Biotest

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Biotest AG

Analyst Conference Q1-Q3 2016

Frankfurt, November 10, 2016

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 2016 at a glance

- Sales in Q1-Q3 2016 up by 9.0% to €455.6 m vs. €417.9 m in previous year period; Increase largely attributable to an increase in volume
- Q1-Q3 2016 EBIT increased to €26.1 m vs. -€82.0 m in the previous year
- Extraordinary tax and interest payment of €14.5 m for final settlement for Biotest AG with respect to business in Russia
- Opening of five plasma collection centres in the US (3) and Hungary (2) to date
- "Biotest Next Level" project is on track
- Guidance confirmed

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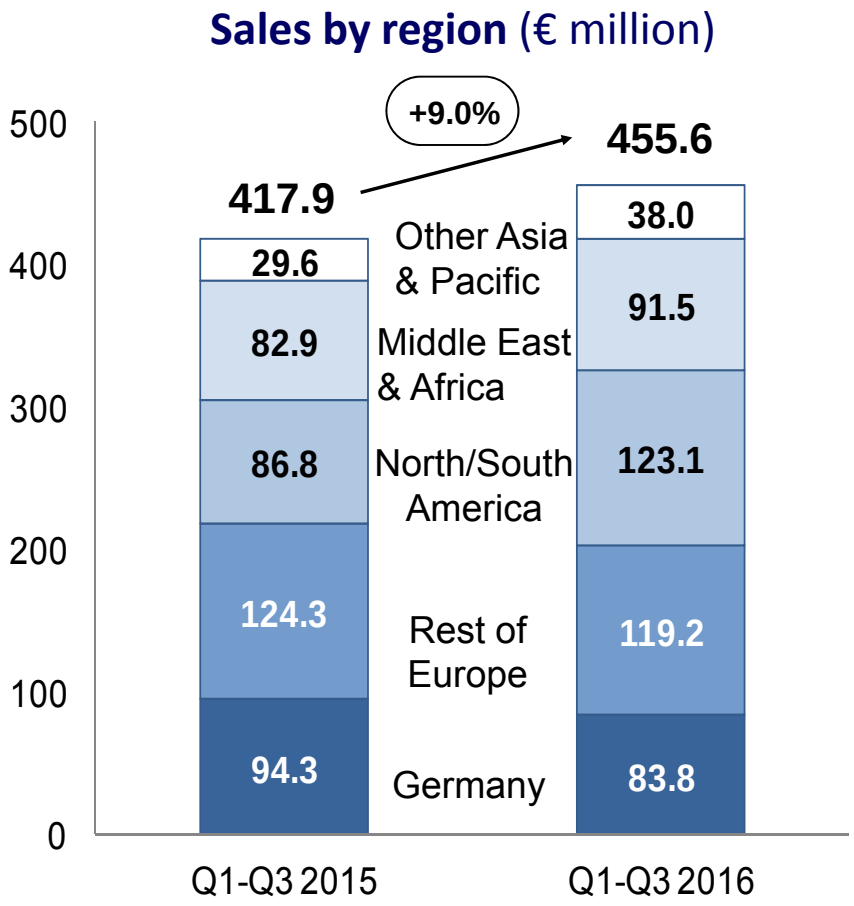
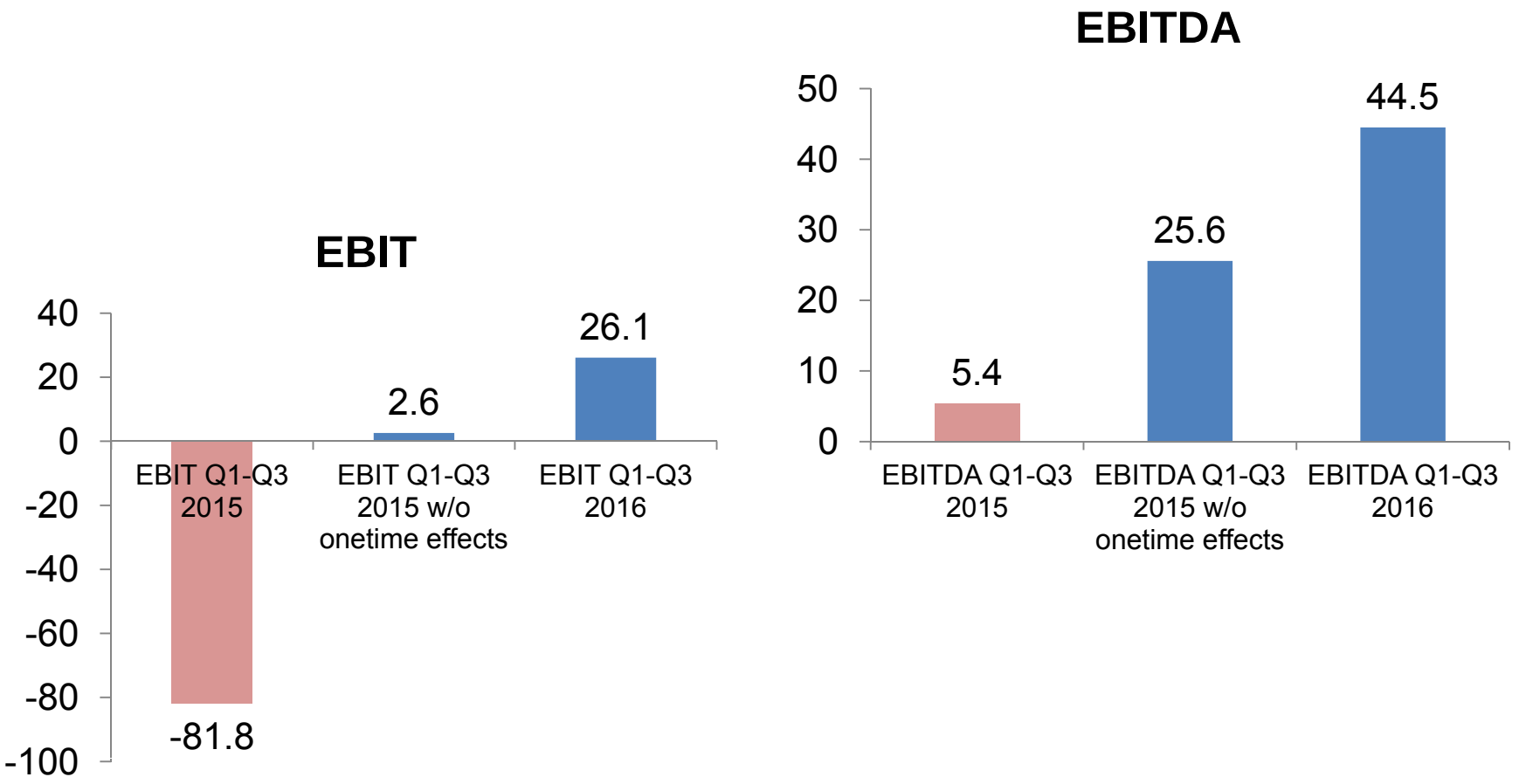
Financials – Q1-Q3 2016

Worldwide sales increases

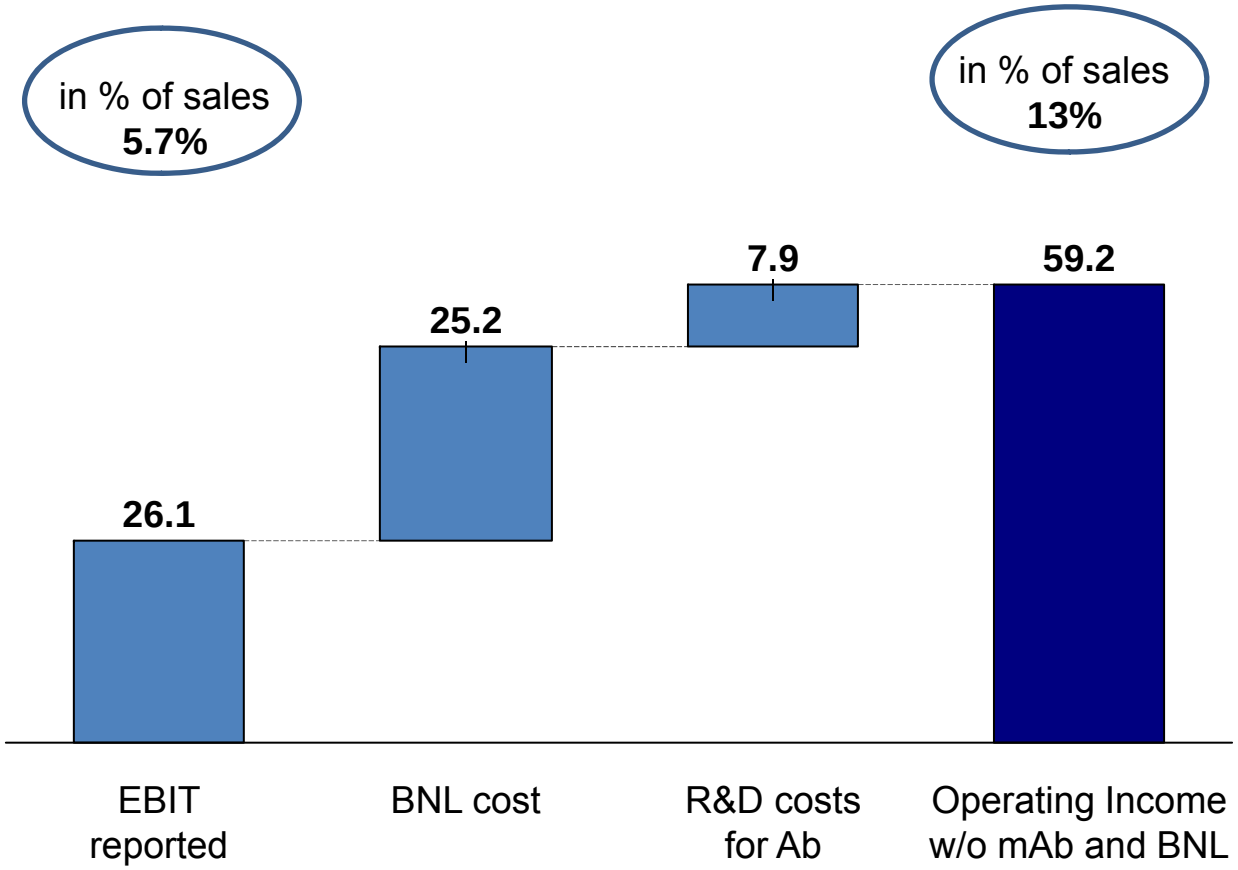


- Markets of North/ South America and Middle East & Africa and other Asia & Pacific made most significant contribution to growth
- Highest growth rates in the US with +43.5%
- Decrease in Germany due to one time effect of high plasma sales in previous year period

EBIT and EBITDA (€ million)



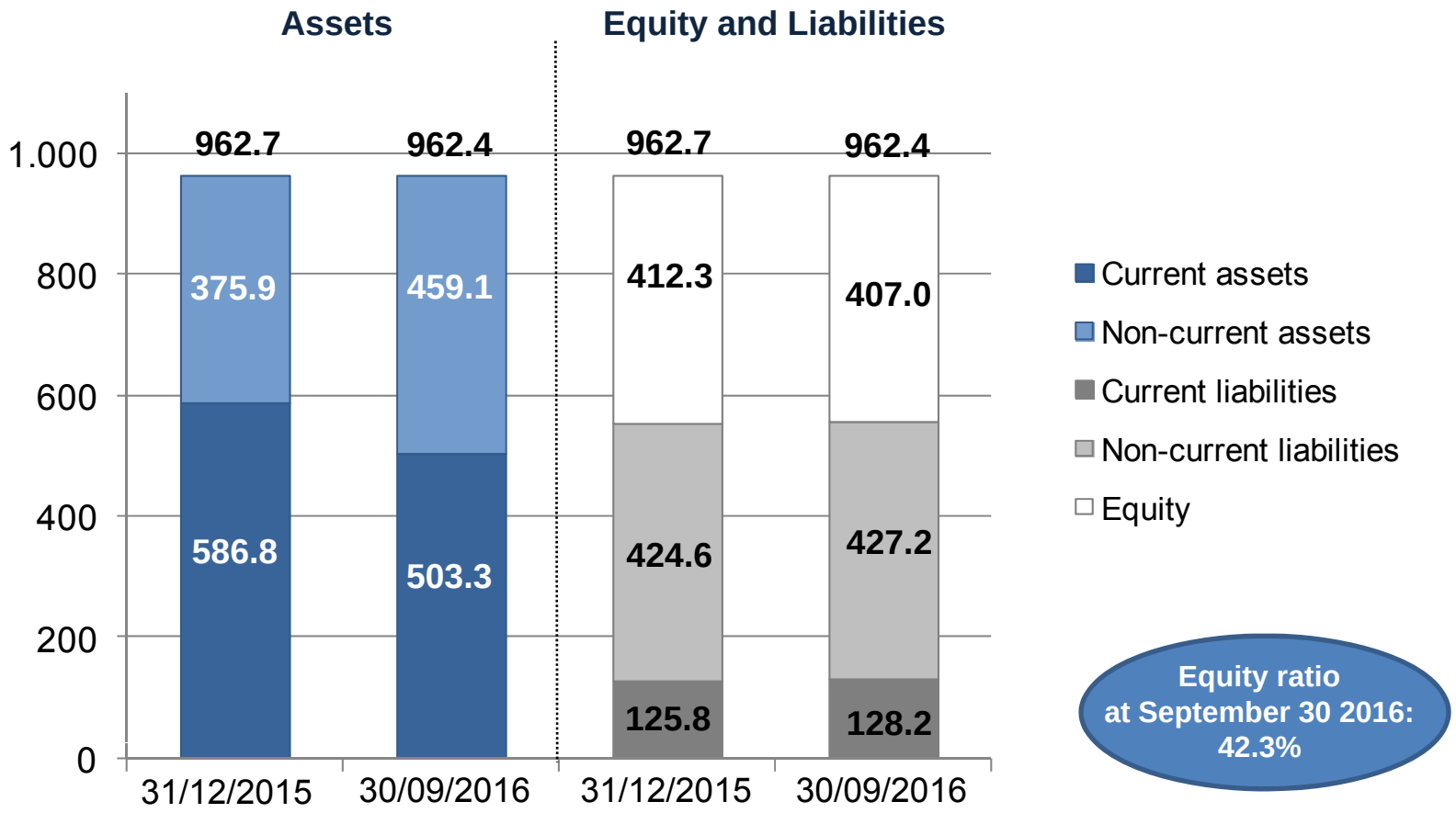
Reported EBIT significantly influenced by mAb and Biotest Next Level (BNL) (€ million)



mAb = monoclonal Antibodies

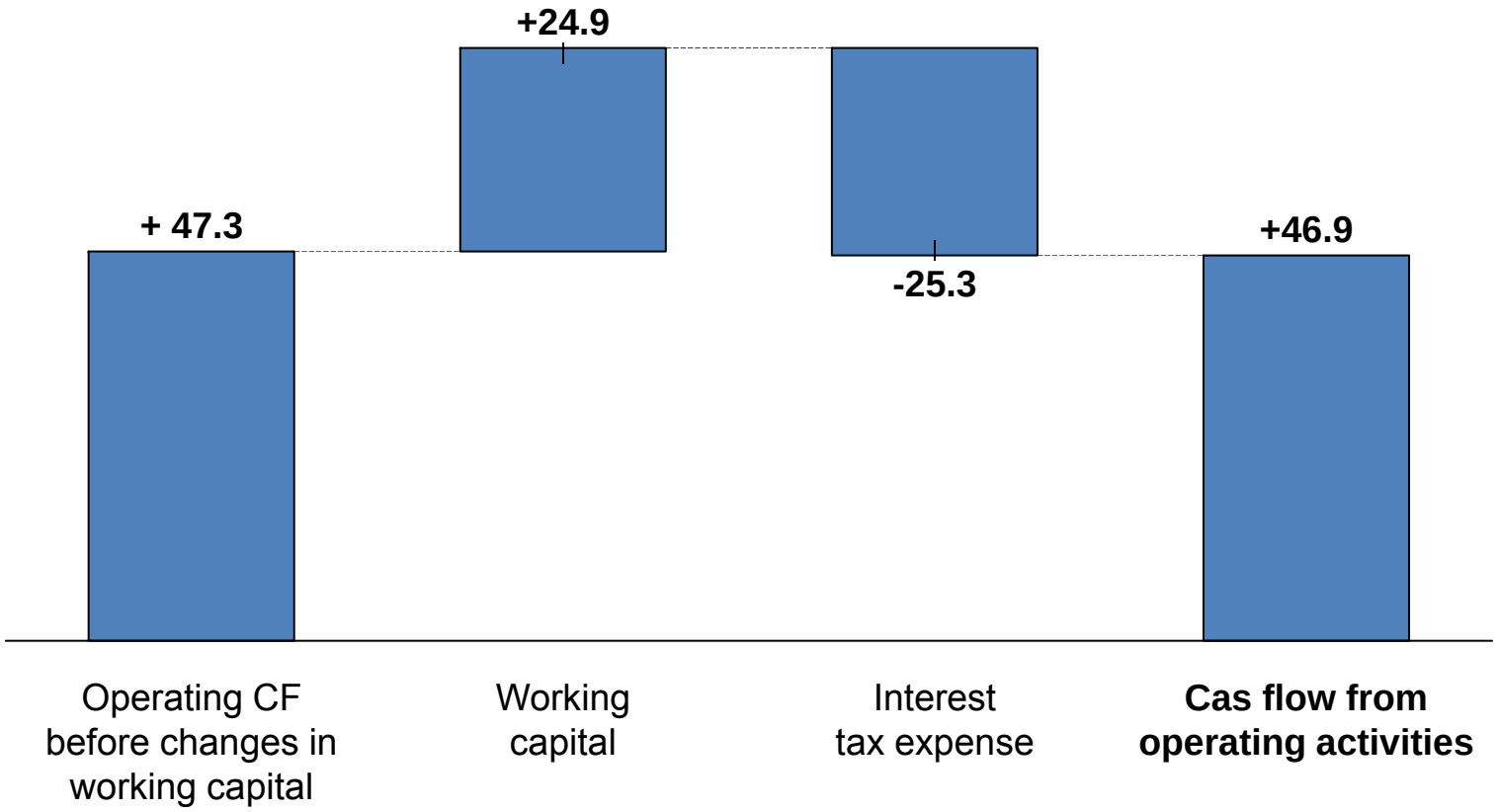
Financial position: strong equity base

Financial position of the Biotest Group (€ million)



Positive cash flow from operating activities

January – September 2016 (in € million)



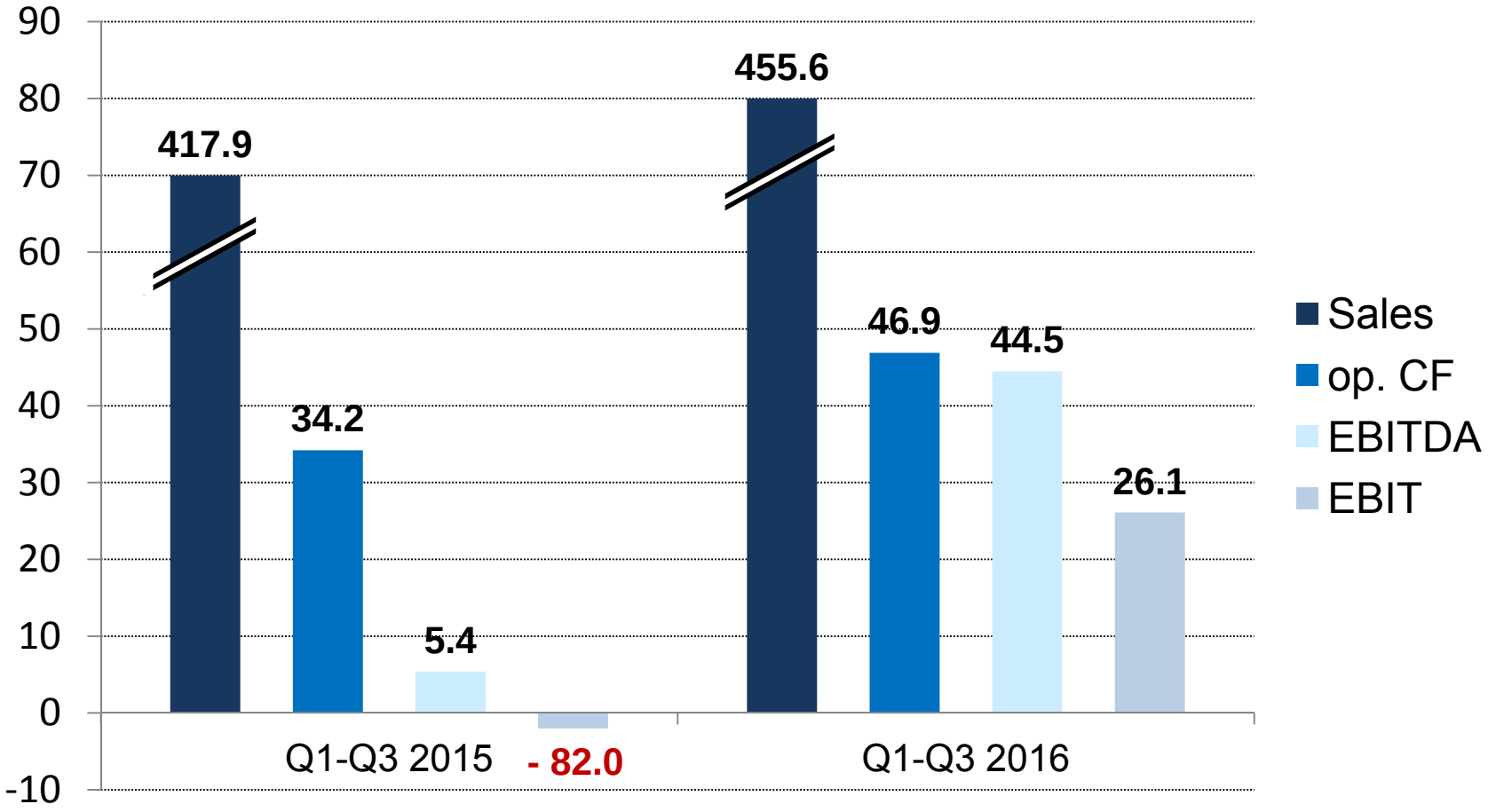
Cash flow from operating activities

January – September 2016 (in € million)

	Q1-Q3 2015	Q1-Q3 2016
Operating CF before changes in Working Capital	6.4	47.3
Cash flow from changes in Working Capital	43.4	24.9
Interest and taxes paid	-15.6	-25.3
Cash flow from operating activities	**34.2**	**46.9**

Positive development of key figures

Sales, operating Cash Flow, EBITDA, EBIT



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Update USA

Update BPC

- Kedrion Distribution & Commercialisation Agreement with BPC has a positive impact on business

- Bivigam® batches on risk:
  - Reduction of risk by € 3.5 million to € 6.5 million
  - In Q3 2016 some of the batches in question were inspected and approved within internal quality systems

- Opening of three plasma collection centres in the US

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Research & Development projects

Biotest product and R&D portfolio

BNL programme

- IgG Next Generation
- IgM Concentrate
- Fibrinogen
- Albumin

Early development

- Haemophilia A Therapeutic

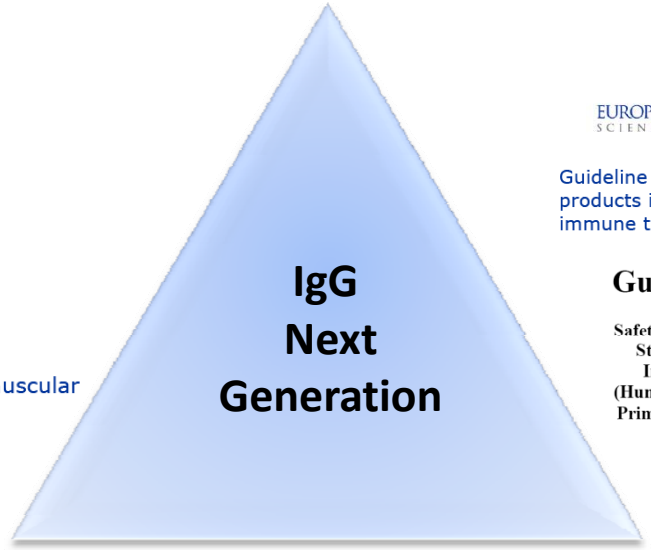
Partnering projects

- BT-061
- BT-062
- BT-063
- Civacir

First Patient treated in global pivotal trial with IgG Next Generation (IVIG)

Study 991 PID* ★ First patient in 11-2016

50 evaluable patients



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SCIENCE MEDICINES HEALTH

Guideline on core SmPC for human normal immunoglobulin for subcutaneous and intramuscular administration

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia

Guidance for Industry

Safety, Efficacy, and Pharmacokinetic Studies to Support Marketing of Immune Globulin Intravenous (Human) as Replacement Therapy for Primary Humoral Immunodeficiency

FDA

Study 993 CIDP* US** ★
under evaluation

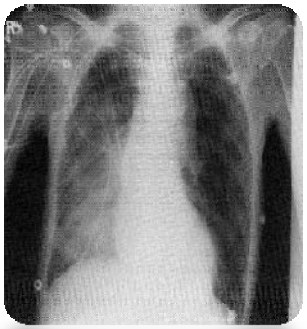
Study 992 ITP** ★
(Ideopathic Thrombocytopenic Purpura)
40 evaluable adult patients

*: Primary Immune Deficiency
**: Immune Thrombocyto Penia
***: Chronic Inflammatory Demyelinating Polyneuropathy

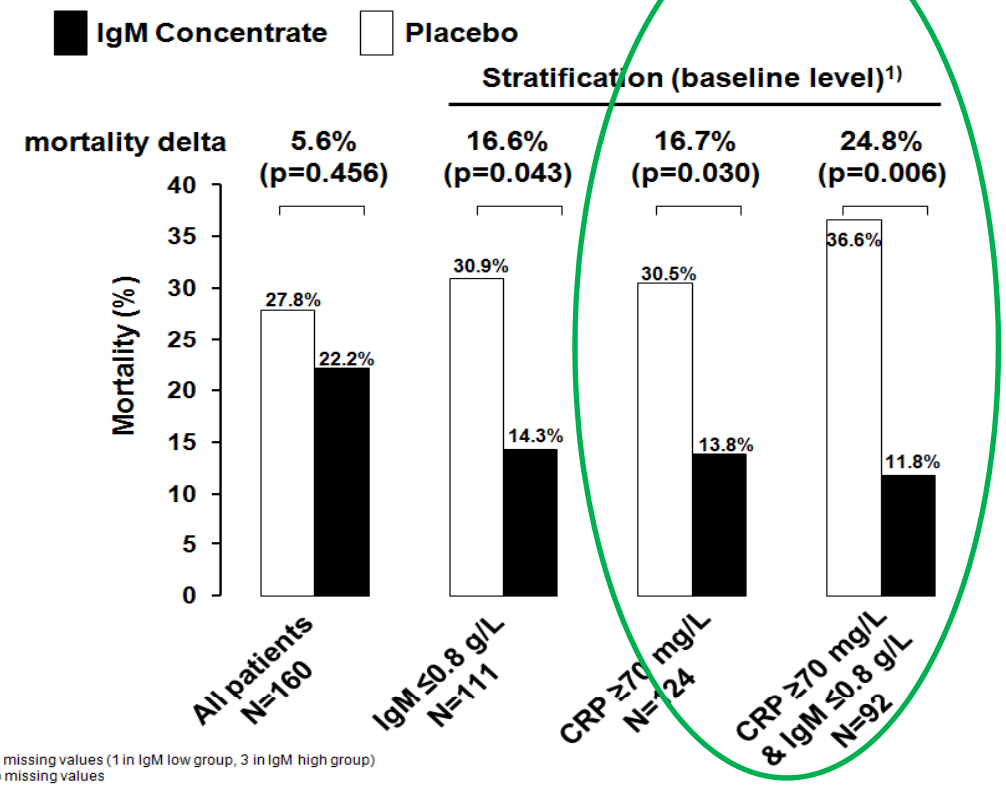
IgM Concentrate – preparation of phase III in sCAP

- Publication phase II results in preparation
- Phase III design in sCAP agreed with FDA and PEI

Phase III selected patient population



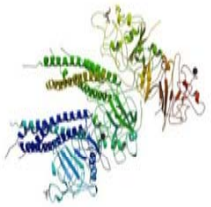
Chest radiograph[3]



*: sCAP: severe Community Acquired Pneumonia

CRP baseline: 4 missing values (1 in IgM low group, 3 in IgM high group)
IgM baseline: no missing values

Fibrinogen



Fibrinogen:
Fibrinogen is a plasma-derived clotting factor for the treatment of acute haemorrhages due to congenital or acquired fibrinogen deficiencies

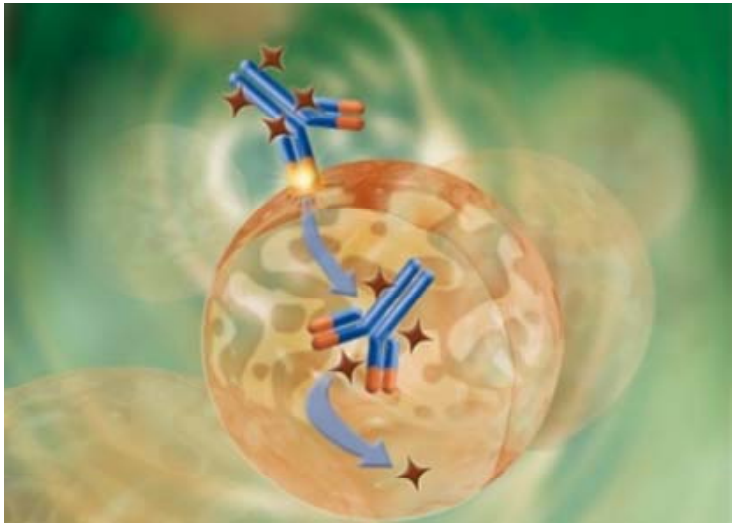
Congenital Fibrinogen Deficiency

- Phase I/III study: phase III part approved and ongoing

Acquired Fibrinogen Deficiency

- Paul Ehrlich Institute (PEI) supports Biotest concept of phase III study
- Phase III in acquired fibrinogen deficiency planned to start in 2017

BT-062 Indatuximab Ravtansine
Overview

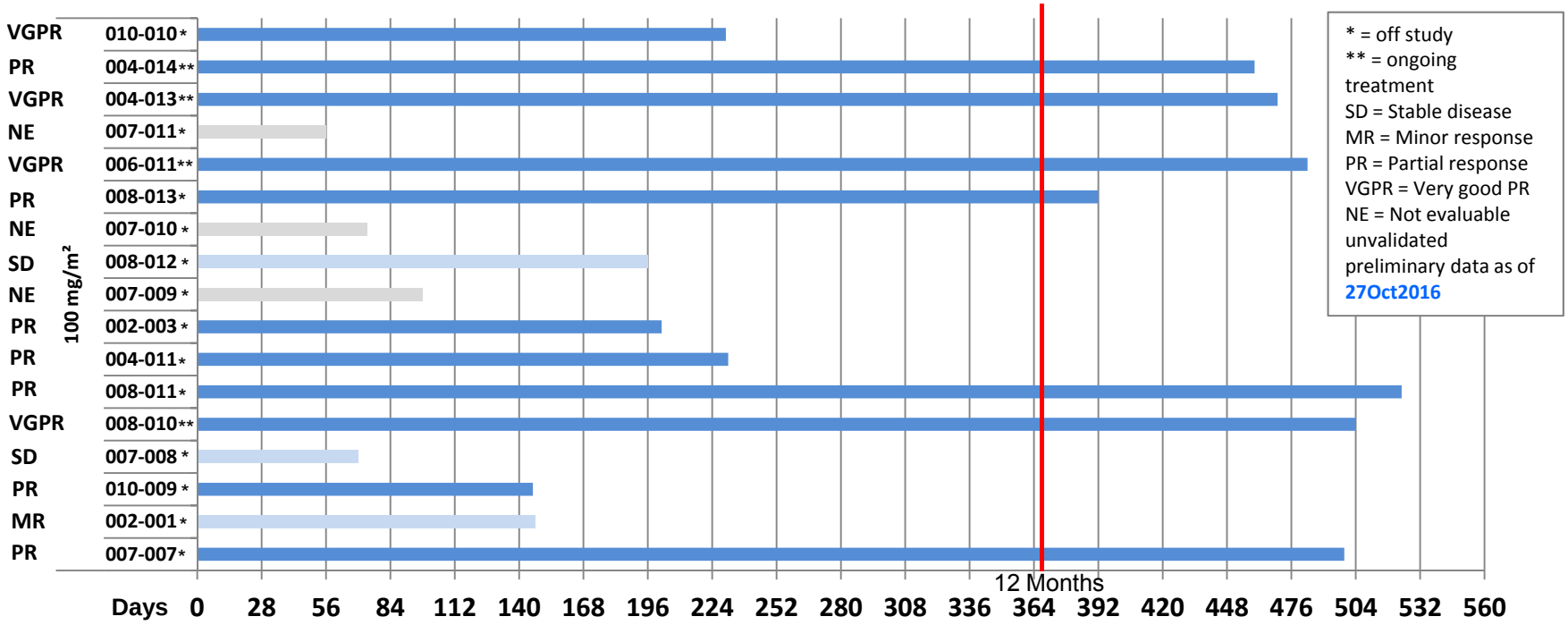


- Antibody Drug Conjugate (ADC), an innovative therapy approach for the treatment of multiple myeloma
- Combination of antibody and cytotoxic agent targets cancer cells
- Combination of efficacy and tolerability
- Multiple myeloma: all patients recruited, treatment ongoing; poster presentation of study at ASH* conference
- Solid tumours: breast and bladder cancer; phase I completed, phase IIa study ongoing

* ASH = American Society for Haematology, Dec 3-6 , 2016 in San Diego, USA; abstract online since Nov 3, 2016

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; Data at ASH*
- 3 patients were not evaluable for response (less than 2 complete treatment cycles)
- 11/14 = 79% showed an objective response (≥ PR) to treatment
- 7 patients without progressive disease for more than 12 months

* ASH = American Society for Haematology, Dec 3-6 , 2016 in San Diego, USA; abstract online since Nov 3, 2016

Indatuximab Ravtansine (BT-062)

Solid Tumor Study no. 989 ongoing - current status

Study design:

Indications: Triple negative breast cancer and advanced bladder cancer

Objectives/ design: To evaluate pharmacokinetic, safety and anti-tumor activity of Indatuximab Ravtansine (BT-062) in selected solid tumor indications

- Phase I: Dose escalation to maximum tolerated dose (MTD)
- Phase IIa: Treatment of patients at selected dose level.

Current status:

- Maximum tolerated dose has been identified and 39 patients were enrolled and treated
- No additional patients required to evaluate safety and anti-tumor activity of BT-062. Relevant authorities had been notified that the recruitment of patients would not be continued

Next steps: As soon as the study is finalized and evaluated Biotest will report results

Interim analysis supports continuation of phase IIa trial in SLE* with 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

Study endpoints:

- Primary: Incidence of adverse events, changes of safety parameter
- Secondary: Improvement of joints, improvement of skin, SLEDAI**

Status:

- The Data Safety Monitoring Board (DSMB) recommends the continuation of the study based on interim analysis from part I of the study.

*: SLE = Systemic Lupus Erythematosus
** SLEDAI: SLE Disease Activity Index

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Biotest Next Level

On track in terms of timeline and budget (October 2016)

Biotest Next Level - construction works on track

- Building shell is completed
- Interior fitting/ work (clean-rooms, laboratories, cold-rooms, doorways etc.) are about to be completed
- Technical installations (power, heating, air-conditioning, water/ waste water) as well as media supply (e.g. compressed air, pristine steam/ vapor, heating/ cooling medium) is currently being commissioned. In parallel the qualification of operations is ongoing
- Installation of process equipment has started

Biotest Next Level
Impressions from inside (1)

Biotest Next Level
Impressions from inside (2)

Guidance 2016 confirmed

Sales: In the financial year 2016 sales will grow in a low single-digit percentage range

EBIT: EBIT in the range of € 33-35 million

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Financial Calendar 2016 / 2017
Contact

Financial Calendar 2017

30 Mar 2017	FY Report 2016
10 May 2017	Annual Shareholder Meeting
10 May 2017	3M Report 2017
14 Aug 2017	6M Report 2017
14 Nov 2017	9M Report 2017

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