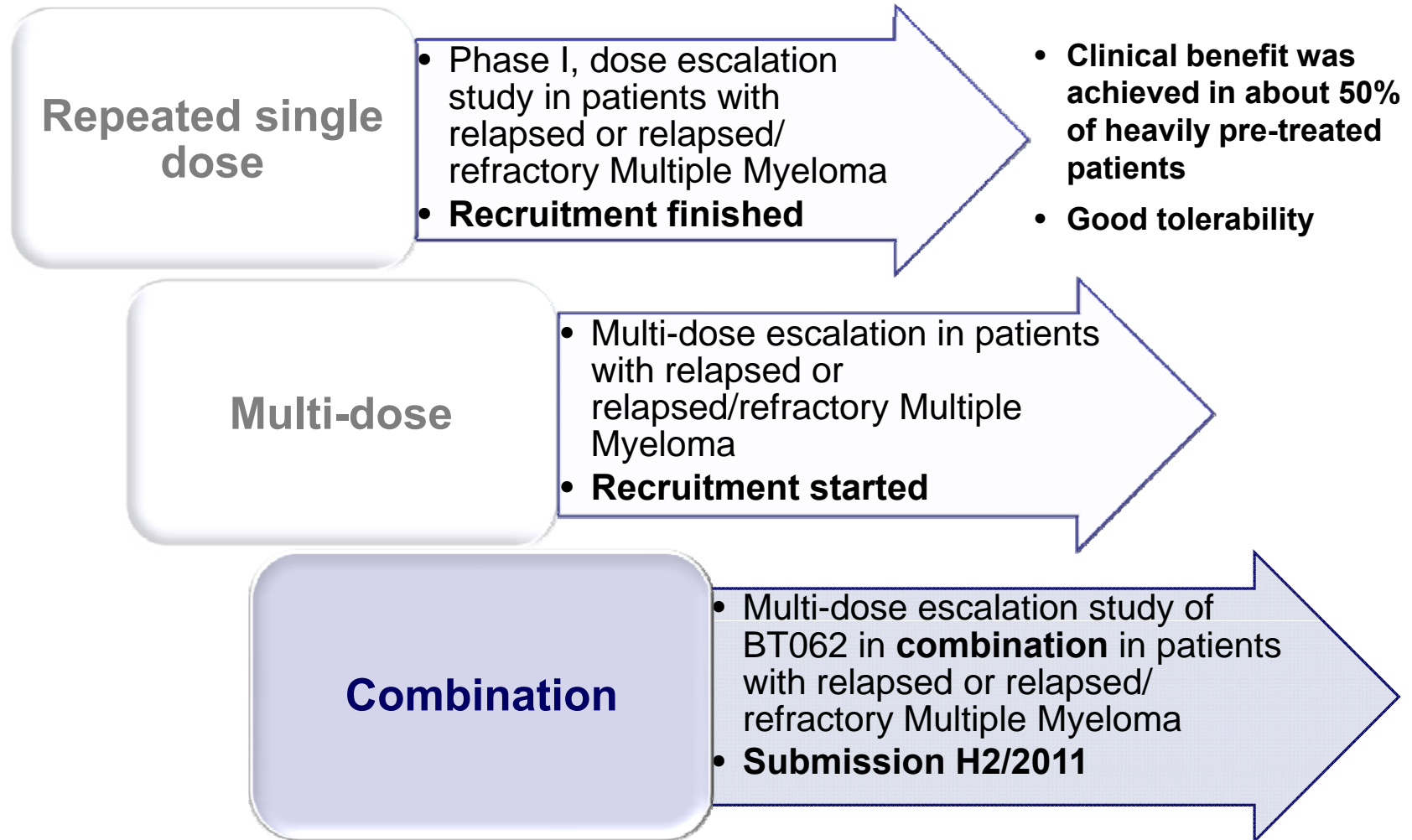
## BT-062 : Good tolerability, proven anti-tumour activity



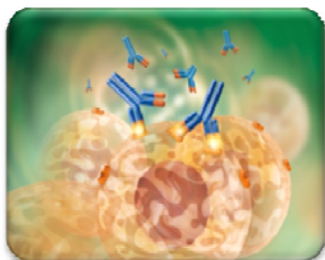
- BT-062: specific and highly effective immunotoxin: toxin part mediates high efficacy – antibody part mediates high specificity
- Phase I Study: Repeated single dose, dose escalation study in patients with relapsed or relapsed/refractory Multiple Myeloma
  - Indications of efficacy already with low dosages:
    - **Disease progression halted in some patients for several months**
    - **Maximum treatment dose defined (160 mg) and recruitment finished**

## Clinical development plan BT-062

### Development expansion to Europe: planned 2011

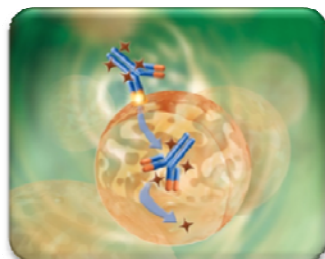


## Outlook Biotherapeutics: Next steps in clinical development Initiated



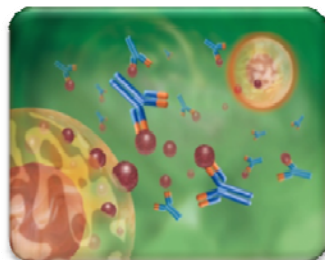
### **BT-061:**

- encouraging clinical data from both lead indications
- phase IIb trial in Rheumatoid arthritis submitted
- negotiations with strategic partners intensified



### **BT-062:**

- first indications of efficacy from dose-escalating study
- multi dose phase I/IIa trial approved by FDA, patient recruitment has started



### **BT-063:**

- treatment in phase I study completed
- report in Q1 2011



## Outlook Biotest Group

- Growing demand for IVIG with corresponding increasing prices mid of 2011
- Stable market for clotting factors and albumin
- Bivigam™ market authorisation expected Q4 (2011); annual market potential ~ US\$ 100 m
- Promising R + D pipeline for plasma proteins and biotherapeutics



**Thank you for your attention!**



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