Biotest

From Nature for Life

Biotest AG

Company Presentation

January 2015

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
- 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
- Ongoing Civacir® Phase III study shows promising data in re-infection in liver transplantation patients
- Recruitment of patients for study "Treat 2b" (BT-061) in Rheumatoid Arthritis completed
- Biotest "Next Level" project is on track
- Marketing authorization granted for Albiomin 20% in China in Oct. 2014

Biotest Group

- Headquarter in Dreieich/Germany (Frankfurt area)
- Subsidiaries in 11 countries worldwide
- Employees (FTE)*: 2,137
  Thereof 59% located outside Germany
- Founded in 1946, IPO in 1987, SDAX in 2007 (preference shares)
- Biotest shares:
  - 6,595,242 ordinary shares
  - 6,595,242 preference shares

Headquarter, Dreieich

*: as of Sept. 30, 2014

Shareholder structure

Biotest AG

Ordinary shares: 6.6 mio
with voting rights

OGEL GmbH*:	**50.03%**
KSK Biberach*:	**~19.95%**
Free Float:	**~30.02%**

50.0% of total capital,
and 100% of voting rights

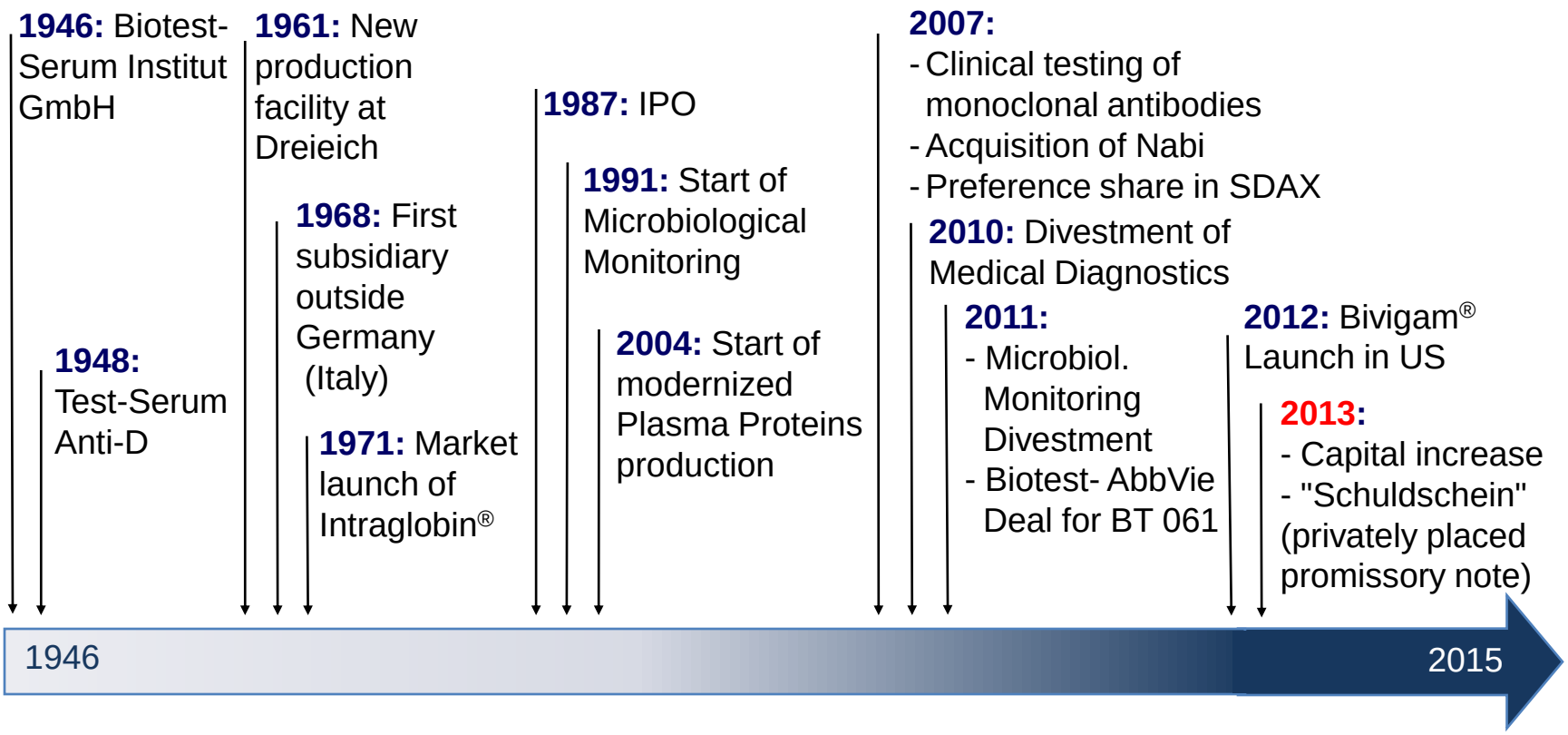
Preference shares: 6.6 mio
no voting rights, but higher dividend

Free Float: 100%

50.0% of total capital,
0% of voting rights

* as of January 2015 based on notifications

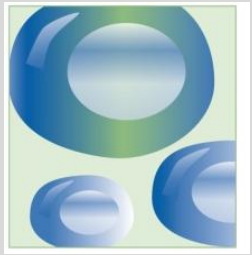
Biotest: History and milestones achieved



Focus of Biotest

Biotest is a pharmaceutical company which develops, produces and sells **biological medicinal products**, that are either obtained directly from human plasma or manufactured using biotechnological methods.

Haematology

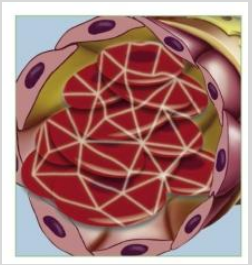


Diseases of the blood and blood-forming system

Clinical Immunology

Disorders of the immune system

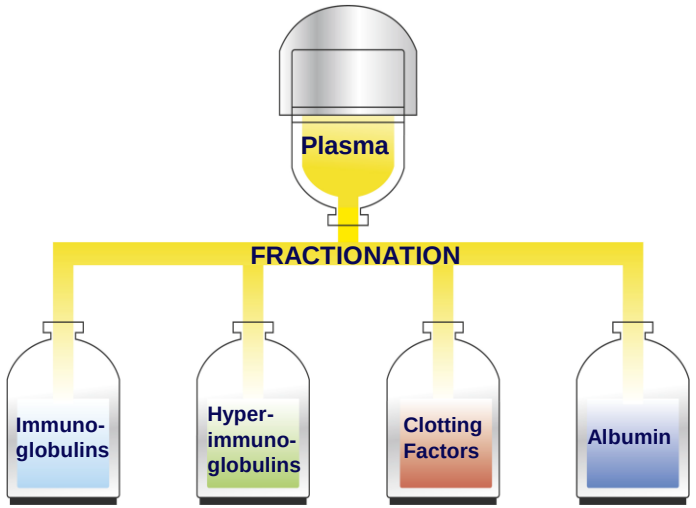
Intensive Care Medicine



Acute, mostly life-threatening diseases

Plasma Proteins business at a glance

Biotest Plasma Protein products



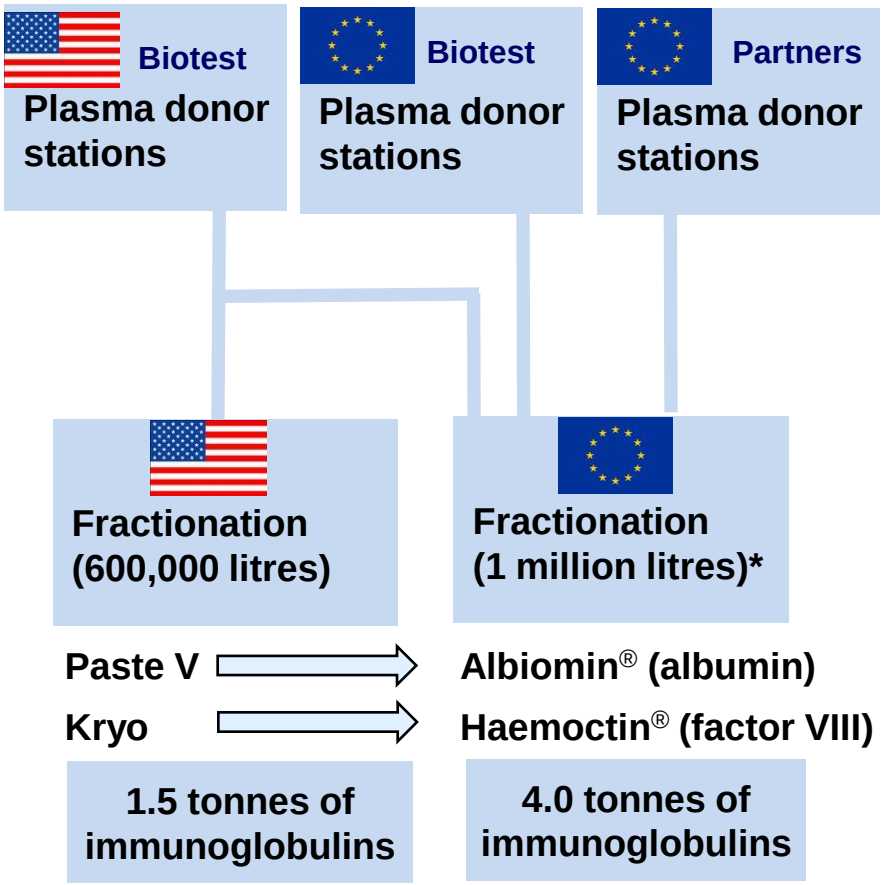
Intratect® Pentaglobin®	Hepatect® Cytotect® Varitect® Zutectra® Nabi HB	Haemoctin® Haemonine®	Human-Albumin Biseko
Infections, immune deficiencies	Hepatitis Cytomegaly Varicella	Blood coagulation defects	Albumin and protein deficiencies

- Intratect® (IVIG) market share in (GER+ AUT+ CH) = ~ 12%
- World market leader with Cytotect® and Varitect®
- Leading position with Hepatect® in Europe and Nabi HB™ in USA
- Biotest covers full value creation chain: plasma sourcing, production, distribution

➡ vertical integration leads to rationalisation and higher productivity

= Biotest products = lead indications

Plasma Proteins – Efficient production network



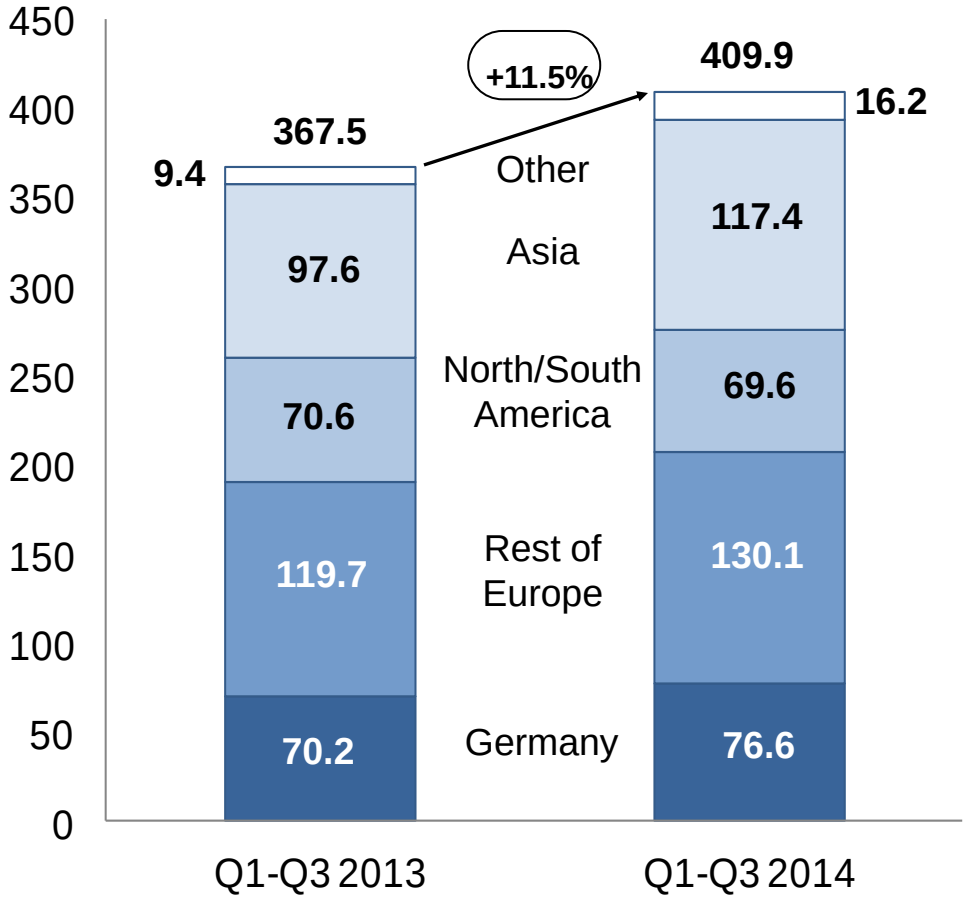
- 27 plasma collection centres
- Level of self-sufficiency: 60% for standard plasma
- Exchange of intermediate products from US to Europe from 2014 onwards
- Network increases EBIT margin

* Production in Dreieich and capacities at partners

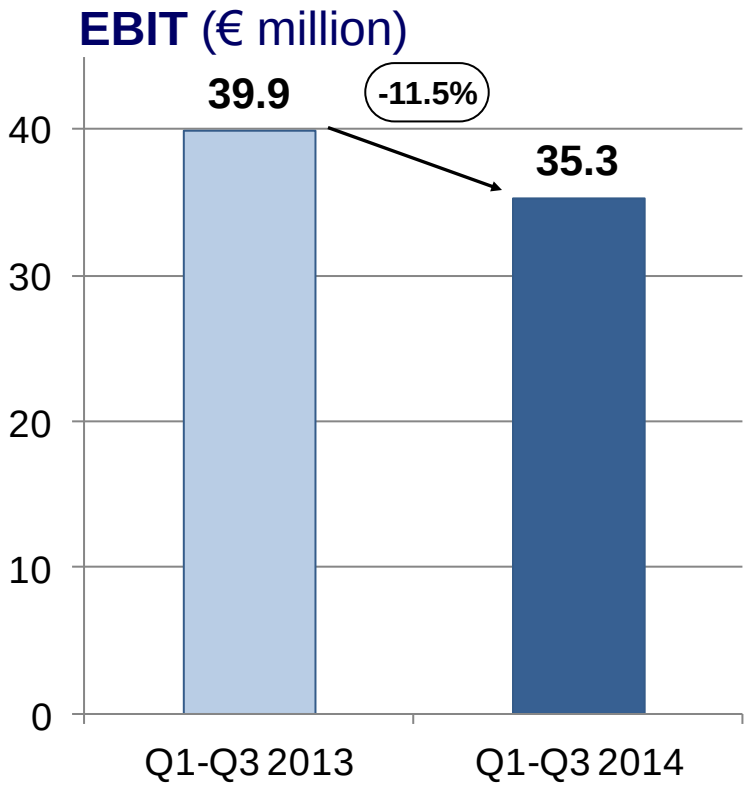
Financials Q1-Q3 2014

Sales growth much stronger than expected

Sales by region (€ million)



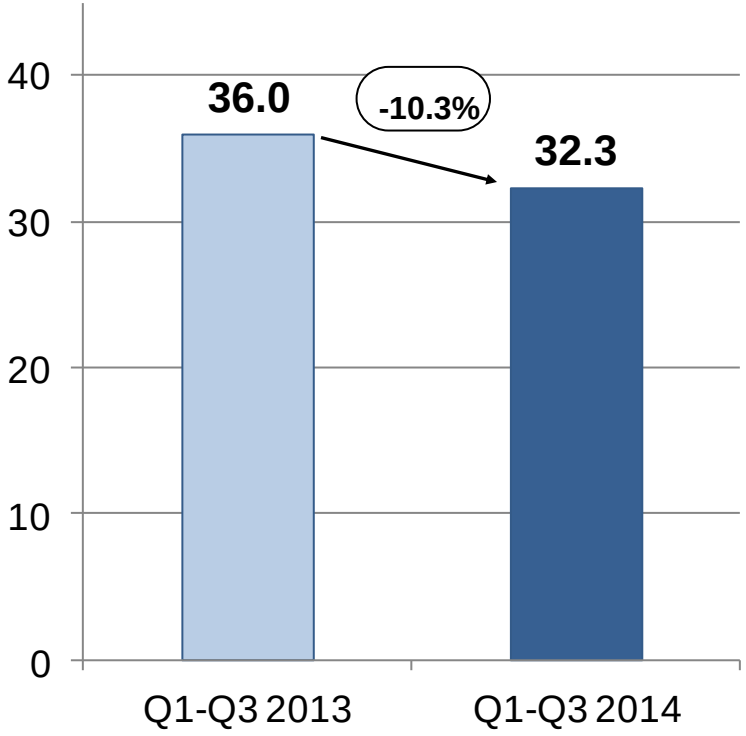
EBIT decrease



- Increased costs for clinical trail material of € 4.0 m for BT-061 and Civacir® 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

Earnings decrease

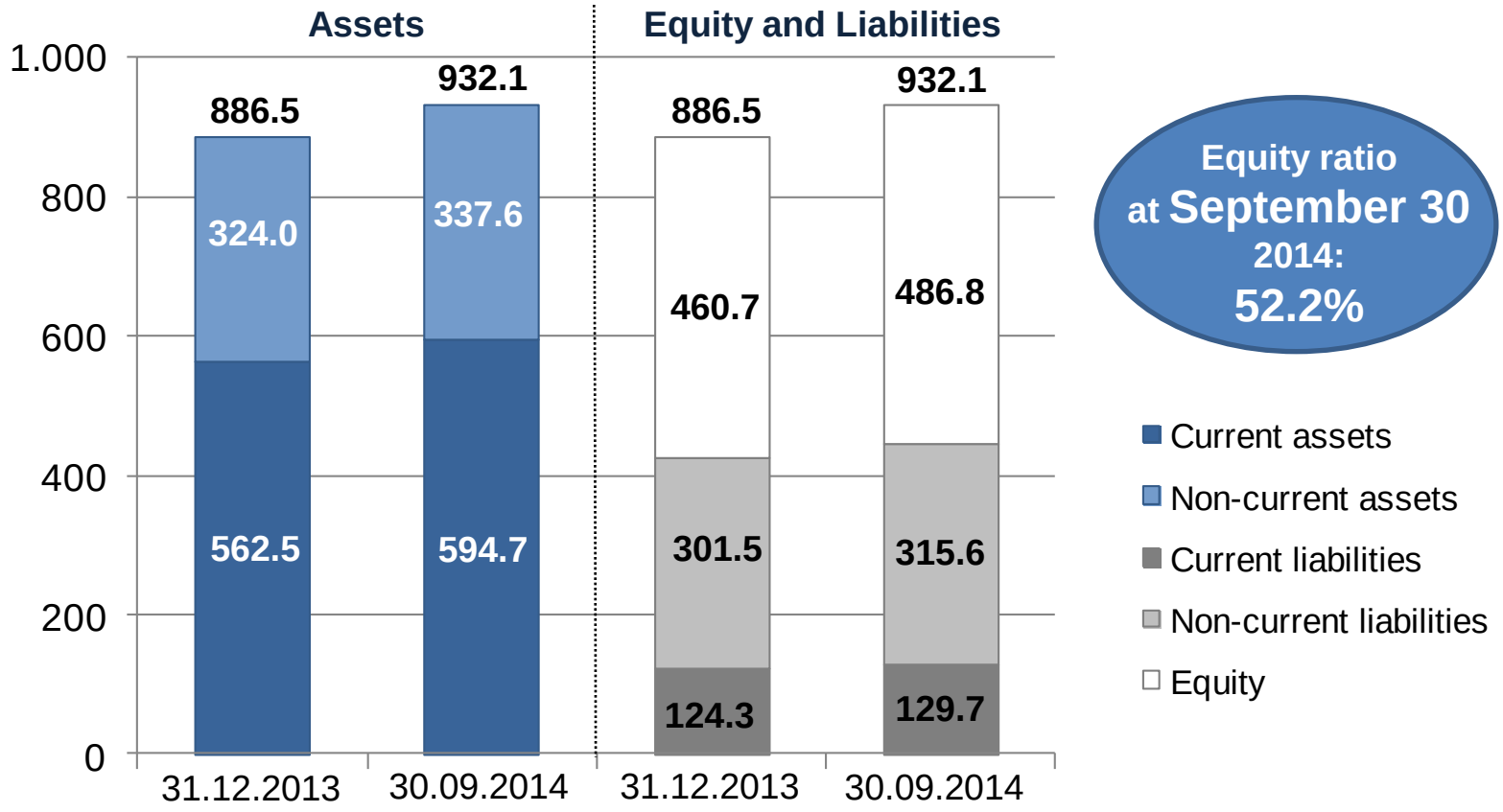
Earnings before taxes (€ million)



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

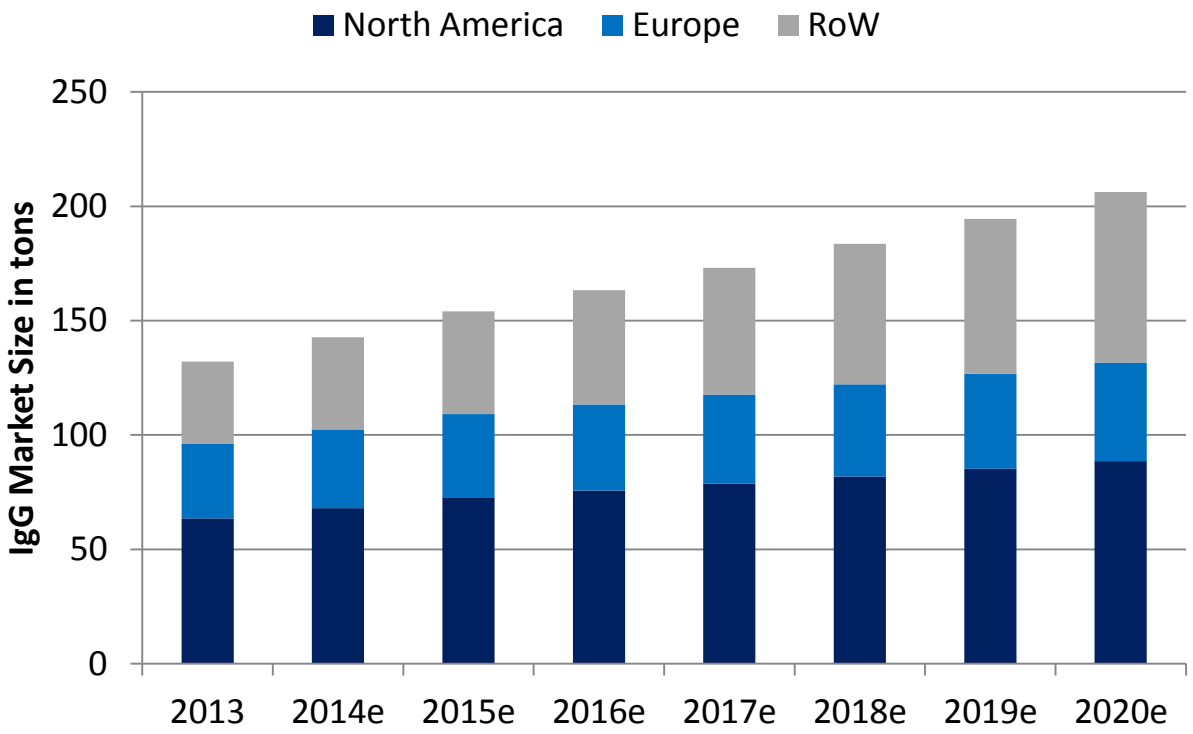
Financial position: strong equity base

Financial Position of the Biotest Group (€ million)



Strategy
Market environment

Global IgG (i.v. + s.c.) Market Forecast



Exp. Annual Growth CAGR 2014 – 2020e	
RoW	11%
Europe	4%
North America	5%
World	6%

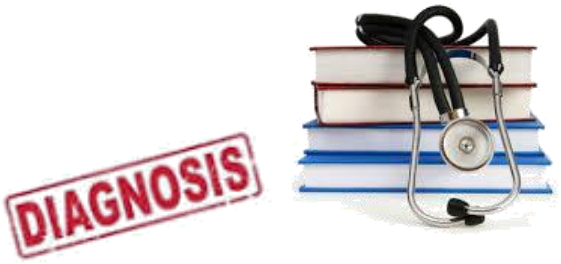
- The global IgG market is expected to grow to over 200 tons by 2018.
- Expected annual growth is highest in ROW countries.

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

Factors supporting growth of IgG and plasma products

Market expansion

- Improvements in wealth and therapy reimbursement
- Improving access to care

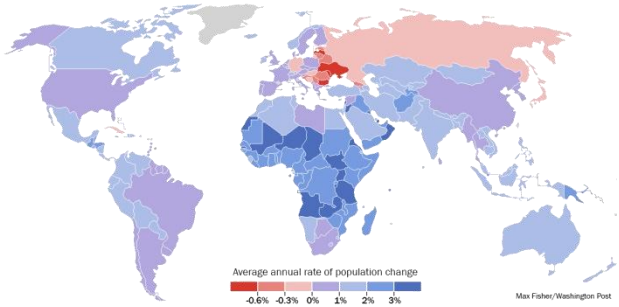


Physicians' Awareness

- Awareness of treatment options and indications still low
- Many patients are still undiagnosed

Demographic development

- Growth of population
- Weight gain



Indications / Usage areas

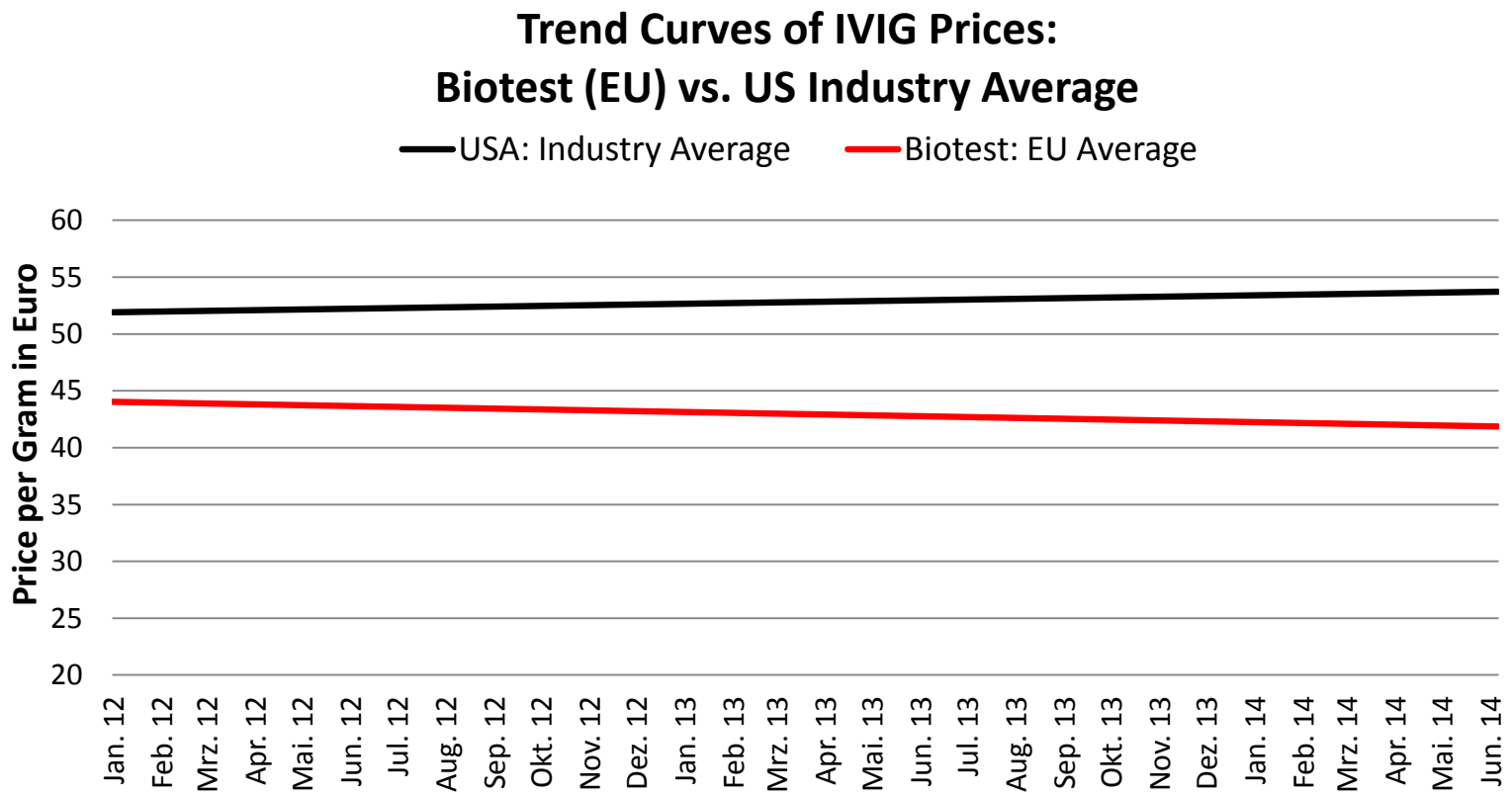
- Use of IgG in a broader set of indications
- Regular treatment of patients with chronic conditions

Per Capita Use 2014e

Region	IVIG (kg per million)	pd + re FVIII (IU per capita)
North America	177,9	7,8
Europe	45,9	4,0
RoW	8,7	0,6
Global	27,0	1,9

Source: Biotest Market Research (Basis: CIA Factbook, MRB 2013).
Country selection according to MRB market definition: 36 European countries, 44 RoW countries.

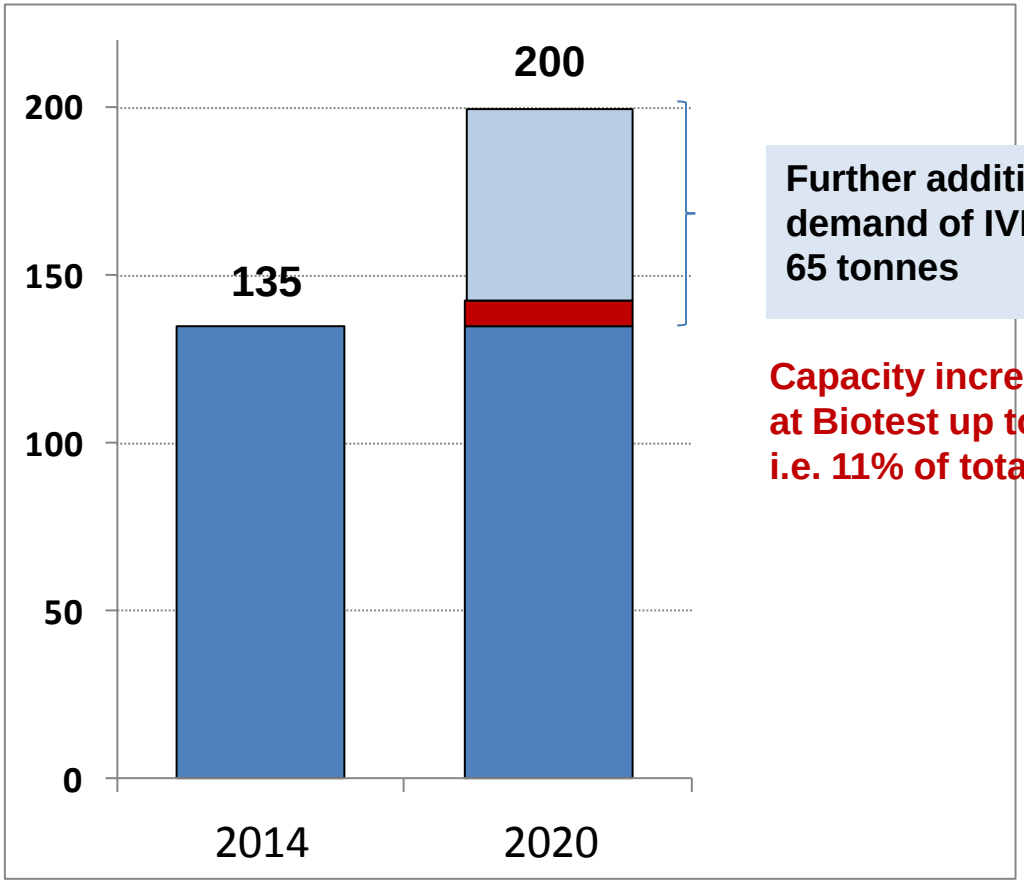
IVIG Price Trends (Jan. 2012 – June 2014)



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 market for immunoglobulins continues to grow

Global market volume for IVIG (tonnes)

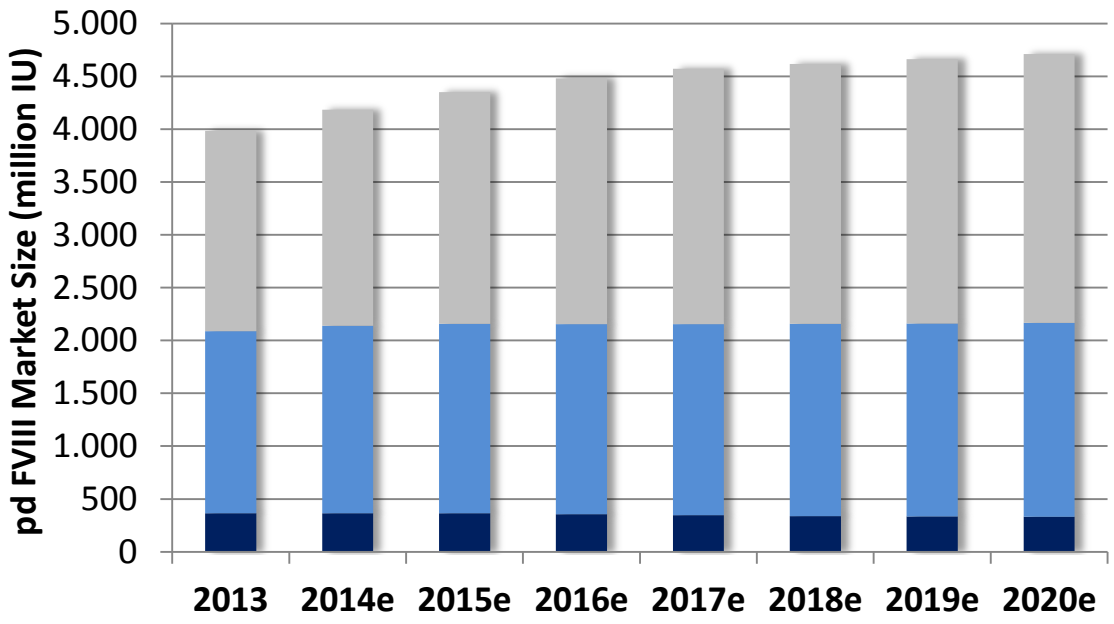


Further additional demand of IVIG up to 2020: 65 tonnes

Capacity increase at Biotest up to 2018: 7.5 tonnes i.e. 11% of total additional demand

Global plasmatic FVIII Market Forecast

Volume Perspective

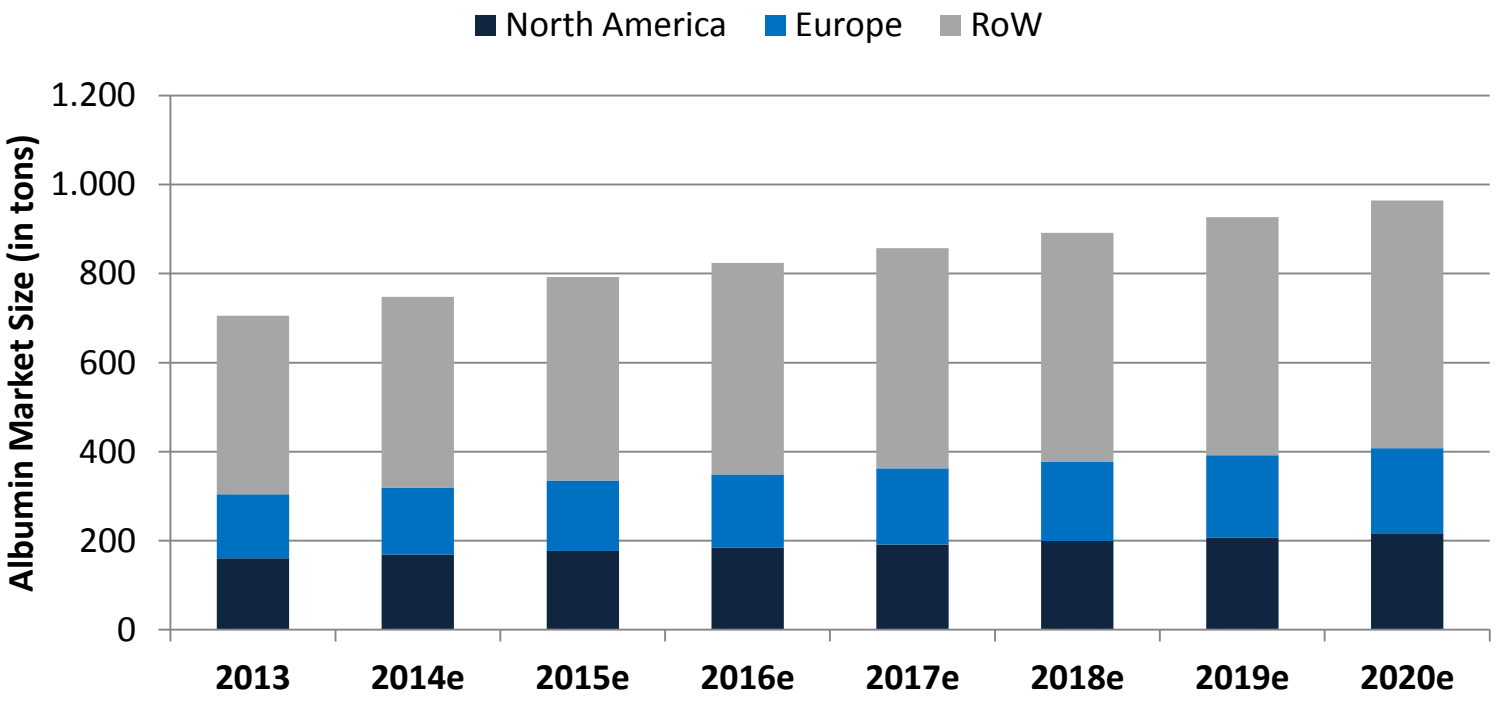


Annual Growth pd FVIII CAGR 2014–20e	
RoW	4%
Europe	1%
North America	-2%
World	2%

- 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

Global Albumin Market Forecast

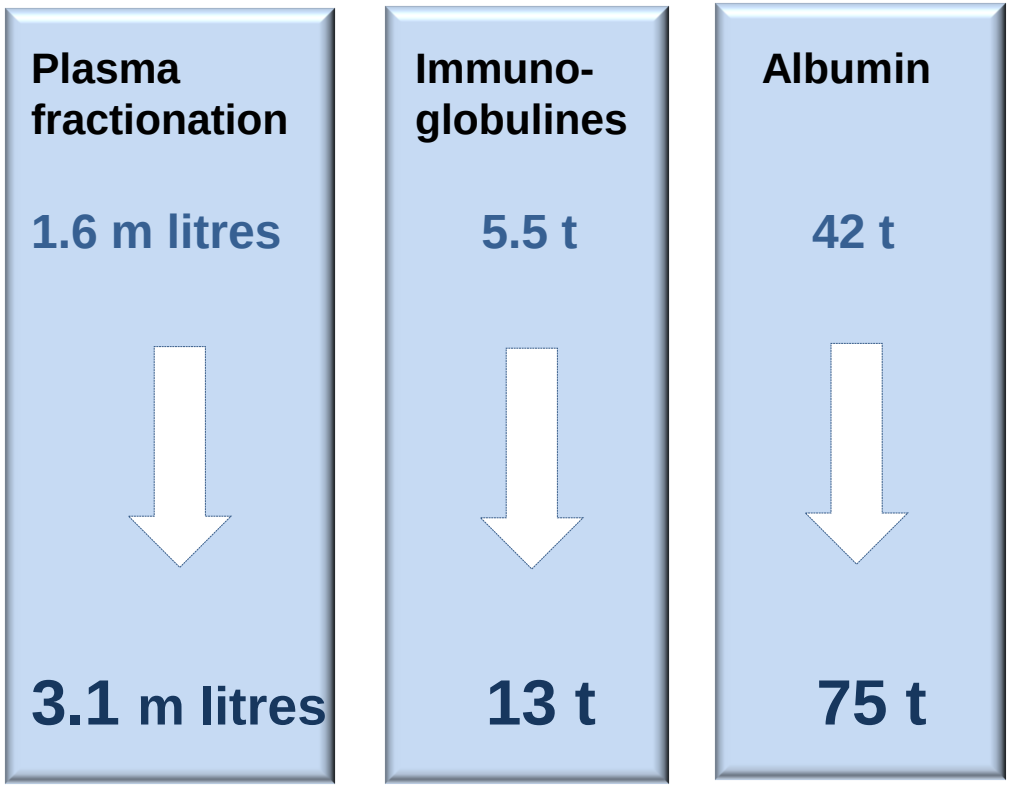


- The global Albumin market is expected to grow to ~965 t by 2020.
- This is equivalent to a global annual growth expectation of ~ 4% p.a. in the period between 2014 and 2020.

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

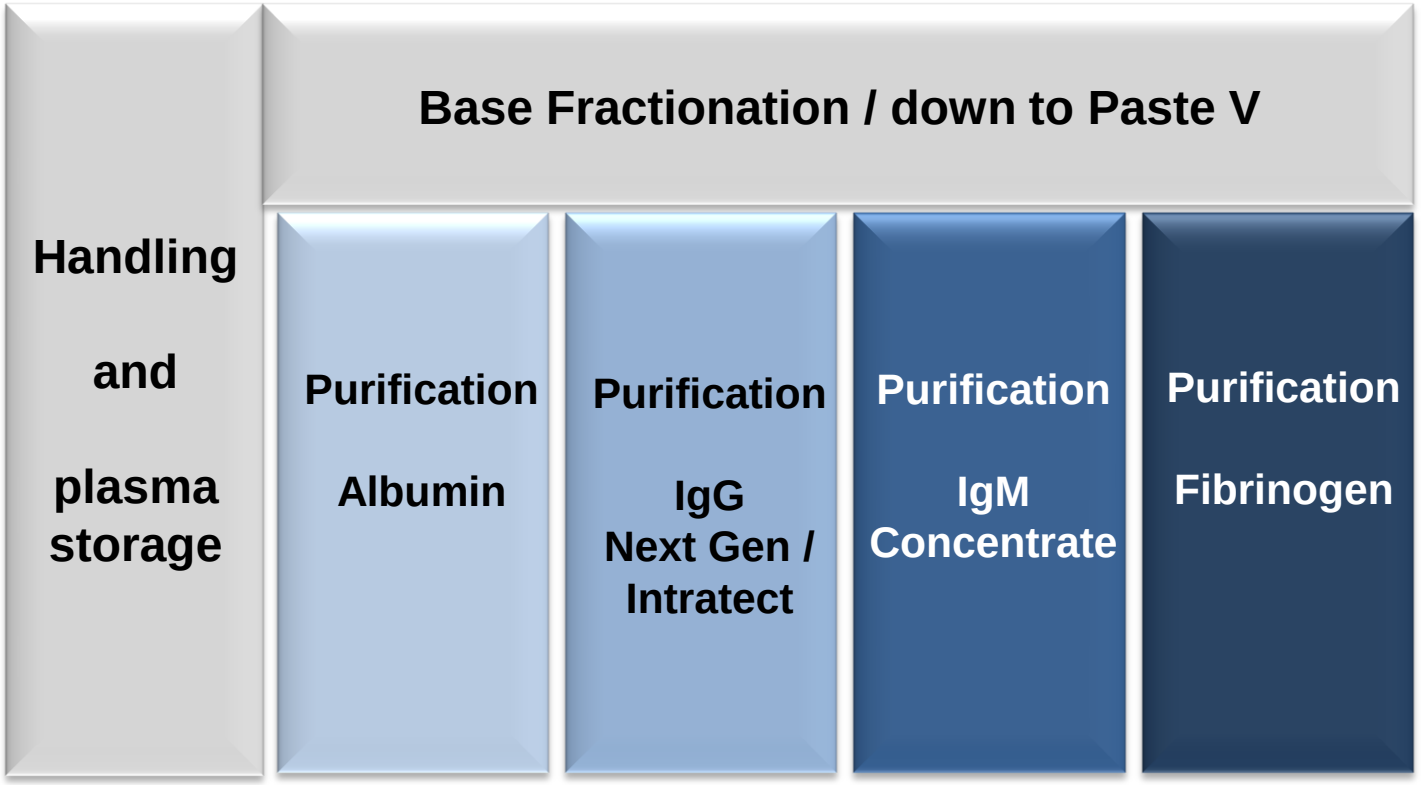
Biotest Next Level: Investments in growth

Increase in global capacity (p.a.) to:



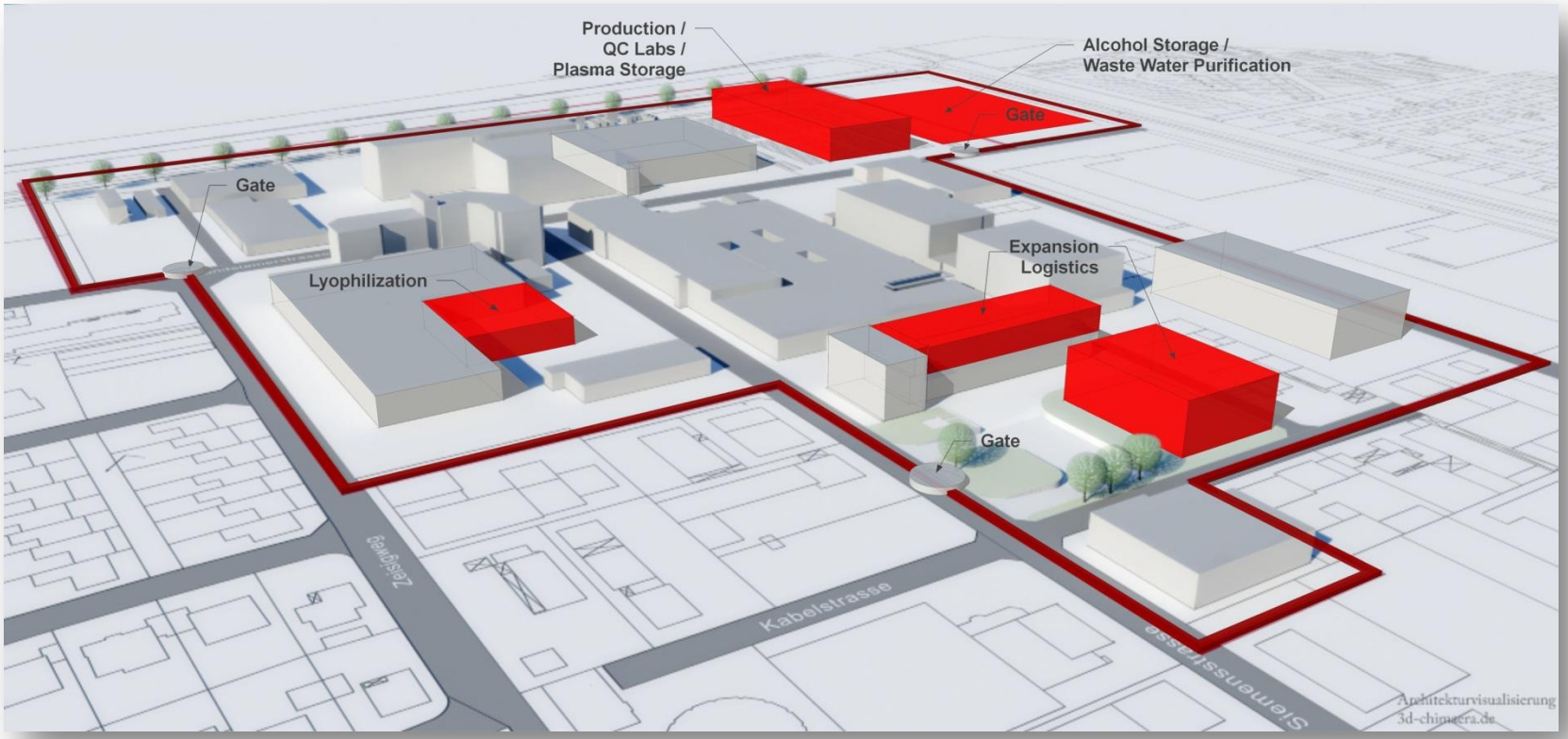
- Programme for increasing capacity at Dreieich
- Construction of new production facilities at the Dreieich location
- Period: 2013 to 2018
- Investment amount: > € 200 million
- More than 300 additional jobs

A modular approach for a production building

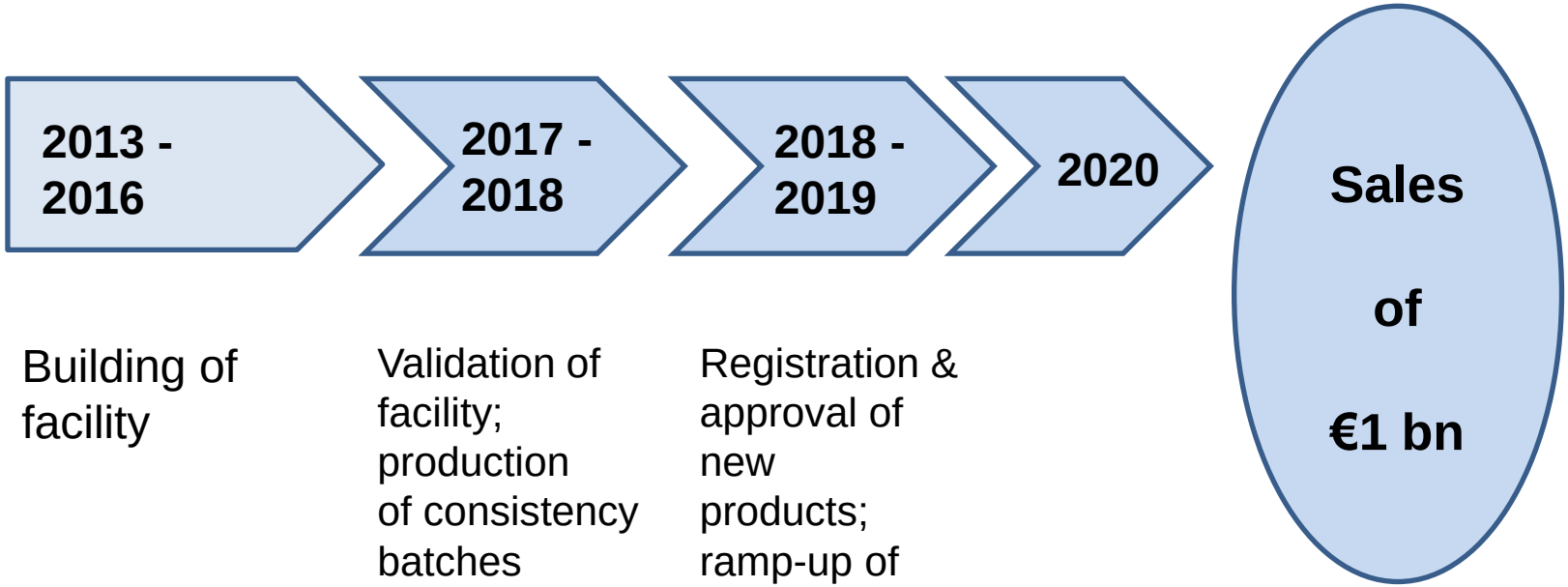


Building(s) and equipment will be implemented stepwise in connection with the progress of the development products.

Location of capacity expansion Dreieich



Timeline


2013 - 2016
2017 - 2018
2018 - 2019
2020
Sales of €1 bn
Building of facility
Validation of facility; production of consistency batches
Registration & approval of new products; ramp-up of production; first sales

"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:

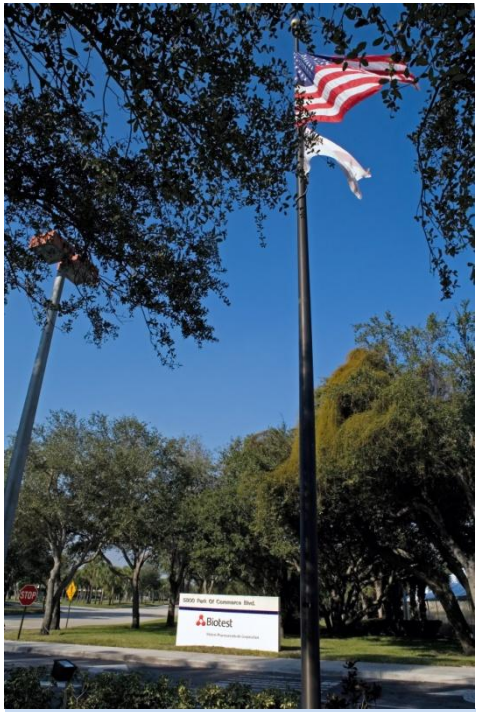
- Plasma goods receipt area
- Virological test laboratory

"Biotest Next Level": Production expansion advancing

- Basic engineering completed in Summer 2014
- Building application 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

KfW = Kreditanstalt für Wiederaufbau

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 increased 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

Biotest

From Nature for Life

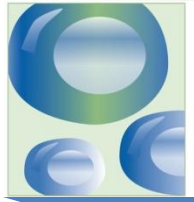
Innovation

Quality

Responsibility

Research & development

Biotest products and pipeline



Haematology

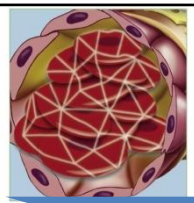
Haemoctin®
Haemonine®

Indatuximab
Ravtansine (BT-062)

Clinical Immunology

Intratect®
Hepatect®, Nabi-HB®
Zutectra®, Fovepta®
Cytotect®
Varitect®
Bivigam®

Civacir®
Cytotect 70 (BT-094)
Tregalizumab (BT-061)

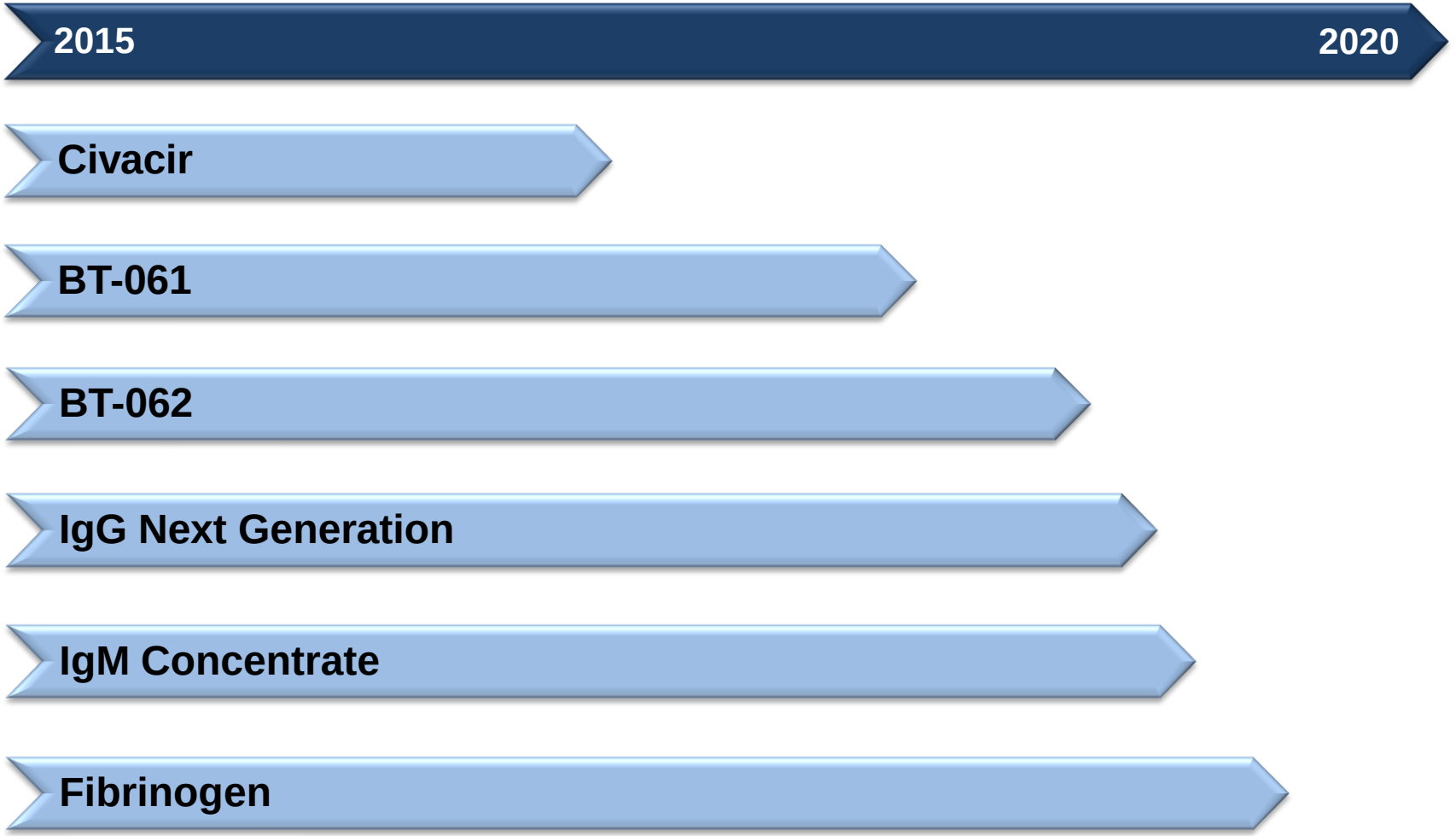


Intensive Care Medicine

Pentaglobin®
Humanalbumin
Biseko®
Cofact®

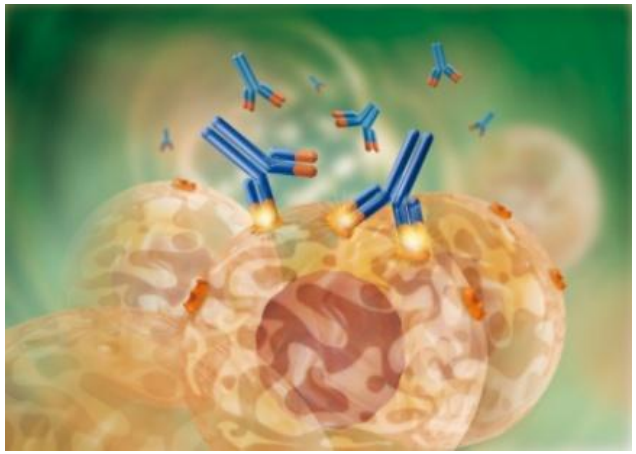
IgM concentrate
Fibrinogen

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

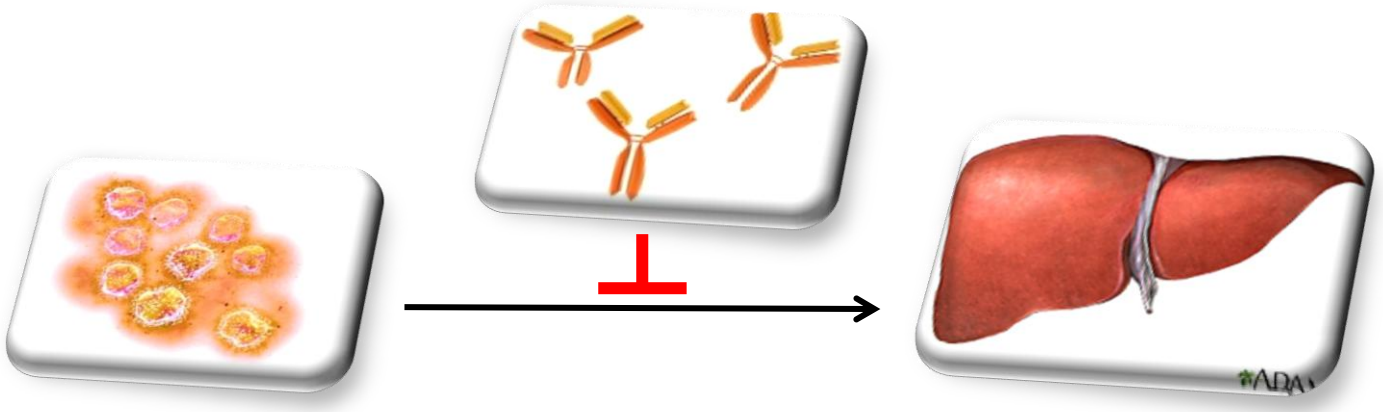
T cell **RE**gulating **A**rthritis
Trial **2b** (TREAT 2b)

- 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

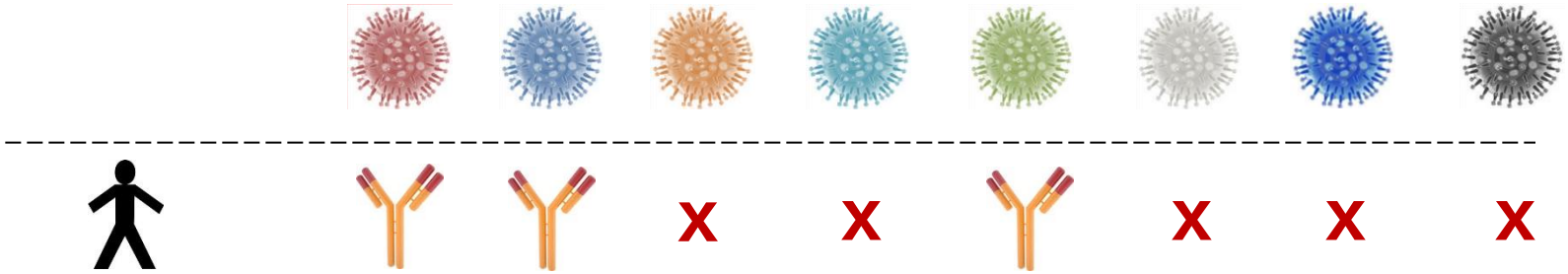
- Intravenous Hepatitis C Immunoglobulin (10% concentration)
- For the prevention of HCV* recurrence in patients undergoing liver transplantation (due to transplantation of HCV damaged liver)
- Utilizes a short duration of new antivirals to reduce viral load just prior to transplantation
- Civacir® antibodies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



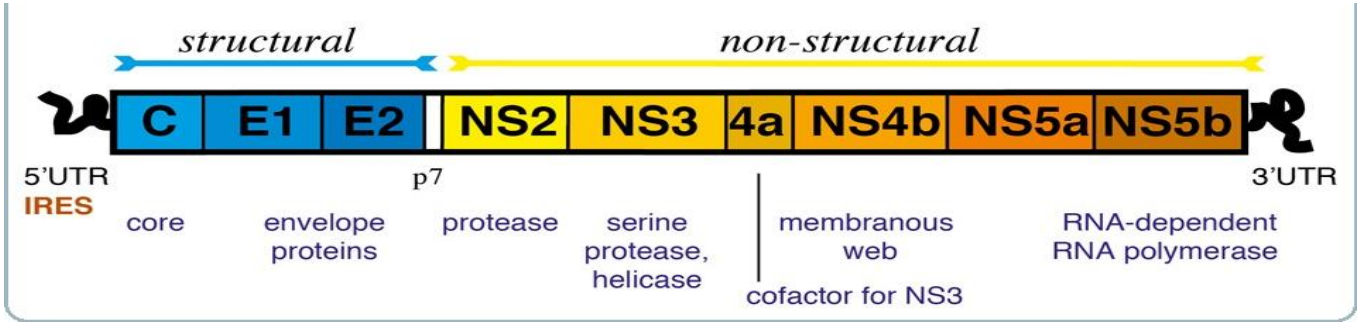
*HCV = Hepatitis C virus

Composition of Civacir®

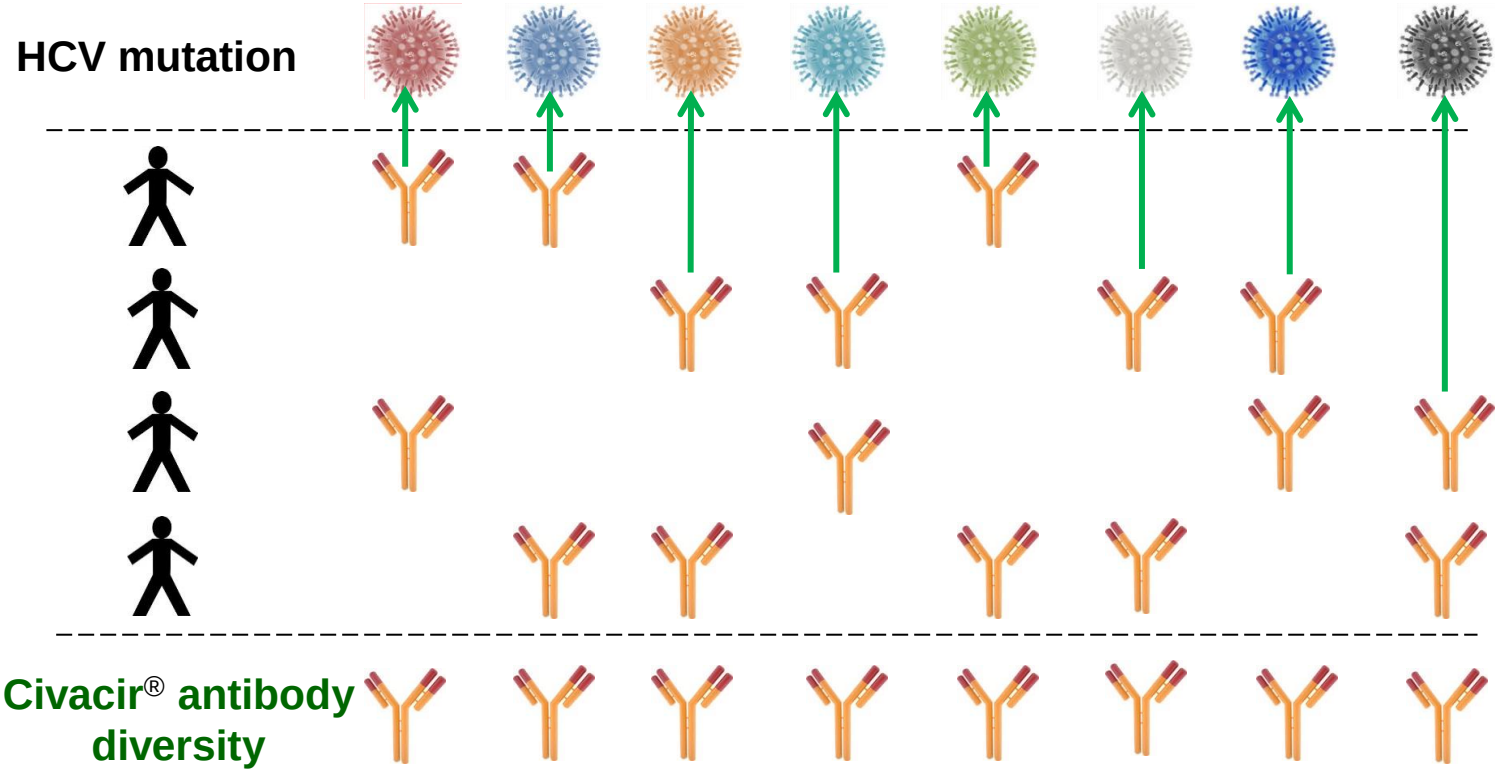
- HCV mutates faster than HIV and an individual can be infected by several HCV mutant populations



- 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

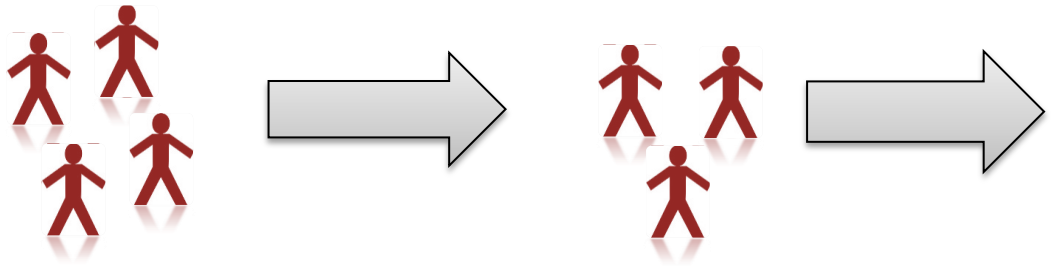


Civacir® therefore provides a spectrum of antibody protection to neutralise HCV and protect the new liver from infection

Chronic HCV patient´s situation today

Status quo: - 150 million patients worldwide with chronic HCV infection (liver damage); many patients undiagnosed
- risk that transplanted liver is re-infected after transplantation

Sofosbuvir+Ribavirin
(new) treatment (up to 48 wks)



64 patients
randomized

41 patients
non-detectable virus
at transplantation

26 patients
(63%) SVR*

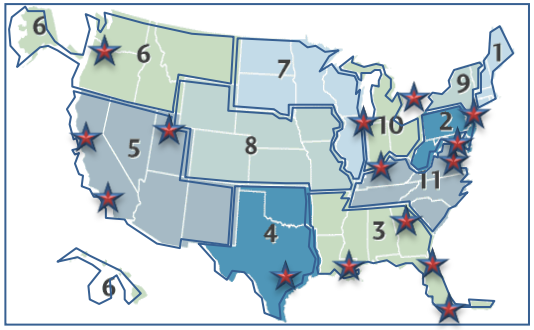
15 patients
(37%) re-infection

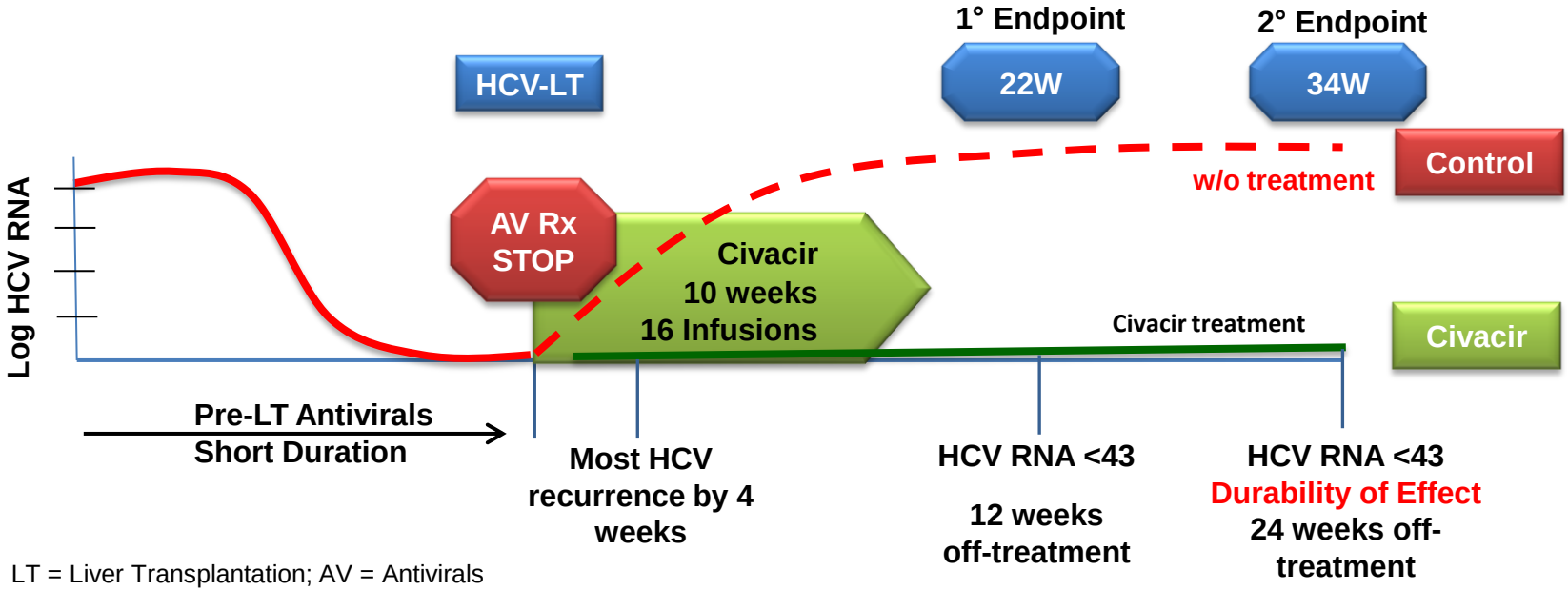
Even with pre-treatment with Sofosbuvir or other new virostatics viral recurrence rate in transplanted patients is still ~40 %

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

Ongoing US Civacir® trial (study 988)

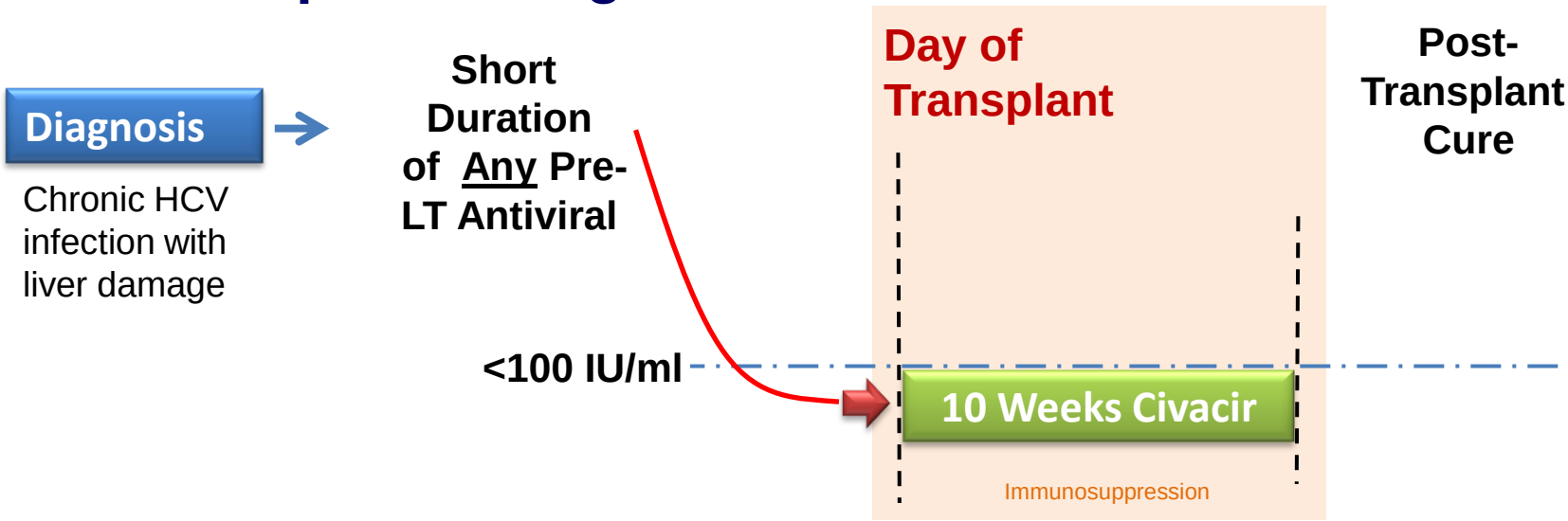
- Evaluation of efficacy, safety & pharmacokinetics of Civacir® in liver transplant recipients
- 24 centres in North America
- Leading hepatologists involved in study
- Enrolling patients infected with HCV genotypes 1 - 6
- Study will enrol up to 84 patients





LT = Liver Transplantation; AV = Antivirals

Goal and positioning for Civacir®



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

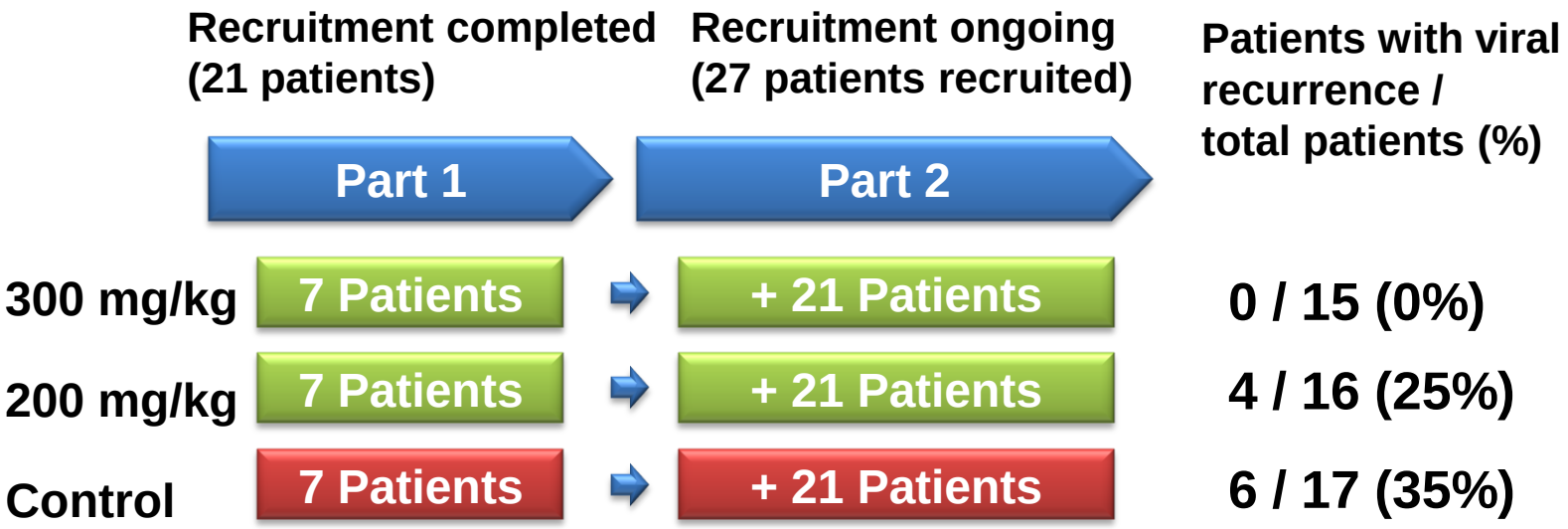
Goal: the Hepatitis C virus is eradicated, the transplanted liver is protected and the patient is cured

LT = Liver Transplantation

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

Primary Objective

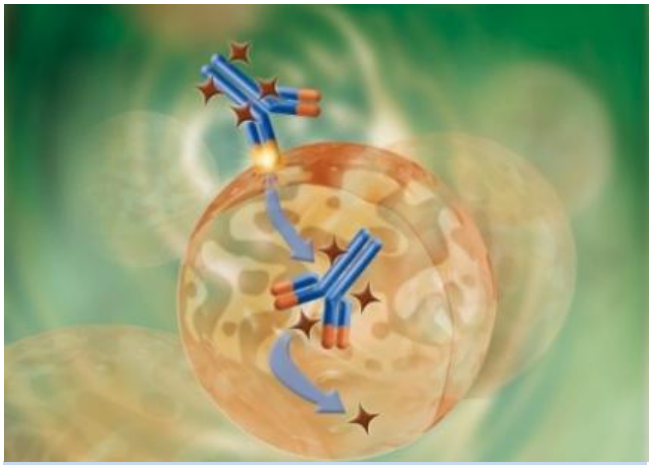
Determine proportion of Civacir® treated subjects with unquantifiable HCV RNA(<43IU/ml) at 22 weeks post liver transplant (LT) compared to the control group



Next update: EASL in April (planned)

SVR = sustained viral response

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) have been presented at the ASH* conference on 6-9 December 2014
- Study amended to include new treatment regimen (Pomalidomide/ Dexamethason)

* ASH = American Society of Haematology

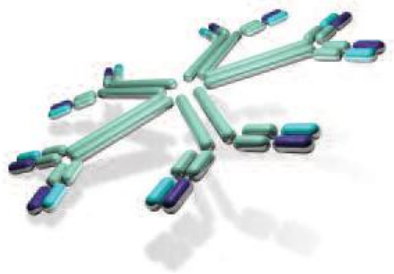
ASH Poster: Indatuximab Ravtansine (BT-062)

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) for MTD is 83% including:
  - 6% complete remissions
  - 37% very good partial remissions
  - 40% partial remissions
- The data was presented at the 56. ASH conference on 6-9 December 2014 in San Francisco, USA (Kevin R. Kelly, et al.)

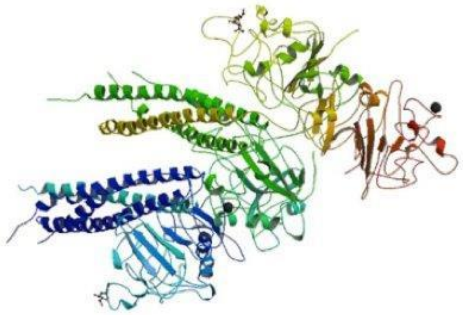
ASH = American Society of Haematology MTD = Maximum tolerated dose

Intensive Care Medicine: IgM concentrate and fibrinogen



IgM concentrate

- IgM concentrate for the treatment of sepsis
- Unique mechanism of action
- Over 150 patients treated to date in phase II study



Fibrinogen

- Fibrinogen for the treatment of severe acute bleeding due to fibrinogen deficiency
- Phase I/II study ongoing

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**