Biotest AG

Analyst Conference Q1-Q3 2015

10 November 2015, Frankfurt am Main

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 – Q3 2015

- IgM Concentrate shows encouraging results in life-threatening pneumonia
- Impairment of US business
- Roofing ceremony at new manufacturing site in Dreieich
- Investigations Russia
  - Trial in Darmstadt ongoing
  - Tax risk for year 2005 – 2008 of up to €16 m (incl. interest)
- FDA submission of RSV-hyperimmunoglobulin (licensed from ADMA Biologics, Inc.)

From Nature for Life

Financials Q1-Q3 2015

What has triggered the impairment test?

1) Ramp-up of **Bivigam** production was delayed twice since sales uptake was weaker than originally planned.

2) Our estimate of the market potential of **Civacir** had to be reduced significantly due to the success of the new antivirals (Sovaldi, Harvoni),
despite the fact that the latest Biotest results of clinical phase III study of Civacir were promising.

Biotest
From Nature for Life

Write down and impairment

(in € m)	P&L effect in September 2015	
Bivigam inventories	-14	Therapy: COGS
Impairment IgG plant, software	-52	Therapy: COGS
Impairment Civacir project	-13	Therapy: R&D
Impairment mAb plant	-3	Therapy: R&D
Other write downs	-2	Therapy: COGS
Total	**-84**	

- Decrease in value of assets in the amount of €84 m ($96 m)
  - This is an accounting effect that represents past cash investments and **does not** impact the company's cash position today
  - Values decreased in the balance sheet
  - Impact does not effect our current business operations

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Reasons for write down of Bivigam inventories

- Pre-production for US market launch and originally planned fast ramp up of Bivigam sales led to high inventories in the beginning of 2014
- Bivigam has a shelf life of 2 years
- Since beginning of 2015 Biotest Pharmaceuticals Corp. (BPC) tried hard to sell short dated material
- Promising Bivigam sales in H1 2015
- Decline of Bivigam sales to distributors in last two months

Reasons for impairment of US production plant

Bivigam

- Lower Bivigam sales in 2015 than originally planed
- Excess Bivigam inventory
- Reduced production activities in immunoglobulin manufacturing plant
- Capacity not fully utilised
- Unabsorbed costs

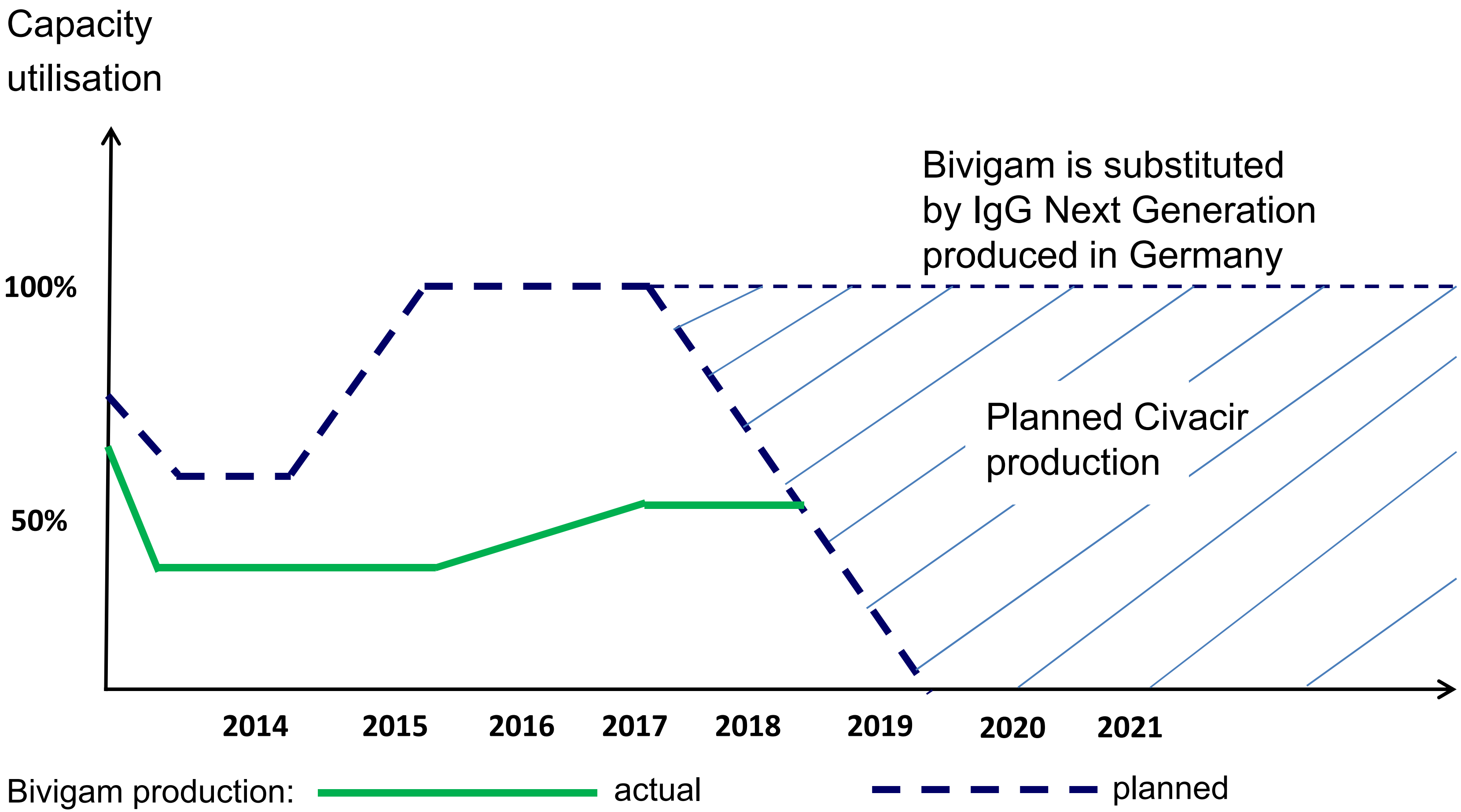
  ➢ Re-evaluation of the value of facility assets (facilities, inventory)

Civacir

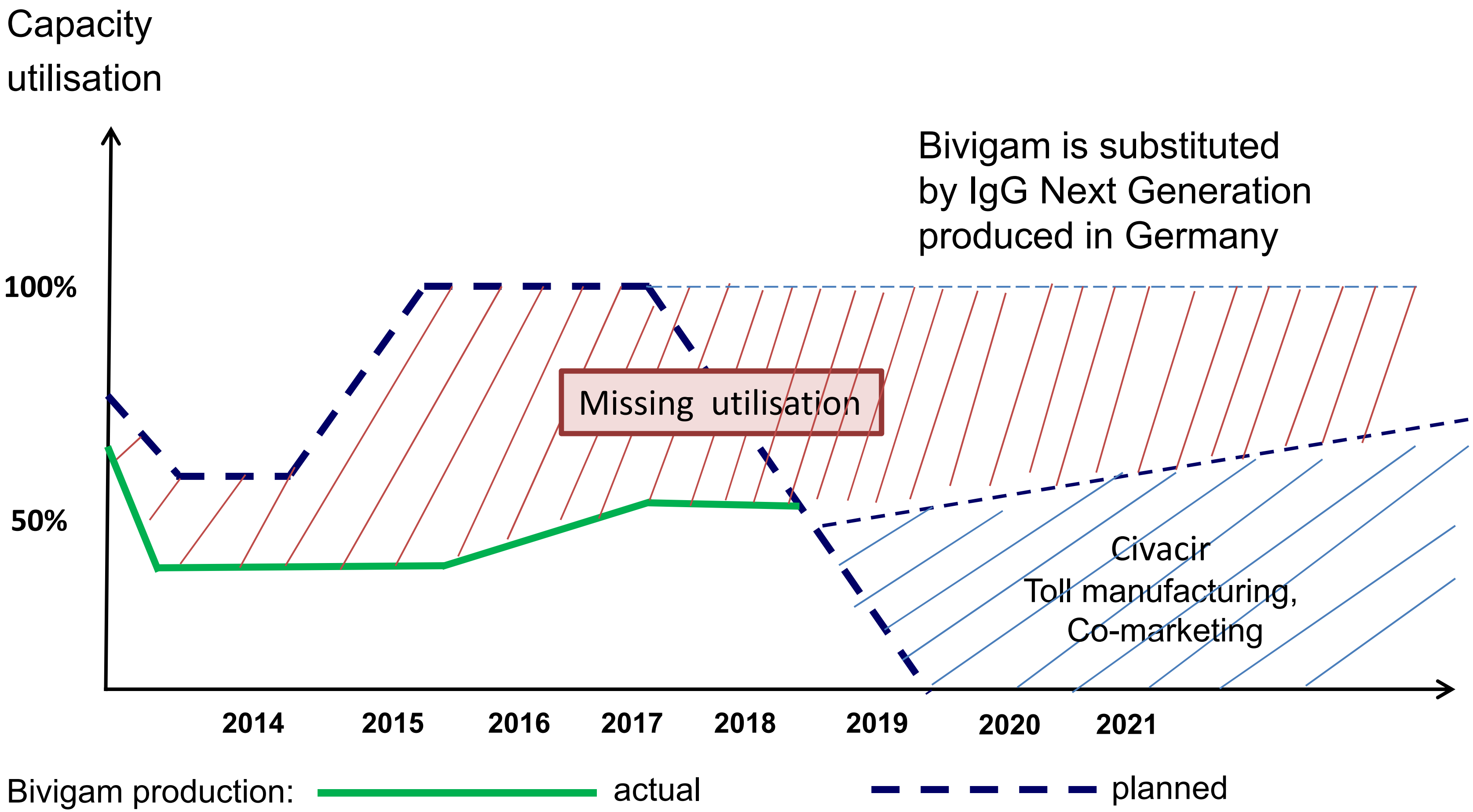
- Despite promising clinical data from an interim analysis, significantly reduced market potential

  ➢ Re-evaluation of the value of assets (project, plasma inventory)

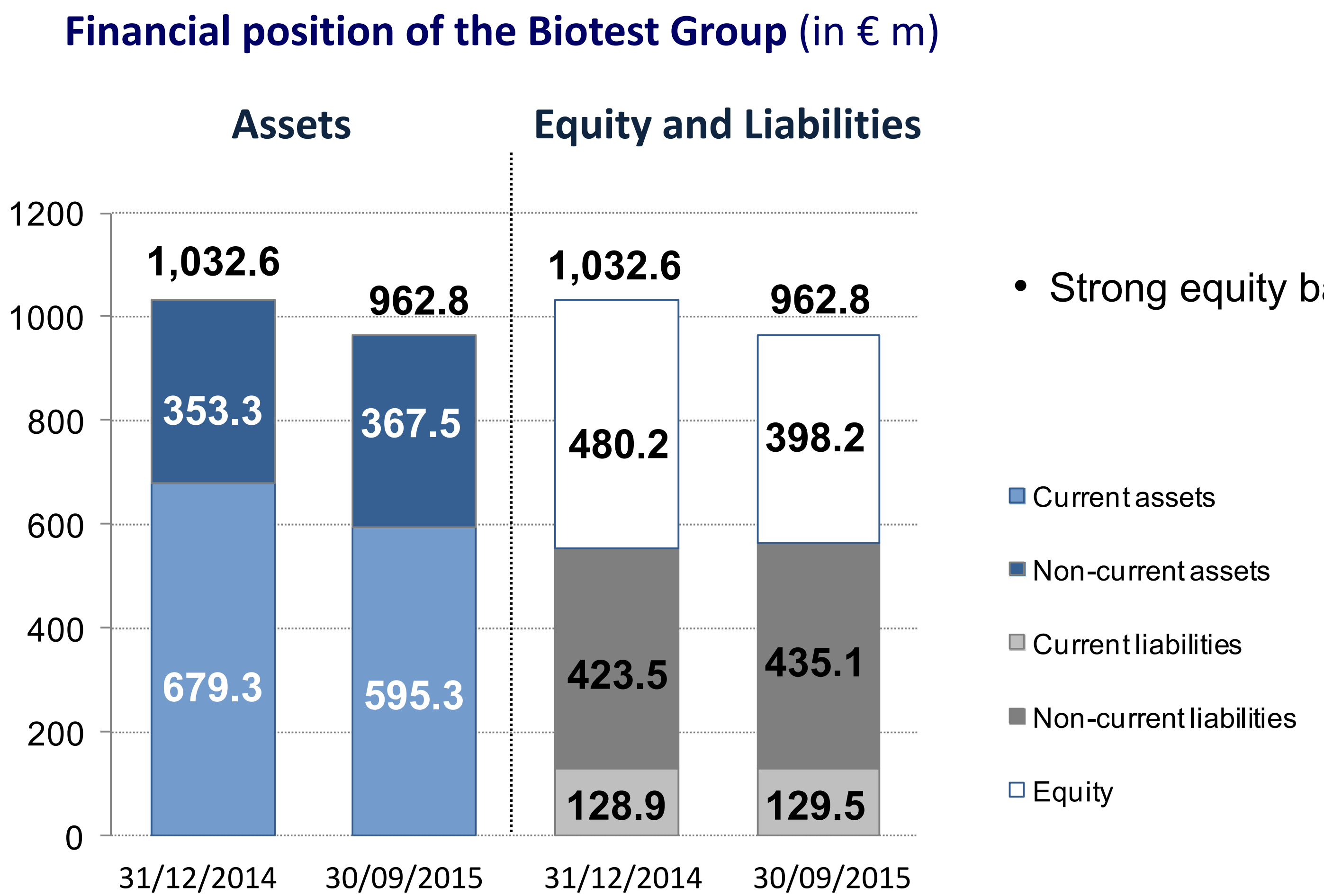
PLAN:
Utilisation of the production plant in Boca Raton



ACTUAL:
Utilisation of the production plant in Boca Raton



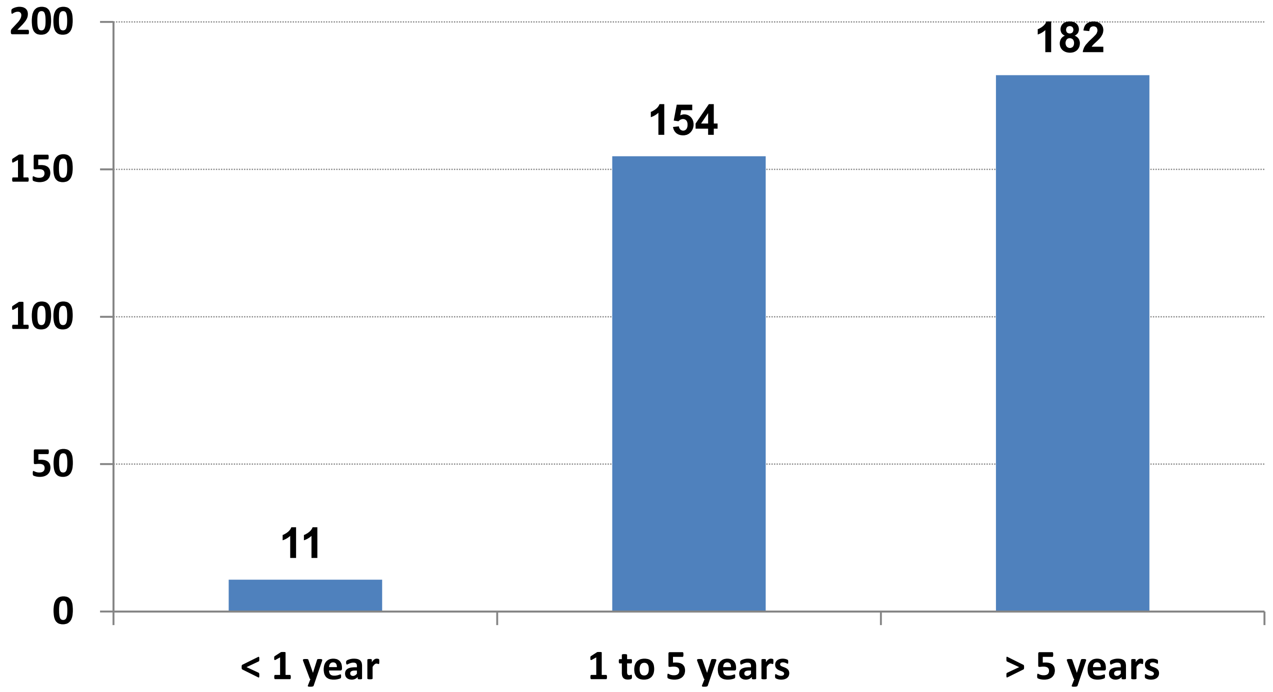
Financial position: long term financed



- Strong equity base

Maturity structure of financial liabilities

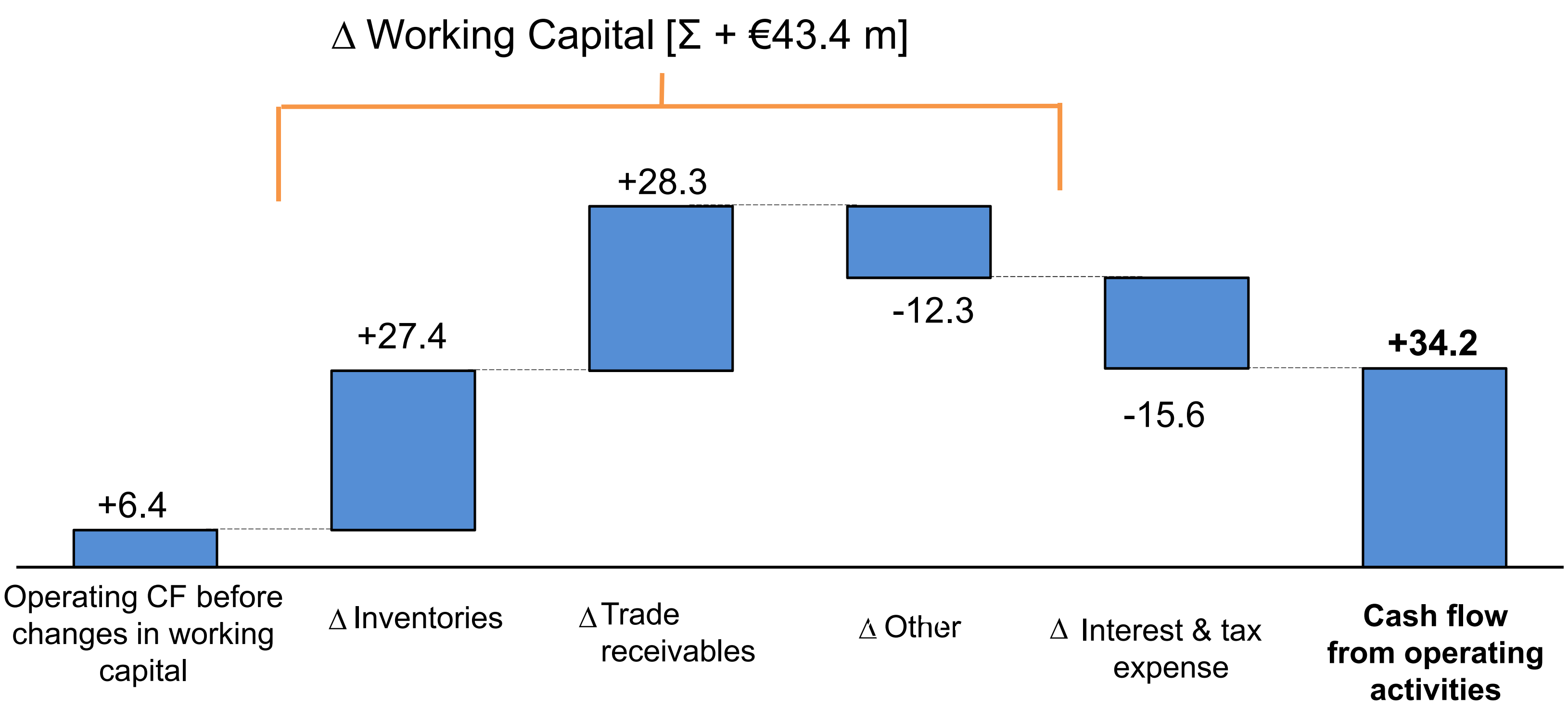
as of 30 September 2015 (in €m)



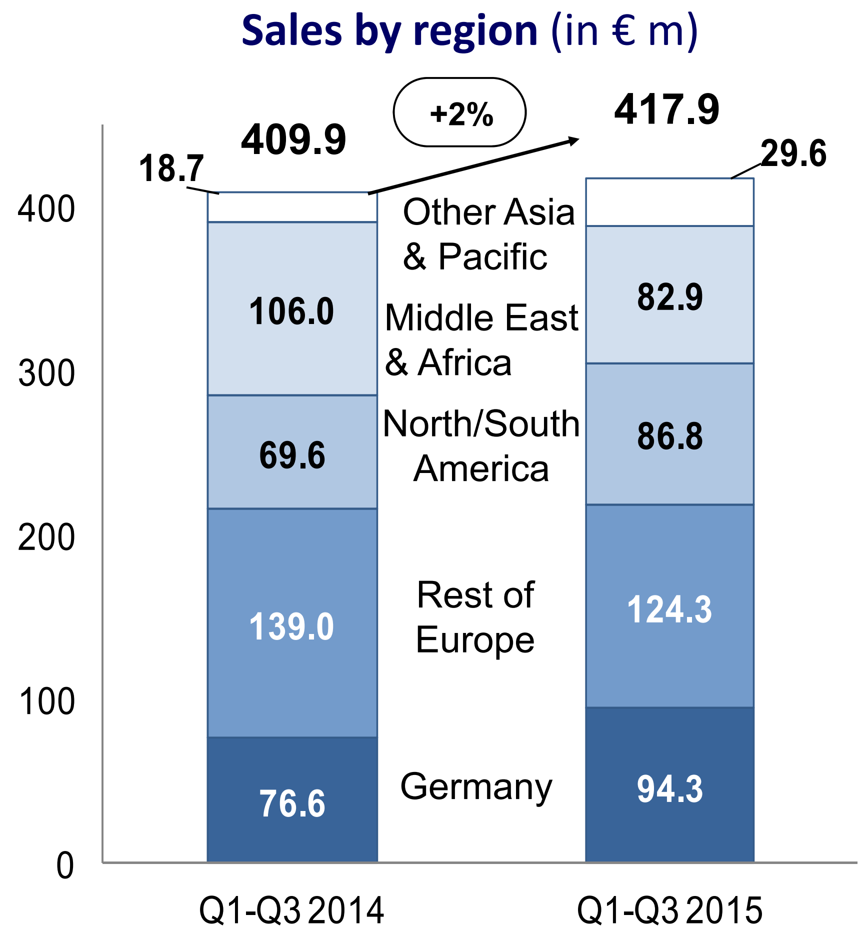
€ 129 m net debt (financial liabilities minus cash)

Positive cash flow from operating activities

January – September 2015 (in € m)



Sales growth slightly above last year



- Strong market position in Germany
- Growth in the Americas and Asia & Pacific
- Lower sales in rest of Europe and Middle East/ Africa
- Therapy
  - Three main products: Immunoglobulin, Albumin and Factor VIII
  - Speciality plasma products approx. 25% of sales

Current reported results – Q1-Q3 2015
(in €m)

	P&L Q1-Q3 2015
Sales	418
COGS	-344
Gross margin	**74**
Distribution costs	-52
Admin costs	-27
R&D costs	-77
OOE*	0
EBIT	**-82**

- **Reported figures are influenced by**
  - Impairment
  - mAb costs
  - Idle capacity costs
  - Biotest Next Level costs

* OOE = Other operating expense

Profitable core business (in €m)

	P&L Q1-Q3 2015	Impair-ment*	mAb costs	Idle capacity costs	BNL costs	adjusted P&L Q1-Q3 2015
Sales	418		-1			417
COGS	-344	68		10	0	-266
Gross margin	**74**	**68**	**-1**	**10**	**0**	**151**
Distribution costs	-52					-52
Admin costs	-27				4	-23
R&D costs	-77	13	42			-22
OOE	0					0
EBIT	**-82**	**81**	**41**	**10**	**4**	**54**

	P&L Q1-Q3 2014	Impair-ment	mAb costs	Idle capacity costs	BNL costs	adjusted P&L Q1-Q3 2014
Sales	410		-5			405
COGS	-245		1	6	0	-239
Gross margin	**165**	**0**	**-5**	**6**	**0**	**166**
Distribution costs	-55		0			-55
Admin costs	-24		0		2	-22
R&D costs	-51		24			-27
OOE	1					1
EBIT	**35**	**0**	**20**	**6**	**2**	**63**

* € 3 million are recognised in monoclonal antibodies

Profitable core business
(in €m)

	Q1 - Q3 2014	Q1 - Q3 2015
EBIT	**35**	**-82**
Impairment and write off*	0	81
Biotest Next Level costs	2	4
Monoclonal antibodies	20	41
Idle capacity costs (Boca & Dreieich)	6	10
EBIT adjusted	**63**	**54**

* € 3 million are recognised in monoclonal antibodies

From Nature for Life

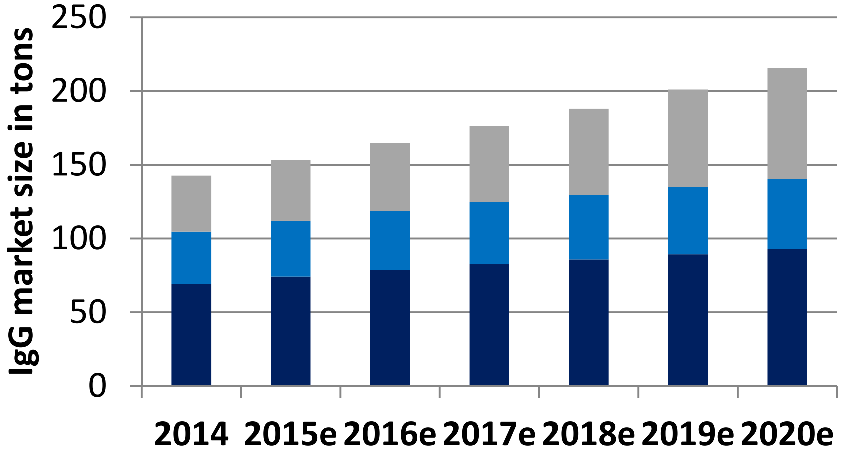
Strategic Adaptation

Necessary adjustments to strategy

- Focus on plasma protein business
- Biotest Next Level: broadening of plasma product portfolio
- Adjustment of R&D programme

Focus on plasma protein business

- Worldwide demand for plasma proteins still growing



Exp. annual growth CAGR 2014 – 2020e

RoW	12%
Europe	5%
North America	5%
World	7%

- Continue to grow business in Europe and RoW

- Strengthen profitability of US business

Sources: Biotest market research based on MRB (2013), PPTA (2015)

Steps to strengthen US profitability

Sales & production still below expectations

Changes in US organisation implemented

1. New head of sales
2. Reorganisation of sales force
3. New CEO

Increase sales

- Increasing share of voice by partnering / co-marketing

Increase production

- Toll manufacturing

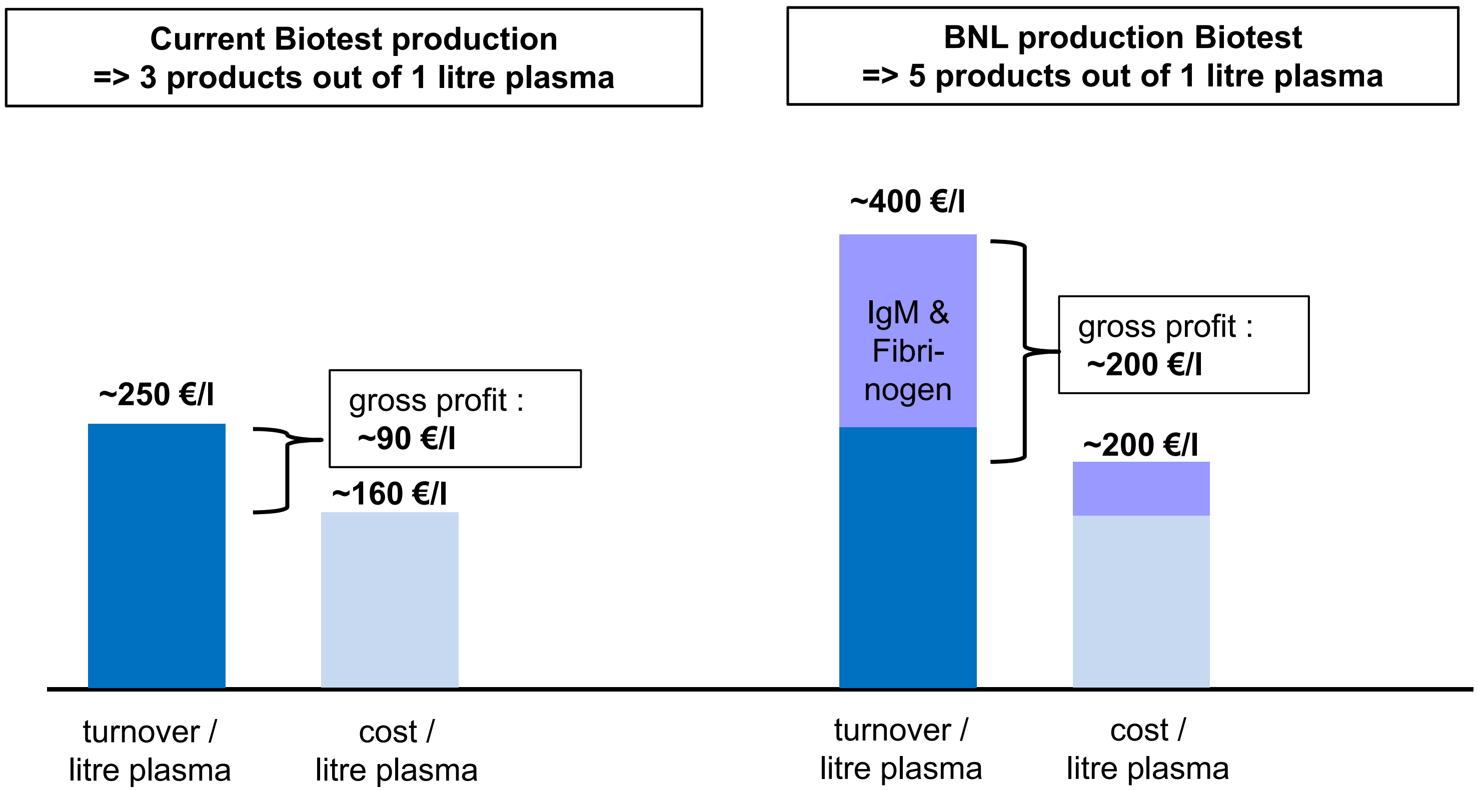
→ Increase sales → increase production → **lower idle capacity costs**

Necessary adjustments to strategy

- Focus on plasma protein business
- Biotest Next Level: broadening of plasma product portfolio
- Adjustment of R&D programme

BNL: Broadening of product portfolio

- Expand product portfolio from 3 products to 5 products out of one litre plasma and double production capacity



Biotest
From Nature for Life

"Biotest Next Level":
On track in terms of timeline and budget (April 2015)

"Biotest Next Level":
On track in terms of timeline and budget (August 2015)

"Biotest Next Level":
On track in terms of timeline and budget (October 2015)

Necessary adjustments to strategy

- Focus on plasma protein business
- BNL: broadening of plasma product portfolio
- Adjustment of R&D programme

Adjustment of R&D programme

- **Prioritise plasma protein R&D programme**
  - IgM Concentrate
  - IgG Next Generation
  - Fibrinogen

- **Adjustment of the monoclonal antibodies R&D programme**

  - Significant reduction in R&D spending for mAb, continue activities up to next milestone to enable partnering

Prioritise Plasma Protein Projects

Biotest
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IgM Concentrate
Phase II CIGMA Study in Patients with sCAP

Objectives

- Evaluation of the efficacy and safety of IgM Concentrate in patients with severe community acquired pneumonia (sCAP)

Primary Endpoint

- Increase of ventilator free days (VFD)s

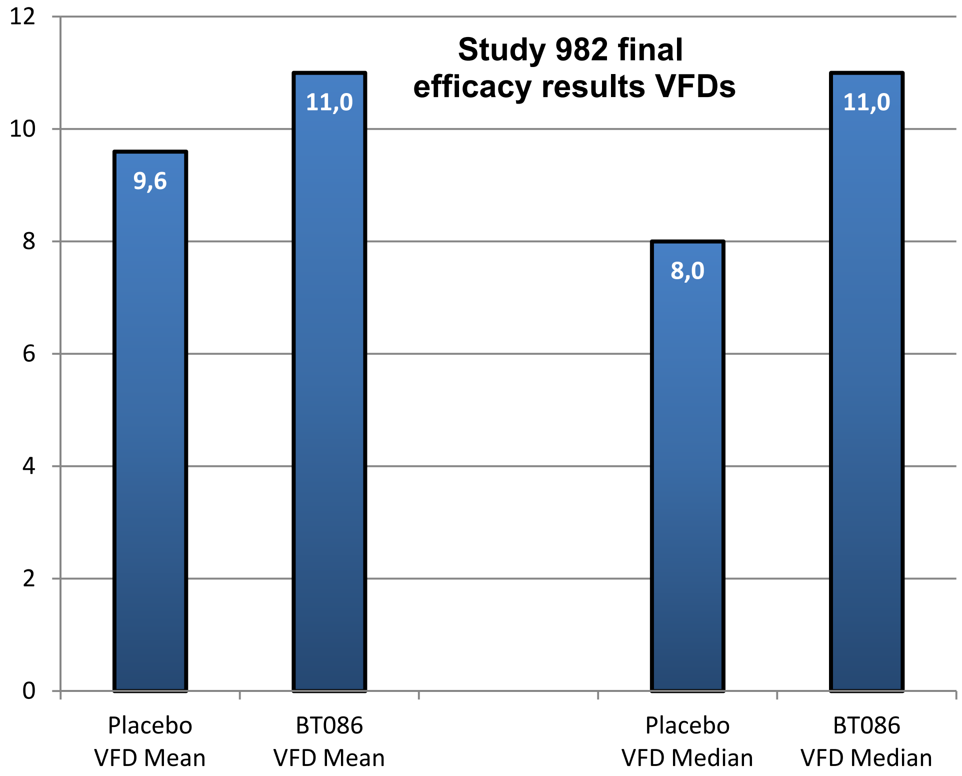
Secondary Endpoints

- **28-day all cause mortality**
- 28-day pneumonia cause mortality
- Time to discharge from ICU (intensive care unit)

VFD = Ventilator free days
BT 086 = IgM Concentrate

Biotest
From Nature for Life

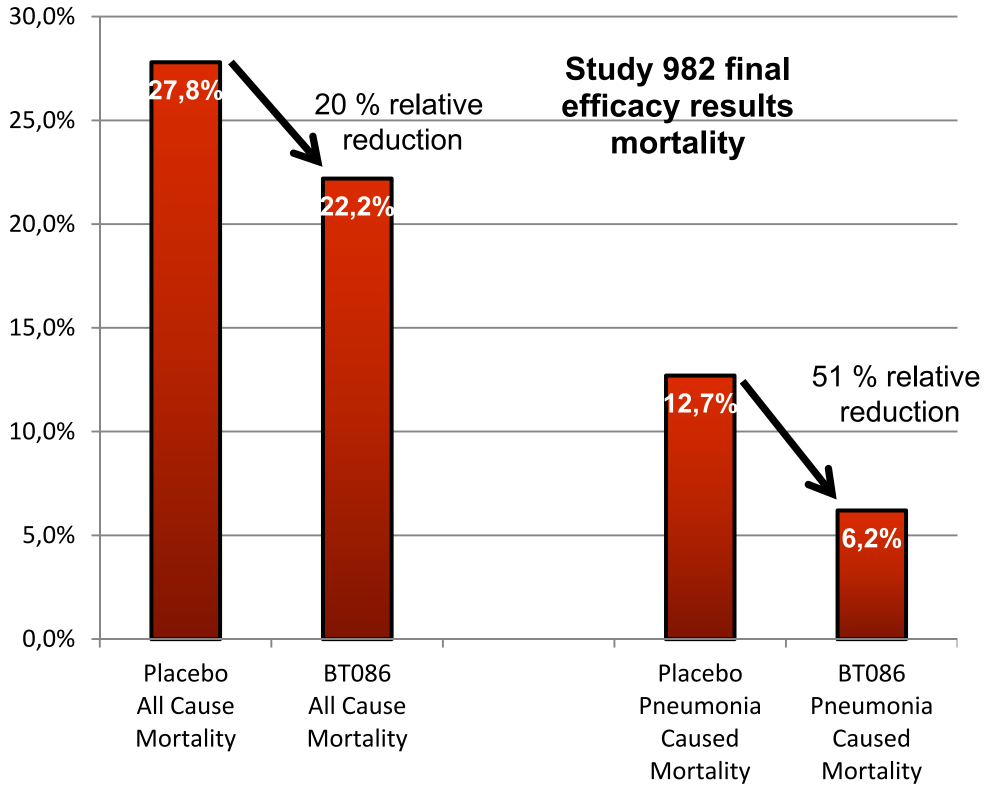
IgM Concentrate - phase II CIGMA study
Final efficacy results – ventilator free days (VFD)



- Shorter duration of artificial ventilation need

VFD = Ventilator free days
BT 086 = IgM Concentrate

IgM Concentrate - phase II CIGMA study
Final efficacy results – mortality



- Approx. 20% relative reduction in mortality
- Even more pronounced reduction with respect to pneumonia caused mortality

BT 086 = IgM Concentrate

IgM Concentrate

Attractive market potential

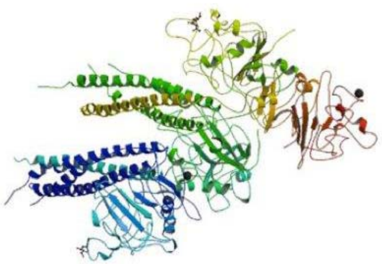
- **Severe Community Acquired Pneumonia**
  - Value driver based on CIGMA study results
  - Market size in sCap approx. 350,000 patients worldwide*
  - Sales potential approx. €500 m p.a.

Potential upside indication (early to market indication)

- **Common Variable Immunodeficiency Disease (CVID)**
  - e.g. IgM deficiency

* Source: Biotest market research

Promising development projects



IgG Next Generation

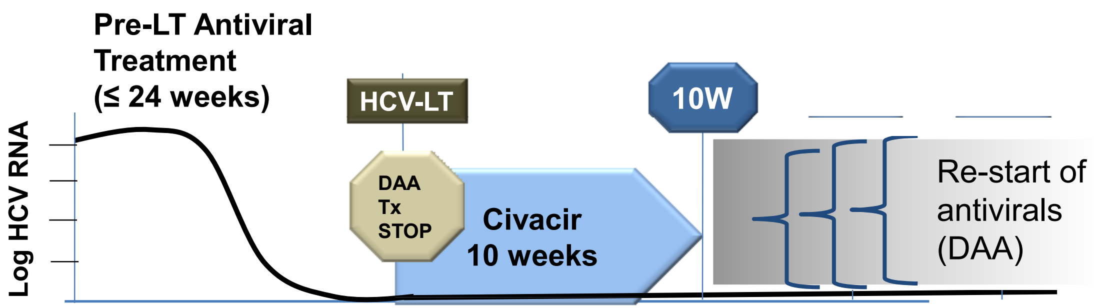
- New development of Intratect® and Bivigam® helps patients with immune system dysfunctions
- Global marketing planned

Fibrinogen

- Fibrinogen is for the treatment of acute haemorrhages due to congenital or acquired fibrinogen deficiencies

What has reduced the market potential of Civacir?

- Original market potential: €350 m /year based on a re-infection rate of 80% and a treatment period of 10 weeks
- With the first generation of new antivirals (Sovaldi) the re-infection rate went down to 30-35%
- **Risk 1**: today's standard of care (treatment with Harvoni) will most likely reduce the re-infection rate even more (< 10%)
- **Risk 2**: Civacir treatment window gets much smaller



LT = Liver transplantation; HCV = Hepatitis C Virus; DAA = Directly Acting Antivirals

Civacir: preliminary efficacy data phase III study

Group	Patients (N)	Reinfections (N / %)	Ongoing[1] (N / %)
Control	32	8 / 25%	7 / 22%
200 mg/kg	20	6 / 30%	0 / 0%
300 mg/kg	28	**1 / 4%**	4 / 14%
all groups	80		

- 94% of patients randomised are treated with sofosbuvir based regimens pre-LT (including 13 patients that received a new sofosbuvir combination (Harvoni))
- No re-infections in patients receiving Harvoni

LT = Liver transplantation

Civacir´s competitors: Vertex & Bristol-Myers

2014

Vertex to stop selling hepatitis C drug Incivek

12 Aug 2014

Tuesday, August 12, 2014

Posted by **HCV New Drugs**

FILE UNDER HCV

Vertex to stop selling hepatitis C drug Incivek
Boston Globe
By *Robert Weisman*
| Globe Staff August 12, 2014

Vertex's decision to stop selling Incivek in the United States as of Oct. 16 was conveyed in a Monday letter to health care providers written by Charles Johnson, the company's vice president of global medical affairs.

"This decision has been taken in view of available alternative treatments and the diminishing market demand for Incivek," Johnson wrote.

http://hepatitiscnewdrugs.blogspot.de/

07 Oct 2014

Bristol-Myers withdraws FDA NDA for asunaprevir

Tuesday, October 7, 2014

Posted by **HCV New Drugs**

Bristol-Myers pulls U.S. marketing application for hepatitis C treatment
Oct 7 (Reuters) - Bristol-Myers Squibb said it withdrew its U.S. marketing application for a drug combination to treat hepatitis C.

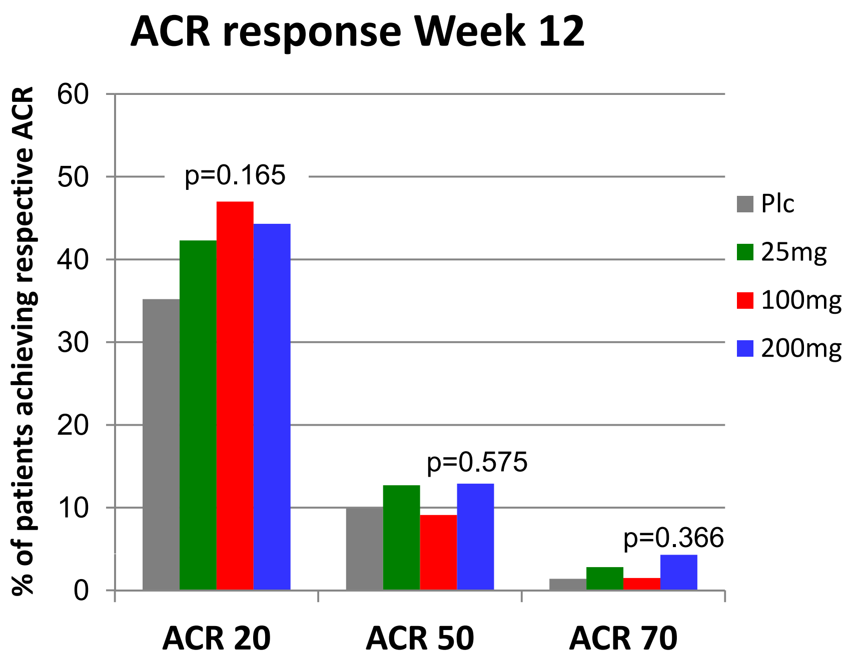
http://hepatitiscnewdrugs.blogspot.de/

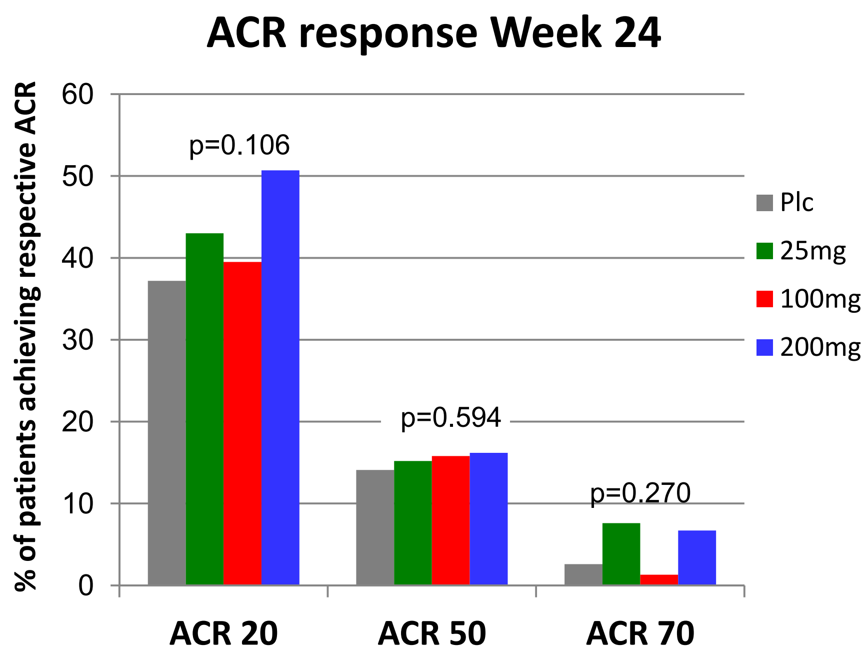
Civacir® – next steps

- Completing phase III trial
- Evaluation of remaining market potential
- Assess Partnering

Update Monoclonal Antibody Projects

Tregalizumab (BT-061) – Status and Next Steps

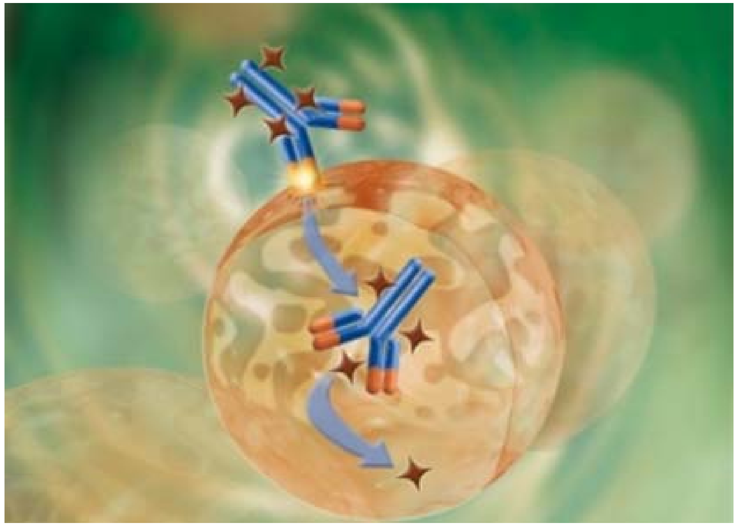




- BT-061 was biologically active but did not translate into medical benefit
- Preclinical studies will be performed in other indications and form the basis for a partnering process

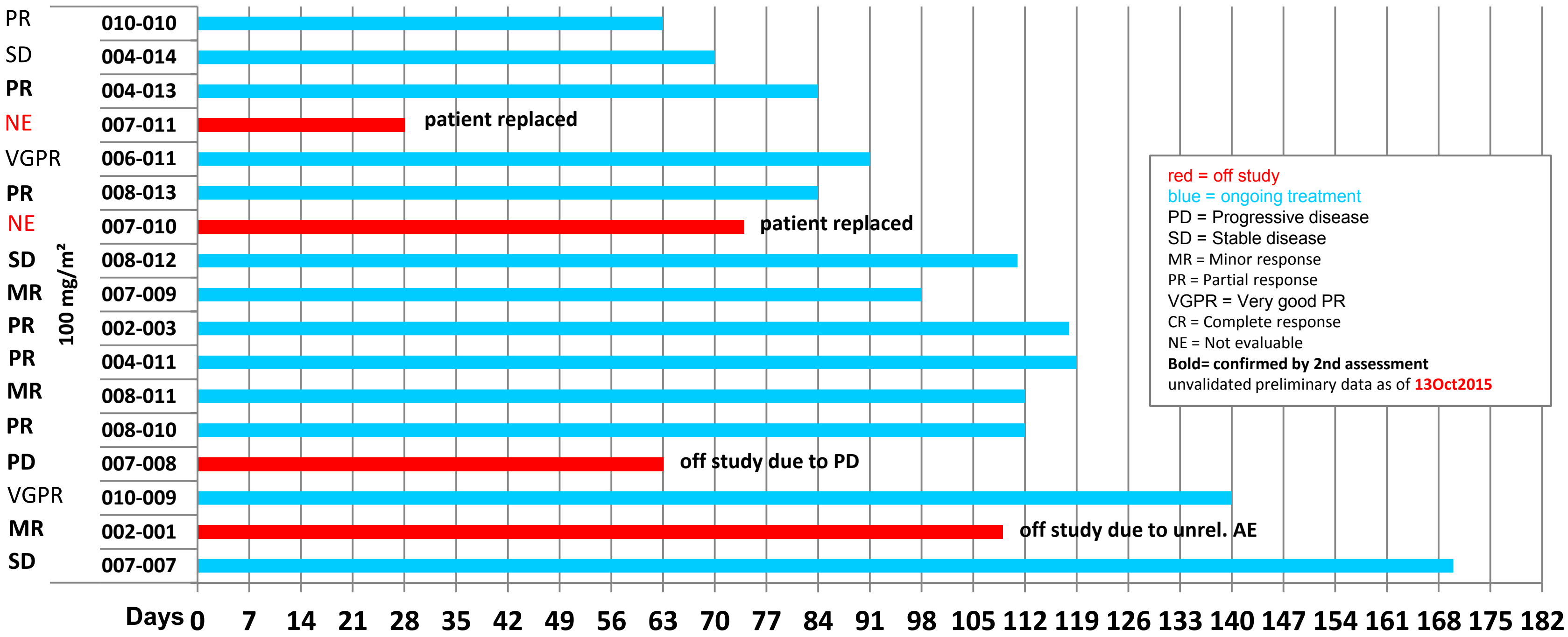
ACR = American College of Rheumatoloy Congress
Plc = Placebo
BT-061 final data presented at ACR on 8 November 2015

BT-062: Indatuximab Ravtansine - Overview



- Antibody Drug Conjugate (ADC), an innovative therapy approach for the treatment of multiple myeloma
- Combination of antibody and cytotoxic agent targets cancer cells
- Combination of efficacy and tolerability
- Multiple myeloma: all patients recruited, treatment ongoing; final study data expected in 2016
- Solid tumours: breast and bladder cancer; Phase I completed, recruitment in Phase II part ongoing

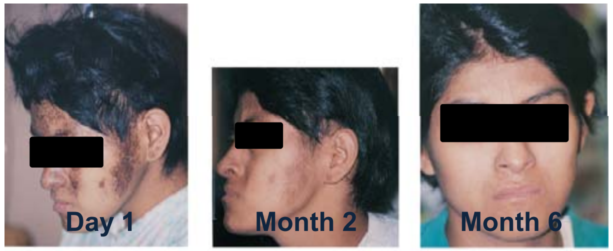
BT-062 Phase I/IIa Study No. 983 in Multiple Myeloma
Results of BT-062 with Pomalidomide / Dexamethasone



- A total of 17 patients were enrolled
- 13 patients are on treatment without progressive disease

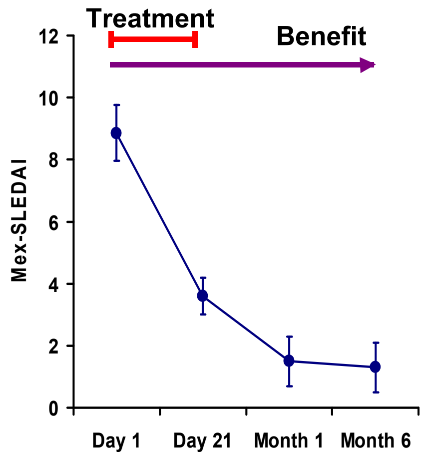
BT-063 in Systemic Lupus Erythematosus (SLE)

1. Efficacy Signals from a pilot study



Evolution of discoid lupus following administration of the anti–interleukin-10 monoclonal antibody in 1 patient

- 6 steroid-dependent SLE patients
- **Treatment:** 20 mg/day for 21 consecutive days
- **Benefit:** 6 months follow-up period



2. BT-063 Clinical Proof of Concept Study Phase IIa Study No. 990

Patients with moderate to severe SLE on stable medication with joint and cutaneous manifestations
Duration: 3 months treatment + 4 months follow up

12 patients, 50 mg

6 patients, Placebo

Interim Analysis

12 patients, XY mg

6 patients, Placebo

First data expected in 2H 2016

* Modified from Llorente et al., Arthritis & Rheumatism (2000)

Outlook & Summary

Profitable business with attractive R&D pipeline

Forecast 2015

- Low single digit sales growth 2015 vs. 2014
- Positive Q4 2015 EBIT of €5-10 m

Preliminary outlook

- Low single digit sales growth expected next year
- Profitability 2016 will be influenced by :
  - Additional requirements in quality and safety ~ €3-5 m
  - Biotest Next Level costs ~ €10-15 m
  - R&D monoclonal antibodies ~ €12 m
  - Unabsorbed costs for idle capacity ~ €8-10 m

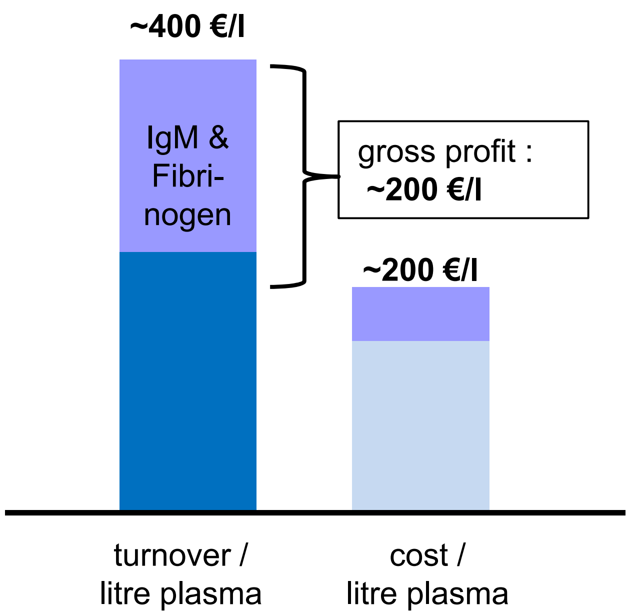
  Despite these factors profitability 2016 in a range of ~ €30 m

Profitable business with attractive R&D pipeline

Summary

- 2015 – very difficult business year
- Measures to strengthen profitability initiated
- **Focus of plasma protein business**
- Broadening of plasma product portfolio
- Adjustment of R&D programme
- Alliances / partnerships in R&D, manufacturing and marketing & sales

BNL production Biotest
=> 5 products out of 1 litre plasma



Contact
Financial Calendar 2016

Financial Calendar 2016

23 Mar 2016	FY Report 2015
10 May 2016	3M Report 2016
11 Aug 2016	6M Report 2016
10 Nov 2016	9M Report 2016

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