

R&D Briefing

December 6, 2012

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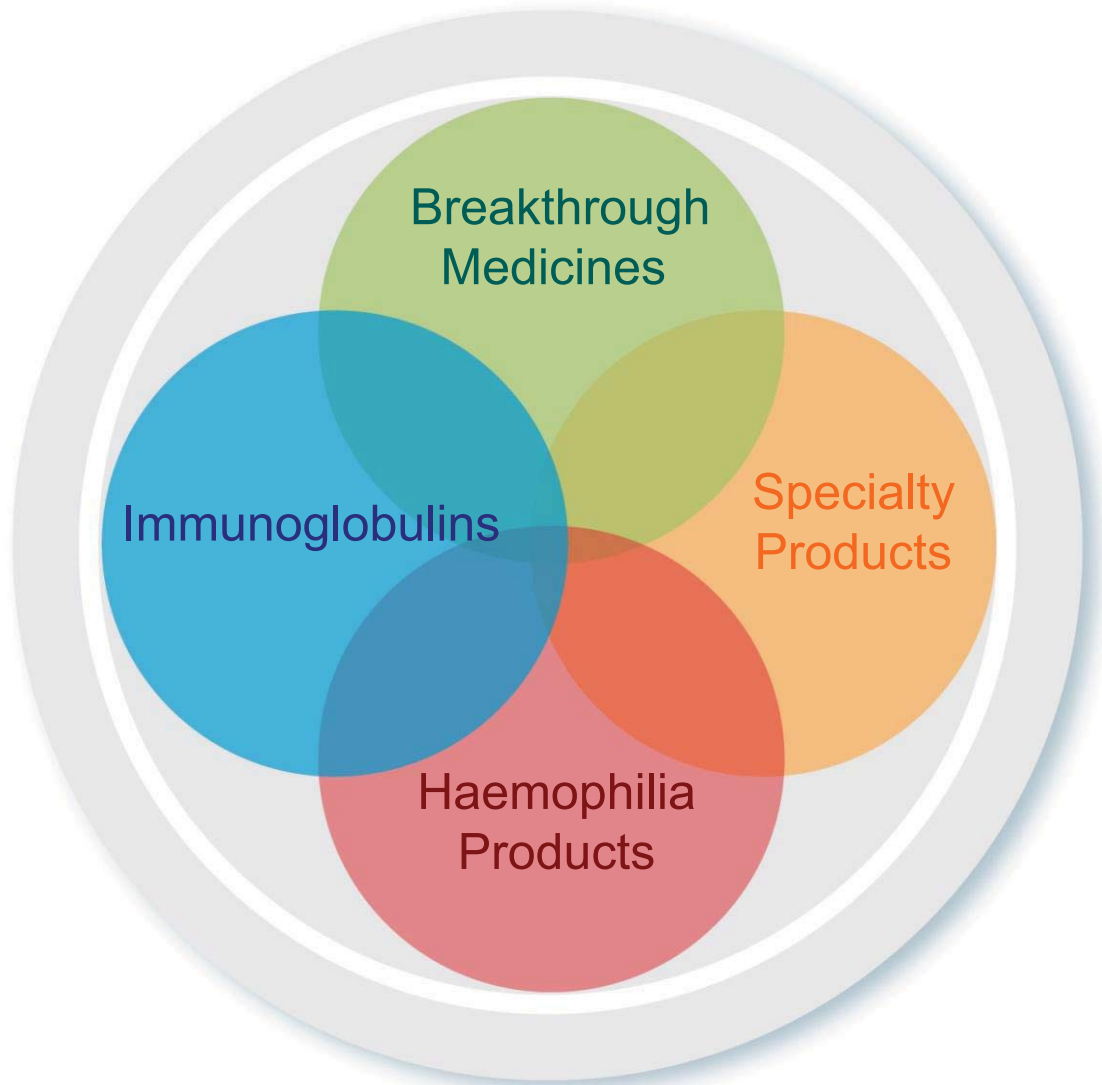
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Agenda December 2012 R&D Briefing

- Welcome
Mark Dehring
- Introduction & Highlights
Andrew Cuthbertson
- Immunoglobulins & Specialty Products
 - Clinical Development
Russell Basser
 - Commercial Opportunities
Lutz Bonacker
- Q&A
- *Break*
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Andrew Cuthbertson
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- Breakthrough Medicines & Licensing
Andrew Cuthbertson
- Summary
Andrew Cuthbertson
- Q&A

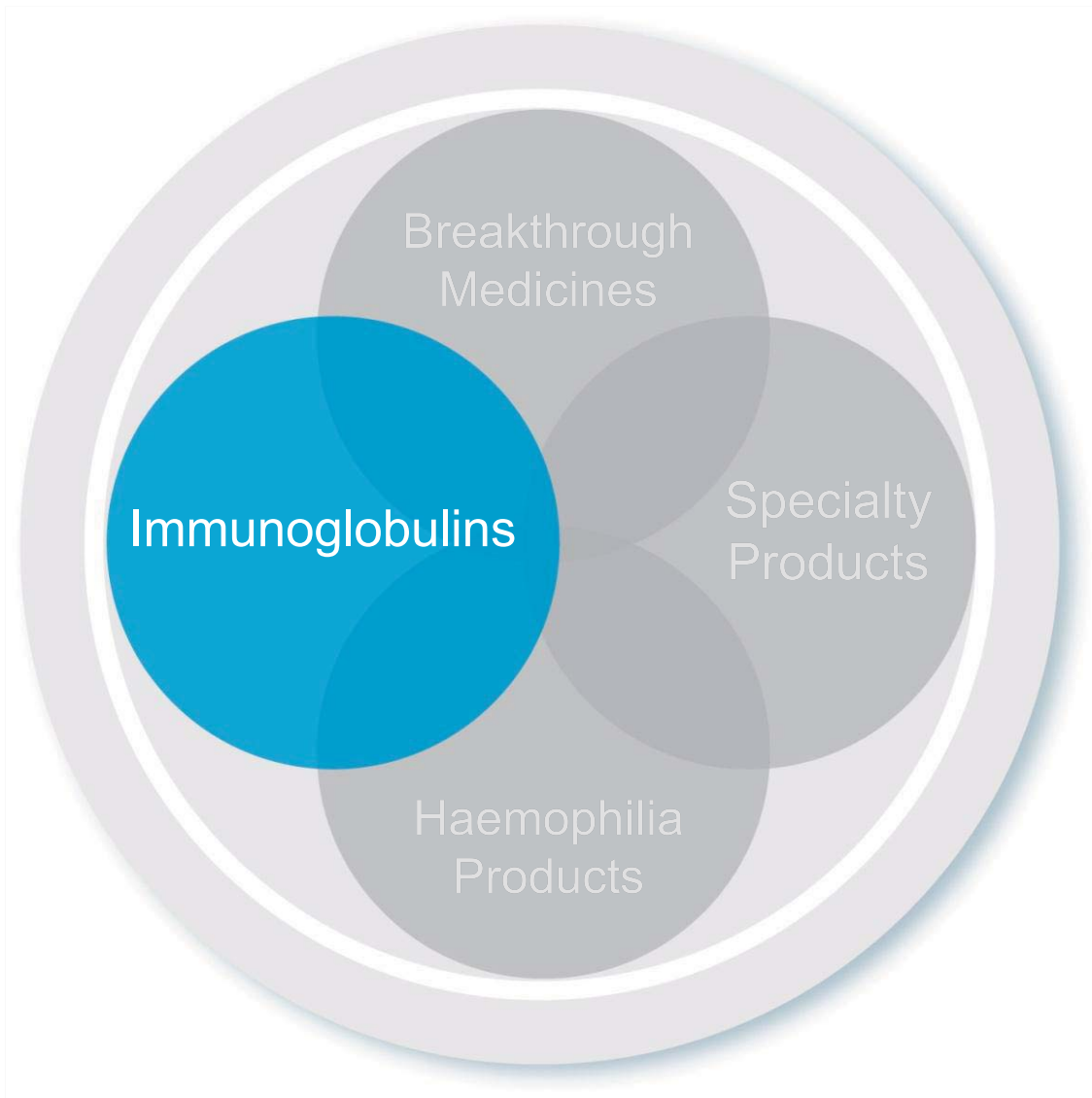
Introduction and Highlights

CSL R&D Strategy



- Maintain commitment to extracting maximum value from existing assets and supporting and improving current products
- Develop new protein-based therapies for treating serious illnesses focusing on products that align with our technical and commercial capabilities

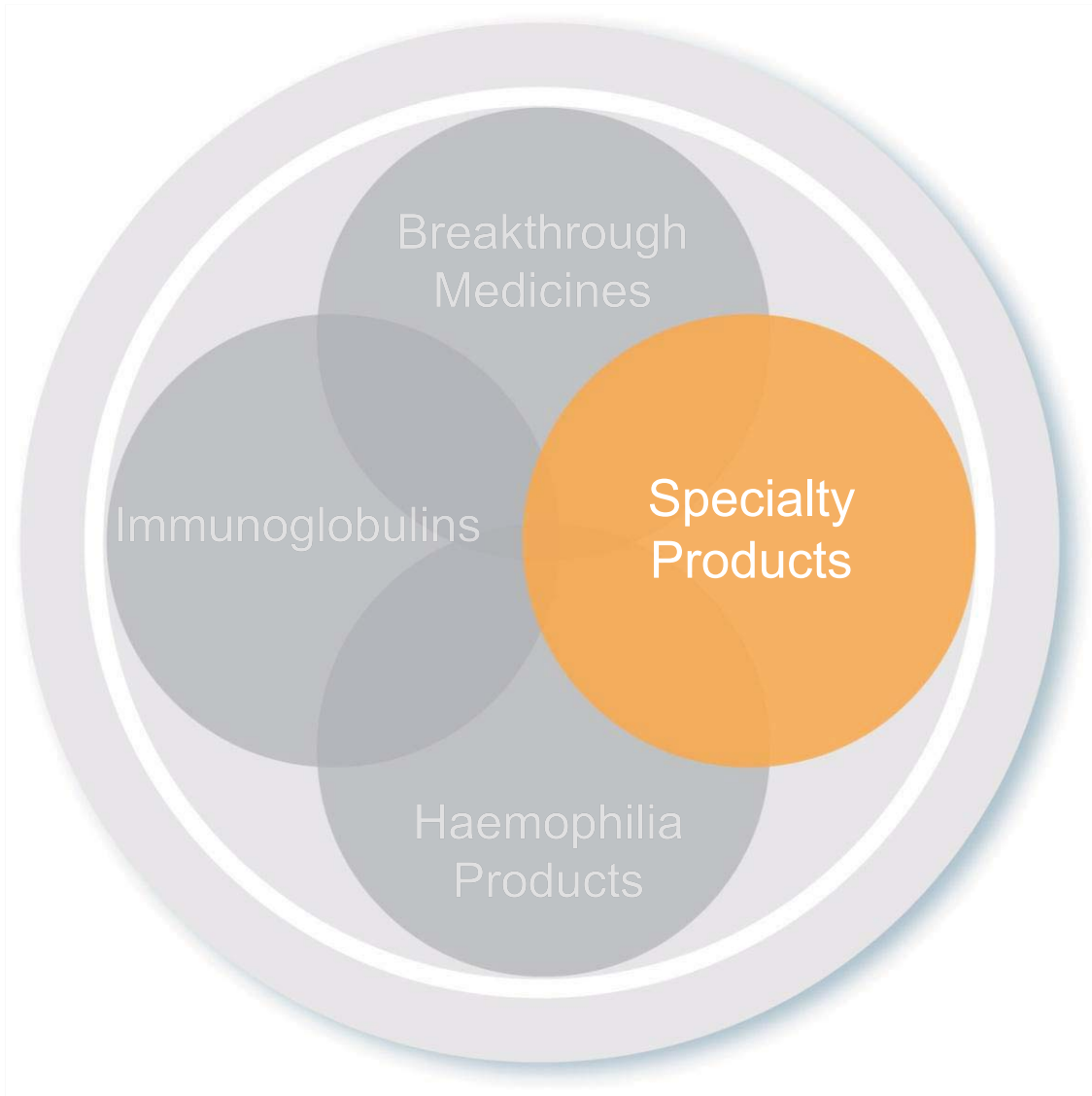
Immunoglobulins Strategy



Maintaining leadership position through focus on:

- Patient convenience
- Yield
- Label
- Formulation science
- Specialty Igs

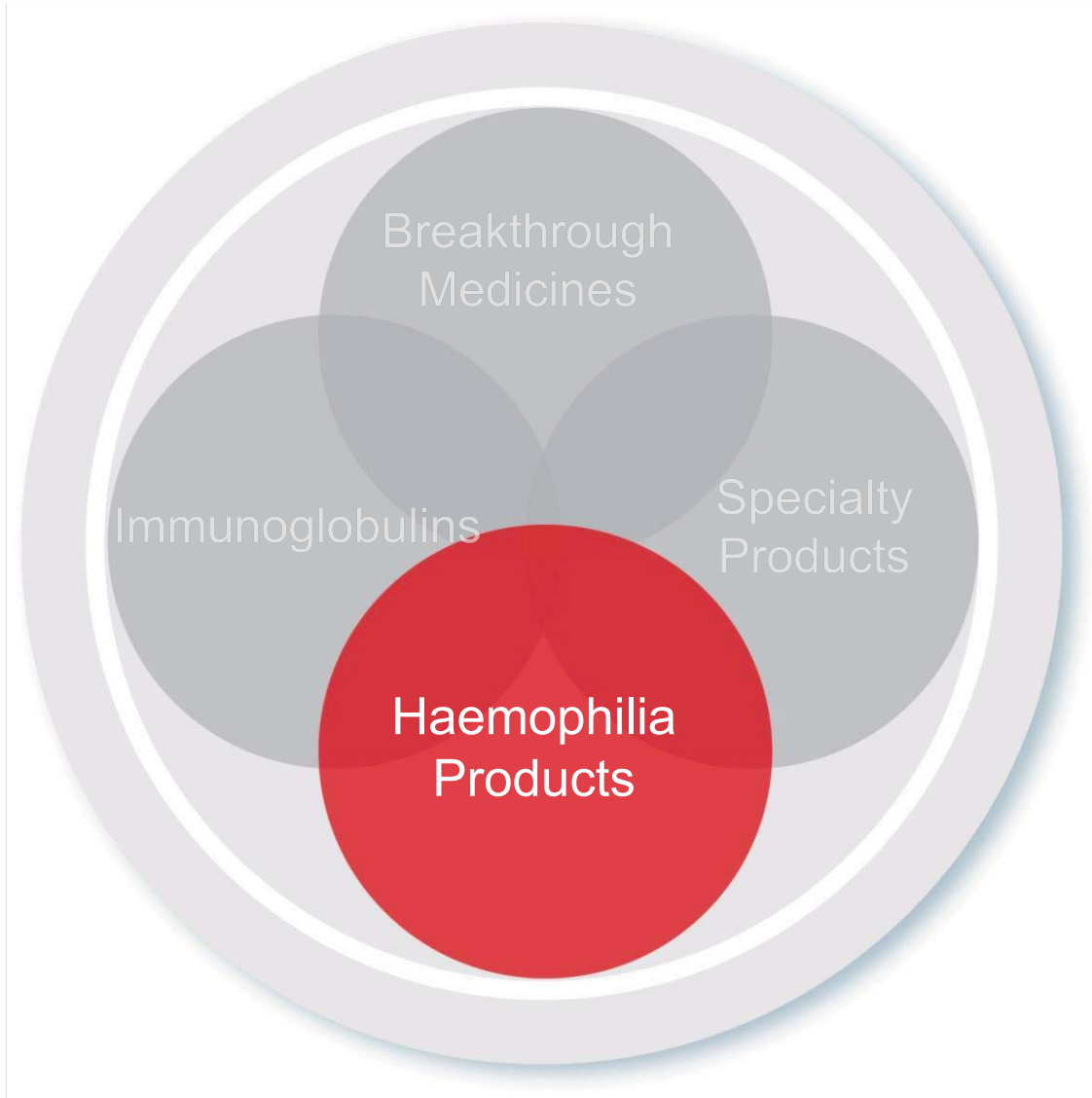
Specialty Products Strategy



Leveraging high quality, broad product portfolio through:

- New markets
- Novel indications
- Novel modes of administration

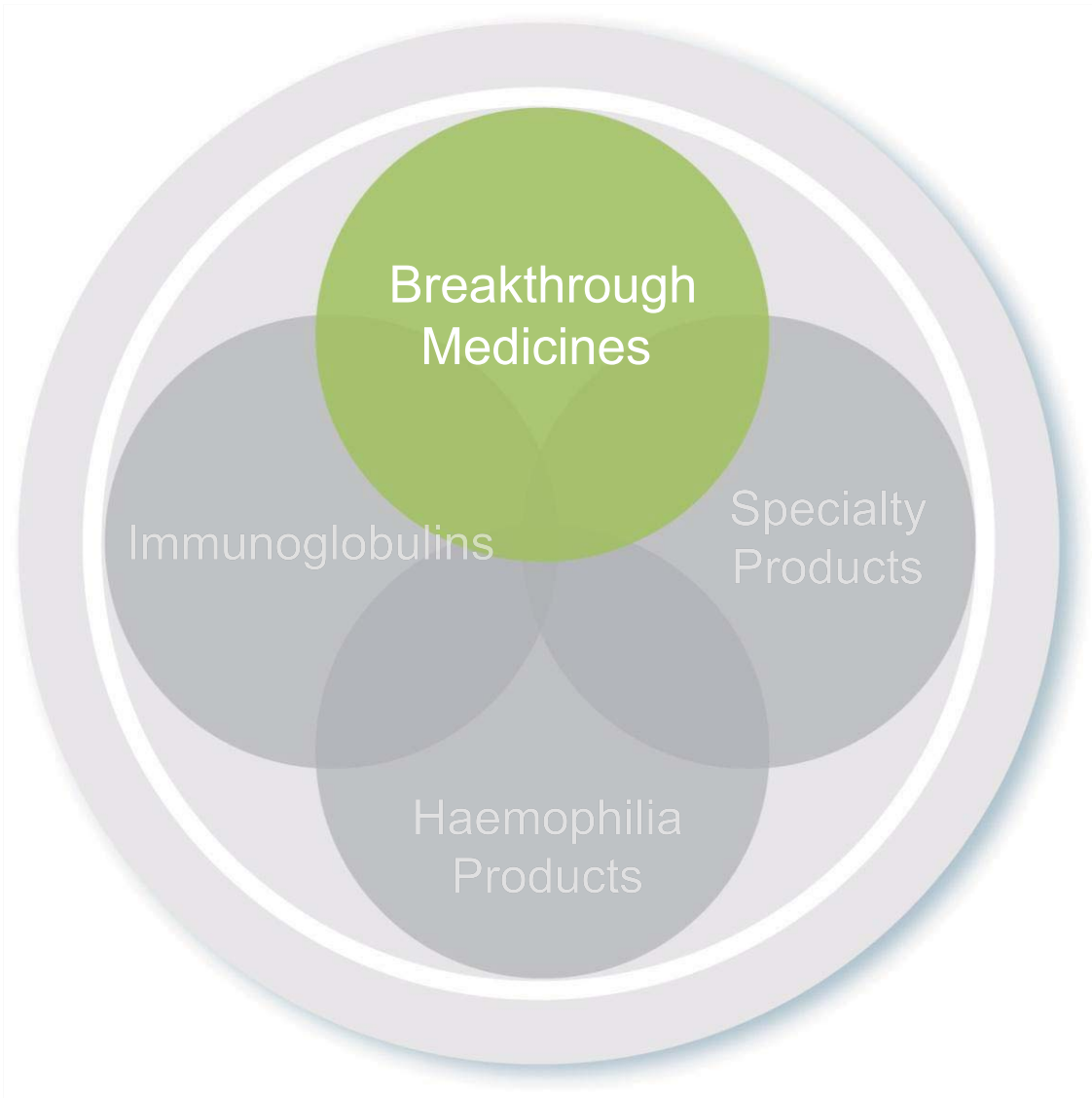
Haemophilia Strategy



Supporting and enhancing plasma products and developing novel recombinant portfolio with focus on:

- Scientific and product innovation
- Patient benefit

Breakthrough Medicines Strategy



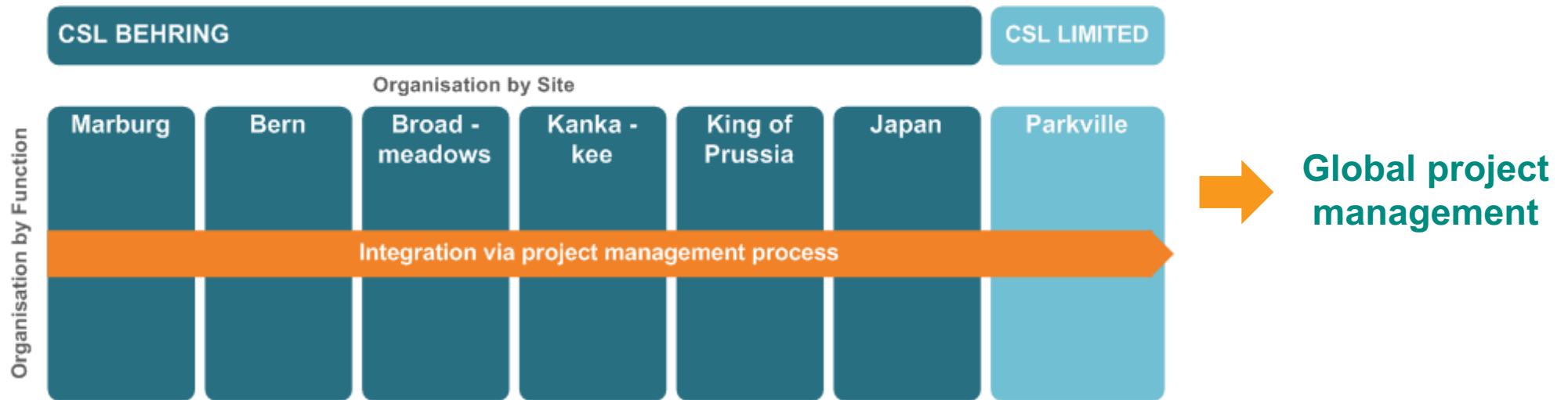
Leveraging clinical and technical insight in developing novel protein-based therapies

- Significant unmet need
- Multiple indications

Optimising value of IP portfolio and assets

- Partner high opportunity products

Leveraging Global Capabilities

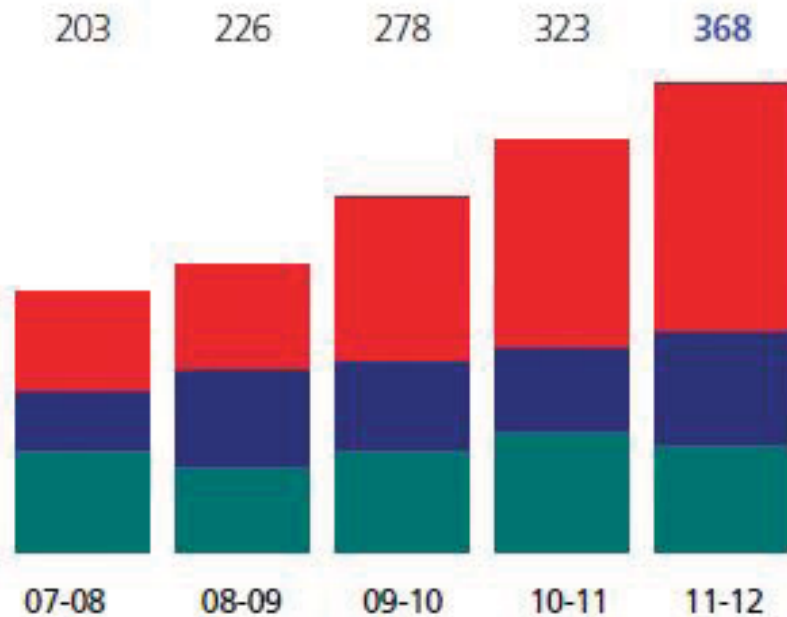


Recombinant protein manufacturing capabilities



R&D Investment

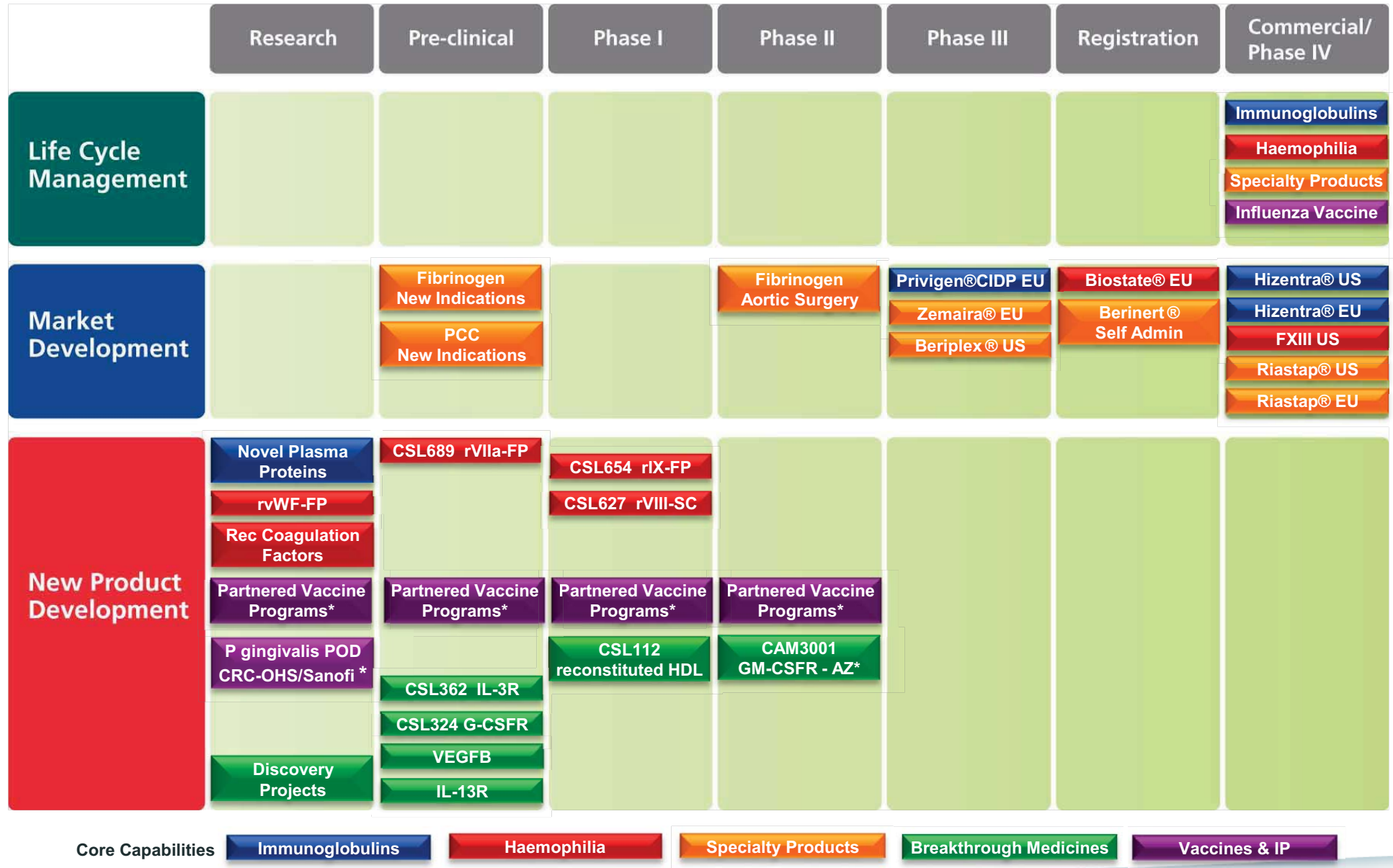
CSL RESEARCH AND DEVELOPMENT INVESTMENT (US\$ MILLIONS)



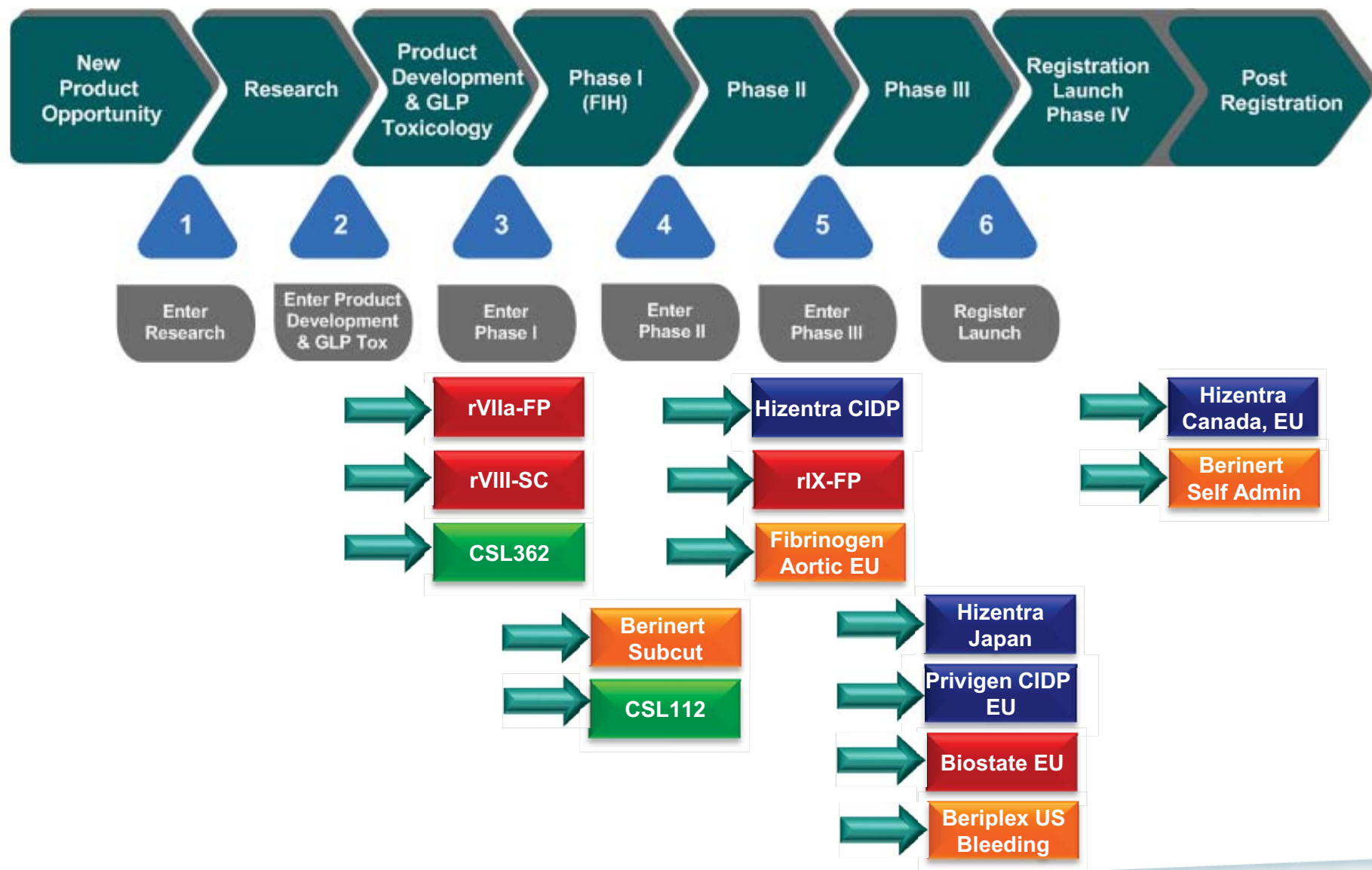
- New Product Development** activities focus on innovative new therapies for life-threatening diseases.
- Market Development** strategies seek to bring therapies to new markets and new indications.
- Life Cycle Management** ensures continuous improvement of existing products.

Global R&D Portfolio

December 2011

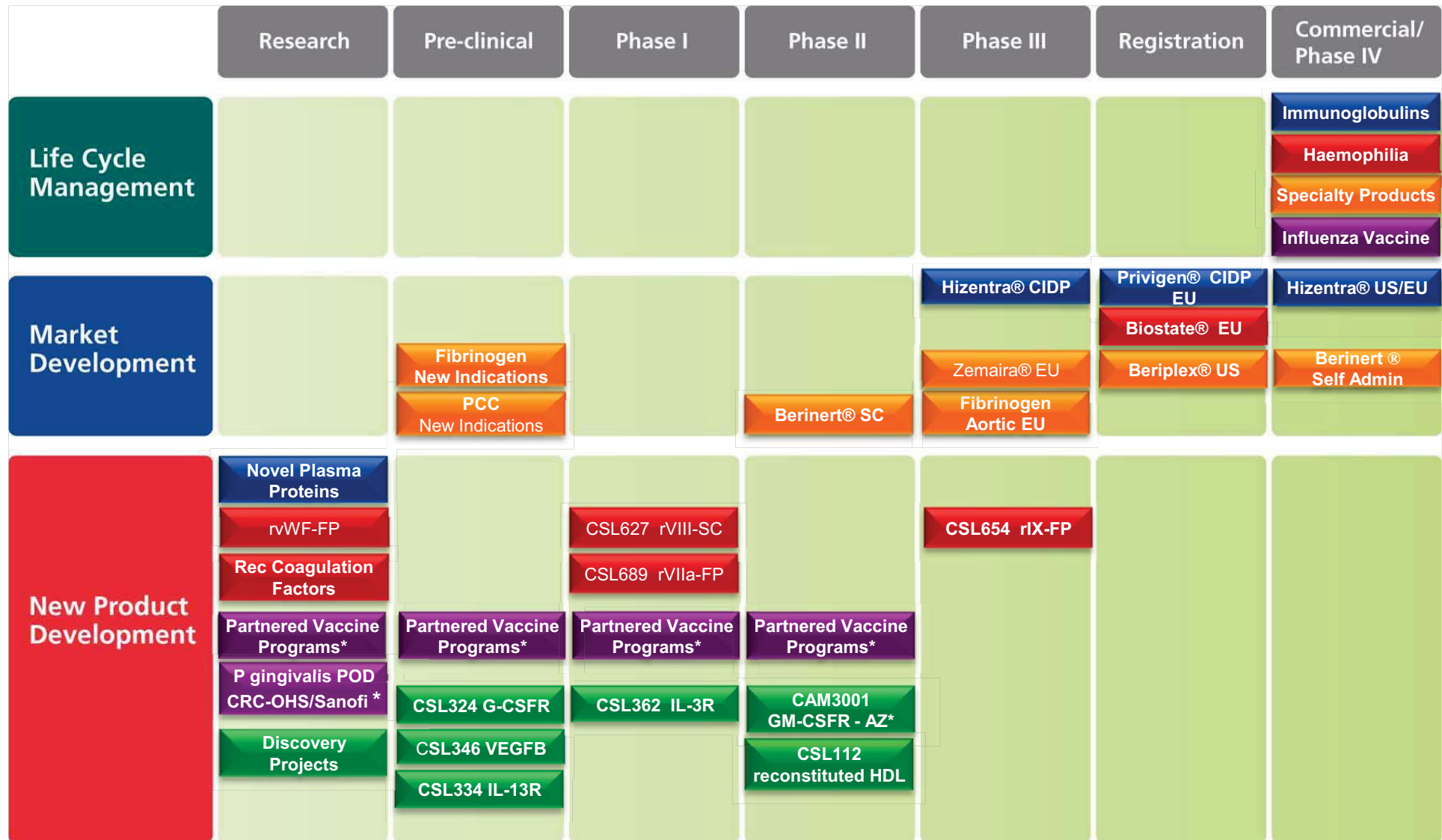


Progress through Stage Gates in 2012



Global R&D Portfolio

December 2012



Core Capabilities

Immunoglobulins

Haemophilia

Specialty Products

Breakthrough Medicines

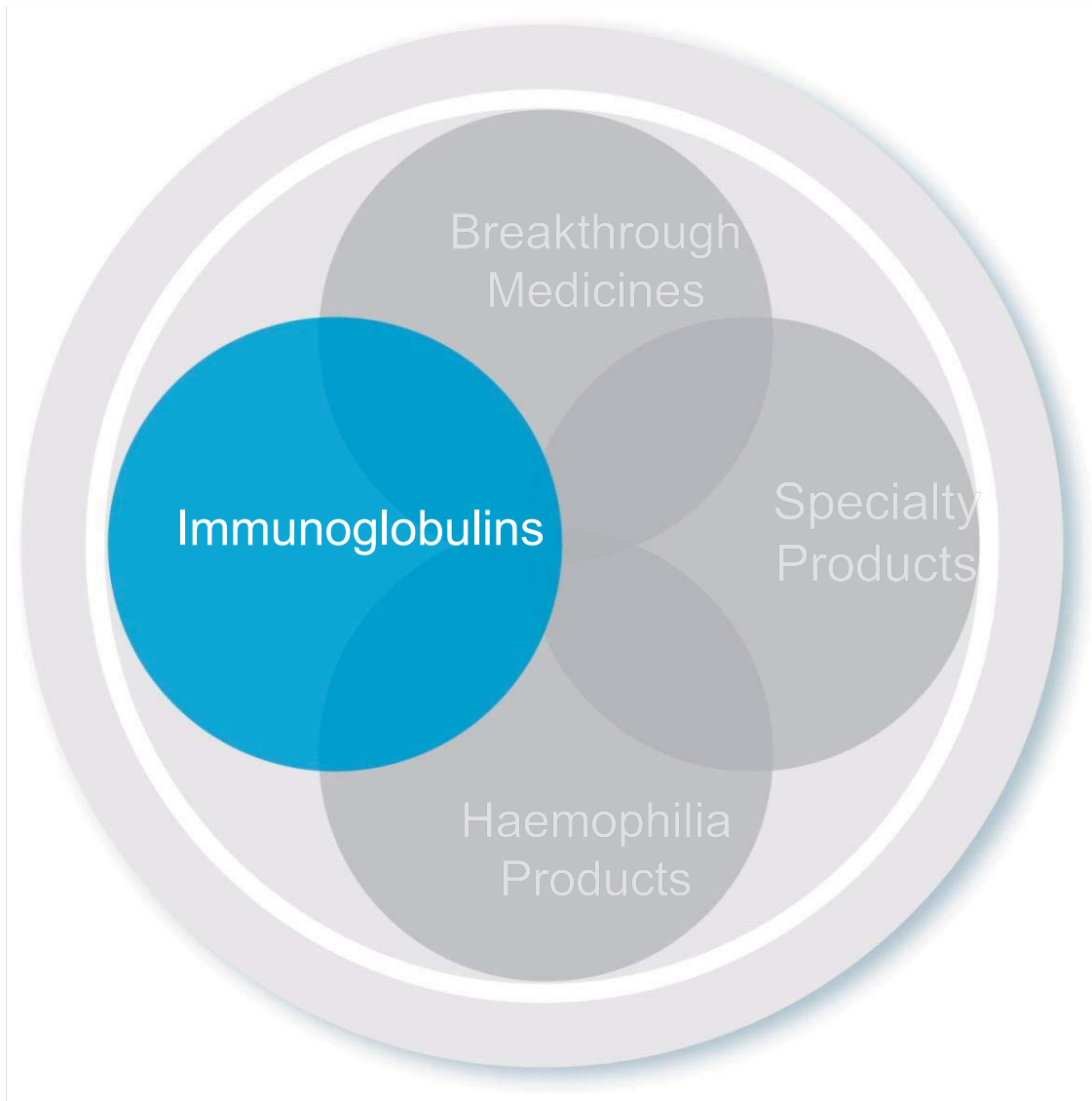
Vaccines & IP

*Partnered Projects

#LCM includes direct post marketing commitments as well as pathogen safety, capacity expansions, yield improvements, new packages and sizes for all registered products

Immunoglobulins

Immunoglobulins



Maintaining leadership position through focus on:

- Patient convenience
- Yield
- Label
- Formulation science
- Specialty Igs

Key Focus

- Hizentra[®]
- Privigen[®]

Innovation to Drive Growth

- Efficient and competitive cost structure
 - Ig yield improvements
- Product differentiation
 - Patient convenience
- Clinical Use and Indications
 - Clinical efficacy
 - Expansion into Neurology
 - Alzheimer's Disease opportunity
 - Prevention of vertical transmission of CMV by Cytogam[®]

The only registered CMV immunoglobulin in the US indicated for the prevention of CMV disease associated with transplantation

- CMV infection is the leading known cause of birth abnormalities in developed countries
- Partnership with US National Institutes of Health (NIH) to determine efficacy of CMV immunoglobulin in preventing mother to baby transmission
 - Large multi-site clinical trial screening >150,000 women commenced December 2011
 - CSL donating Cytogam®
 - Primary analysis expected 2016



The first 20% high concentration low volume SCIG for convenient self administration providing steady-state Ig levels and an established long-term safety record with chronic administration

Global Introductions Continue

- Launched in US since 2010
- Broad approvals in EU and Canada
- Japan Phase III licensing study complete
 - supports safety and efficacy of Hizentra[®] for PID
 - new drug application submitted to PMDA in Sept 12

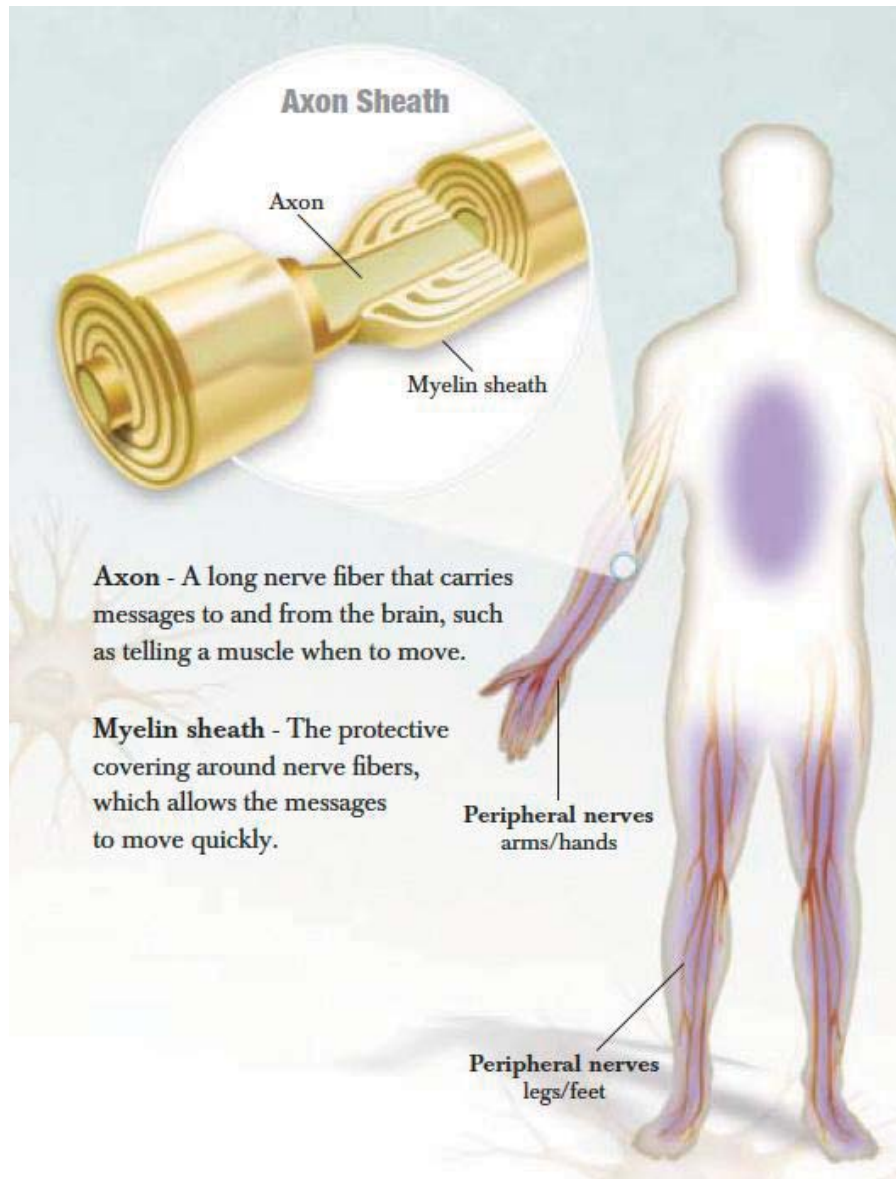


Alternate schedules for Hizentra®

- Hizentra® is indicated weekly for patients with PID
- Enhancing patient options through provision of additional schedules
 - Efficacy expected to be maintained
 - Safety not expected to be different



Chronic Inflammatory Polyneuropathy (CIDP)



- A chronic peripheral nerve disease with progressive muscle weakness and loss of sensation, usually occurring in elderly patients
- Most common chronic autoimmune neuropathy

Potential benefits of Hizentra® in Patients with CIDP

Current maintenance therapies

Oral steroids

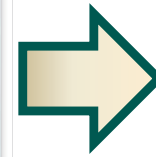
Adverse effects with long term use

IVIG

Less convenience
Levels show peaks & troughs
Hospital visits

Plasma Exchange

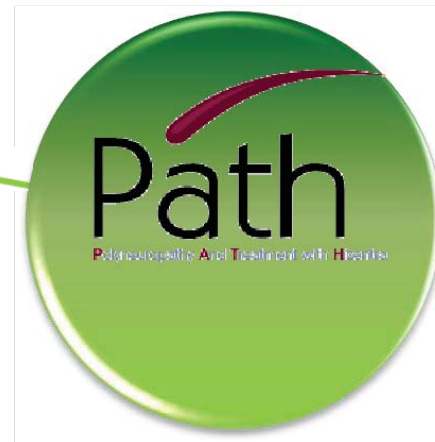
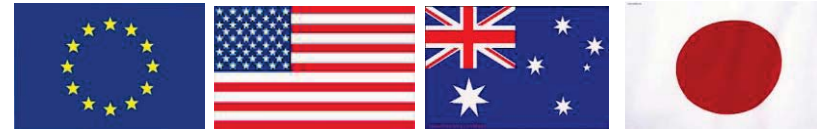
Invasive therapy
Limited availability
Short term efficacy



Hizentra®

- Avoids drawbacks of i.v. route
- Reduced volume
- Increases patient autonomy
- Less systemic side effects
- More stable IgG levels

The PATH Trial: Hizentra[®] in CIDP



- 150 patients
- 2 doses vs placebo
- Study approved by FDA, EMA, PMDA
- Recruiting in US & EU

The first and only 10% liquid intravenous immunoglobulin (IVIg) therapy that is proline stabilised with room temperature storage up to 36 months

Building Capacity to Address Patient Needs Globally

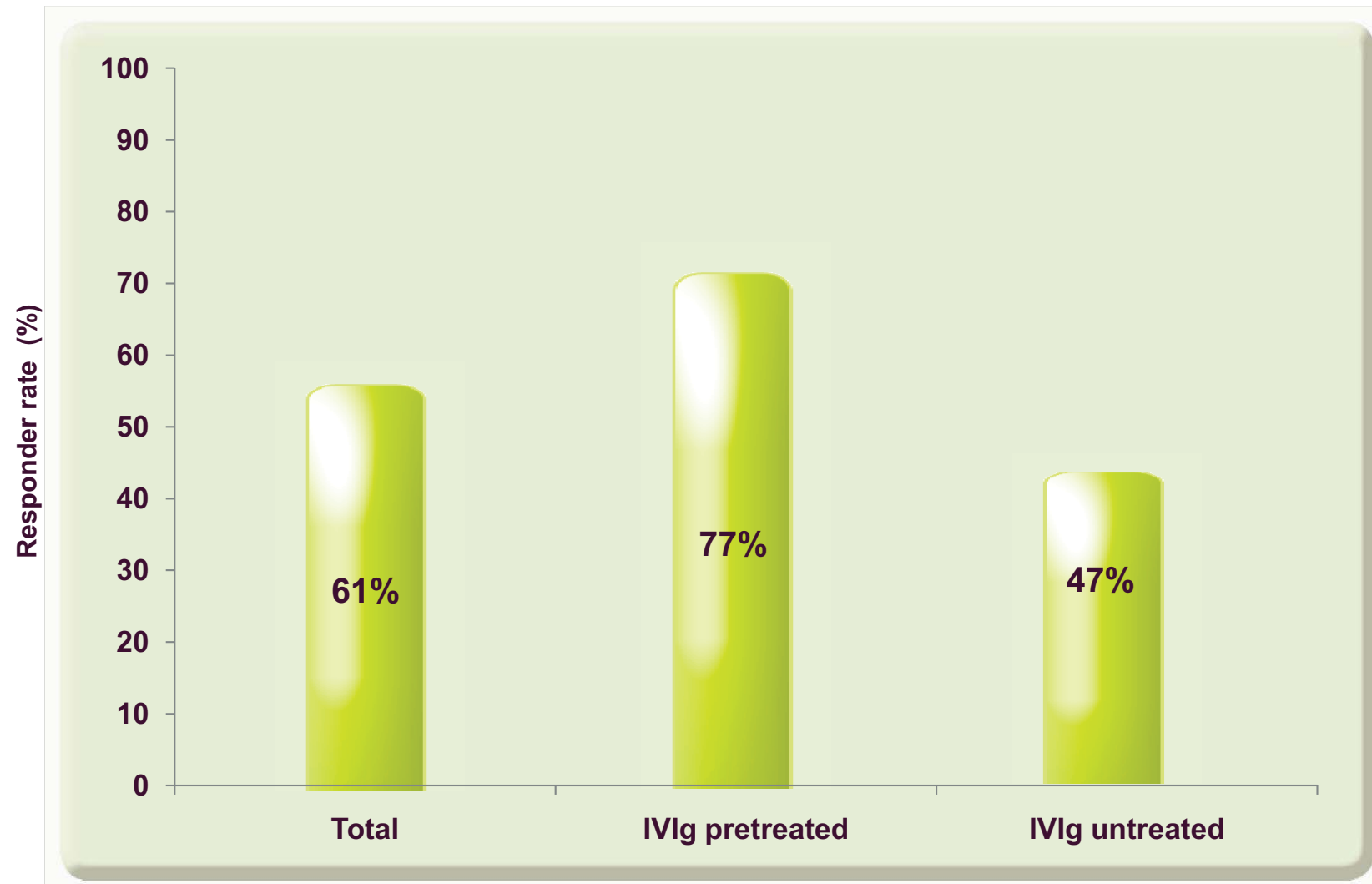
- Privigen approved broadly in US, Europe, South America
- New Ig manufacturing facility in Broadmeadows

Strengthening Presence in Neurology Market

- Phase III study in CIDP completed in Europe
 - Study shows treatment with Privigen® improved function in patients with chronic CIDP
- Dossier submitted to EMA in May 12

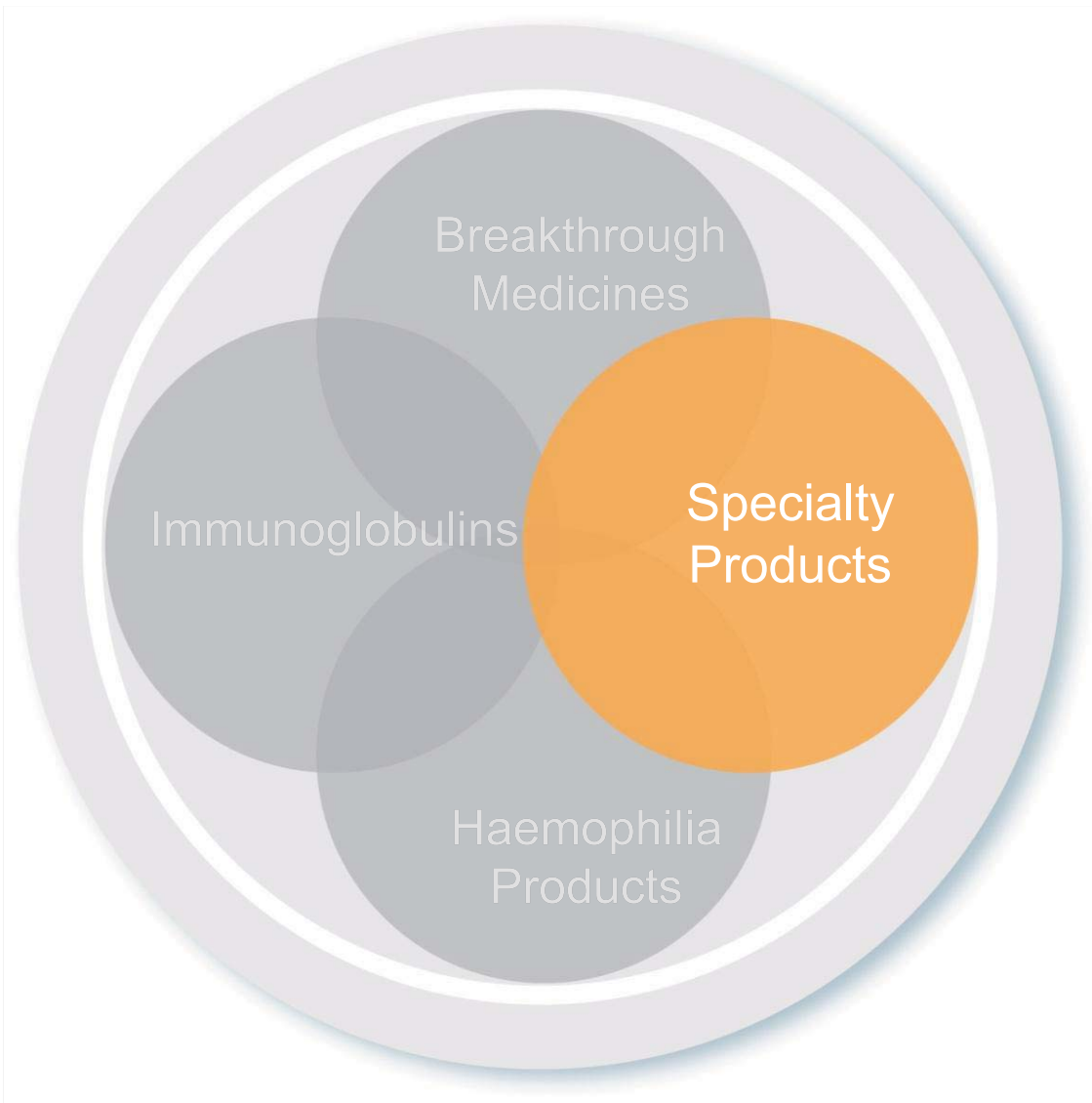


Privigen[®] in CIDP: Rate of Response



Specialty Products

Specialty Products



Leveraging high quality, broad product portfolio through:

- New markets
- Novel indications
- Novel modes of administration

Key Focus

- Beriplex[®]
- Fibrinogen
- Zemaira[®]
- Berinert[®]

- Prothrombin Complex Concentrate = PCC
 - vitamin K-dependent coagulation factors (FII, FVII, FIX, FX)

Seeking approval for use of Beriplex[®] to reverse the effects of vitamin K antagonists for:

- Bleeding related to over-anticoagulation
- Patients needing surgery

2 large randomised, controlled clinical trials

- Bleeding study completed
- Surgical study recruitment completed

BLA submitted in US for acute bleeding

- Accepted for standard review

The first and only treatment approved by the US FDA for acute bleeding episodes in patients with congenital fibrinogen deficiency

Europe

- Peri-/post-operative control of coagulopathic bleeding
- REPLACE Phase III study
 - 200 subjects – recruitment commenced Jan 2012
 - Aim to complete recruitment end 2013

US

- Coagulopathic bleeding related to complex cardiac surgery
- In dialogue with FDA

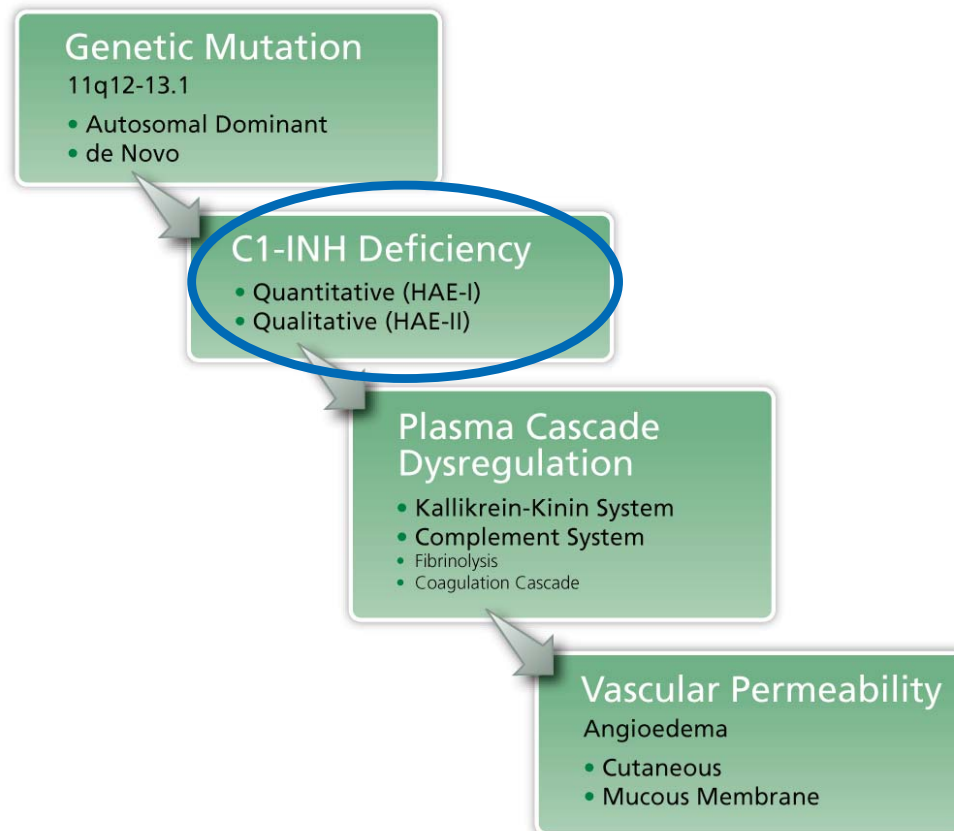
Zemaira is the first highly purified alpha-1 augmentation therapy approved by the FDA for chronic augmentation and maintenance therapy of adults with Alpha-1 and emphysema

Seeking to broaden commercial reach through launch in EU, Canada, Brazil

- EU requires demonstration of a clinical outcome (disease modification)
- Increase diagnosis and treatment

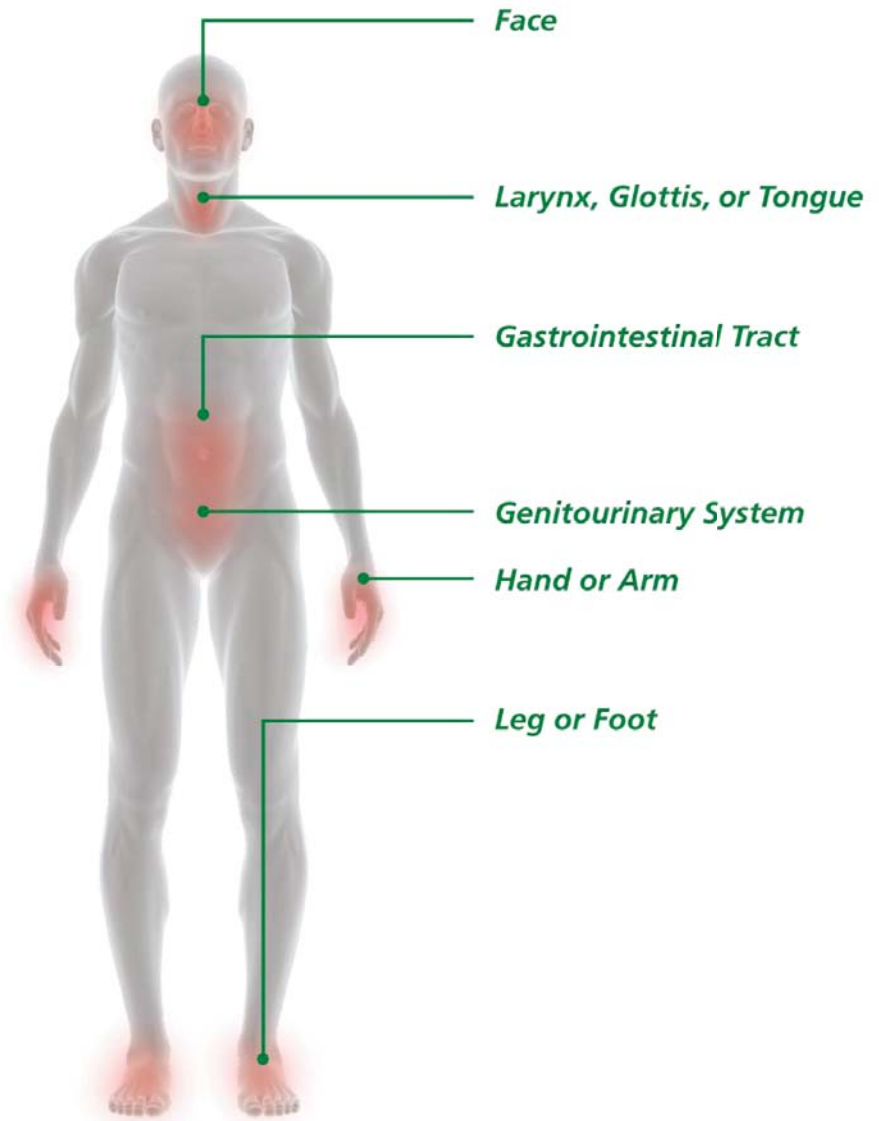
Anticipating pivotal efficacy data early 2013

Plasma derived, pasteurised & nanofiltered concentrate of C1 Esterase Inhibitor indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adults and adolescents



What Happens to Patients?

- Recurrent episodes of swelling, sometime with a rash
- Unpredictable and occur anywhere in the body
- Life-threatening if laryngeal swelling
- Attacks caused by stress, infection, menstruation, some drugs, unknown causes



Plasma derived, pasteurised & nanofiltered concentrate of C1 Esterase Inhibitor indicated for the treatment of acute abdominal or facial attacks of hereditary angioedema (HAE) in adults and adolescents

US and European approved label expansion for self administration of HAE

- As part of US label expansion Beriner[®] now also indicated to treat life-threatening laryngeal HAE attacks, as well as facial and abdominal attacks

Overcoming Challenges in Long-term Prophylaxis of HAE Attacks

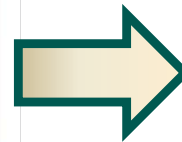
Current prophylactic therapies

Oral androgens

- Limited by adverse effects, especially in women and children

Intravenous C1-INH

- Inconvenience and risks of repeated i.v. administration



High concentration subcutaneous (sc) Berinert®

- Avoids drawbacks of i.v.
- Low volume for s.c. administration
- Builds on well-established safety profile

Berinert® Subcutaneous Prophylaxis Program

COMPACT

Clinical Studies for **O**ptimal **M**anagement in
Preventing **A**ngioedema with low-volume
subcutaneous **C**1-inhibitor Replacement **T**herapy

Safety and pharmacokinetic study

- Study ongoing in US and Germany - due to complete 1H 2013
- Select safe and efficacious dosing for clinical efficacy trial - due to commence 2H 2013

Commercial Opportunities and Activities

Immunoglobulins

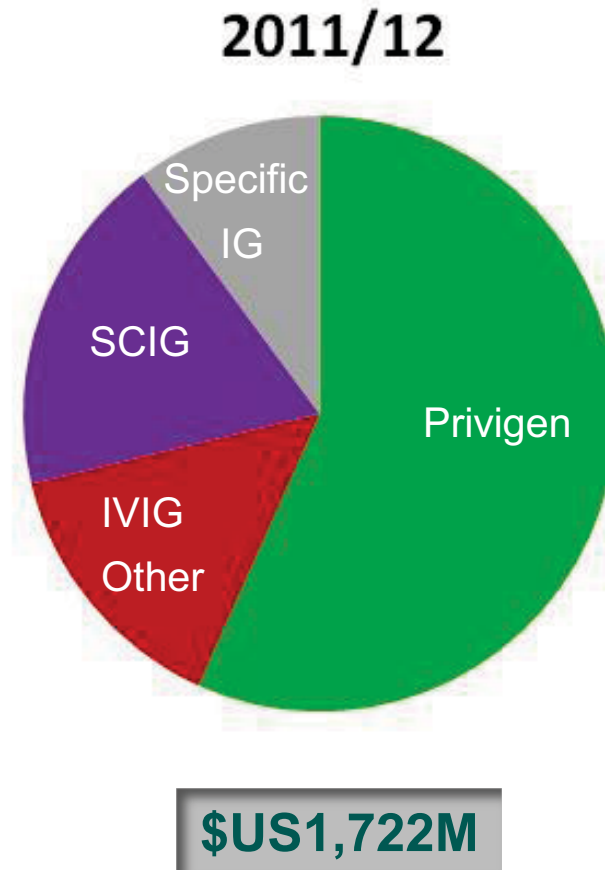
The Immunoglobulin Market is attractive



- Market includes IVIG, SCIG and Hyperimmunes
- Growing Market
- CSL is well positioned

CSL's Immunoglobulin Portfolio

- Globalise portfolio
- Expand into neurology
- Increase convenience



Ig Portfolio Positioning



First and only Proline-stabilised IVIG

- High purity 10% liquid IVIG
- Optimal dimer formulation throughout shelf life for improved tolerability



First and only 20% Proline-stabilised SCIG

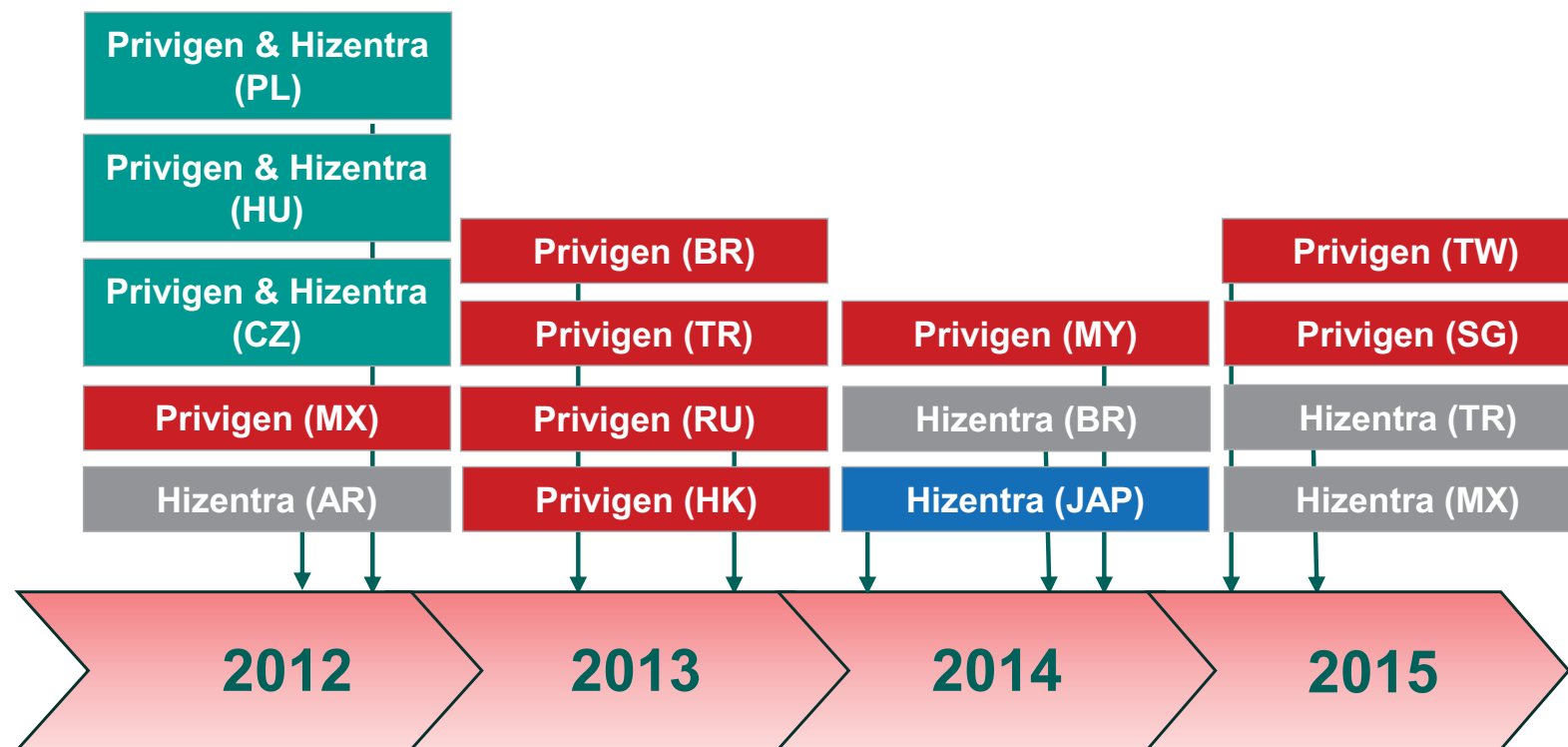
- Low administration volume increases efficiency
- Convenient – few sites & fast infusion



Lyophilised IVIG

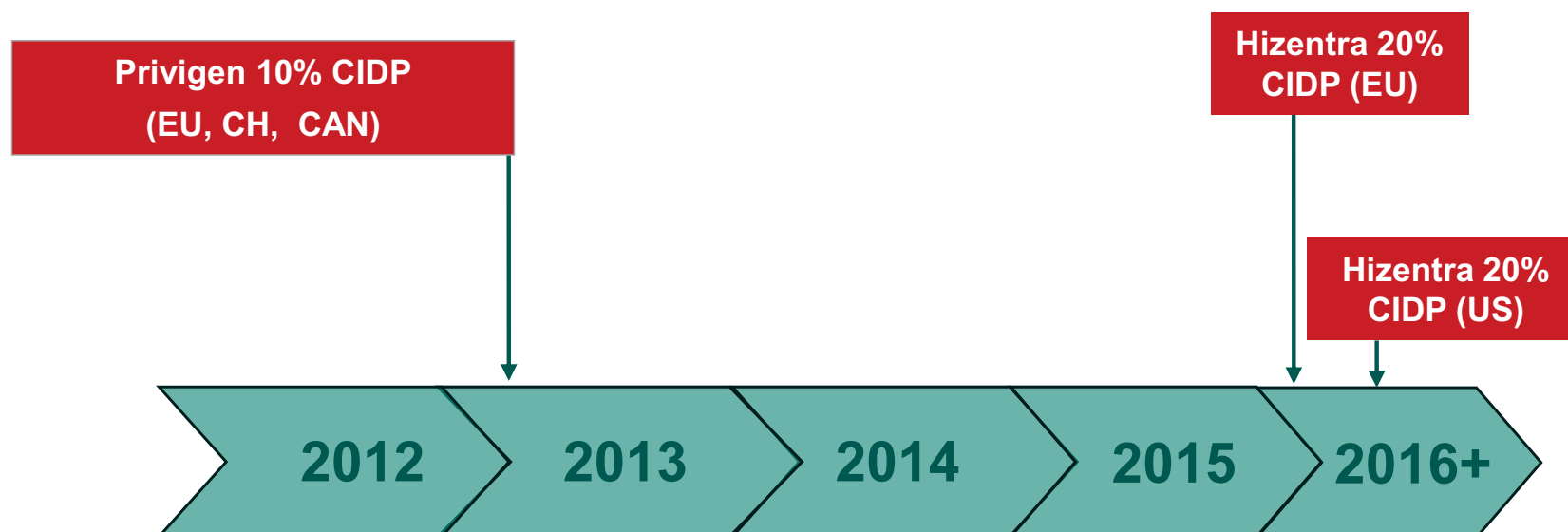
- Long track record of safety & reliability
- Broad indications
- Reconstitution options

Globalise Portfolio



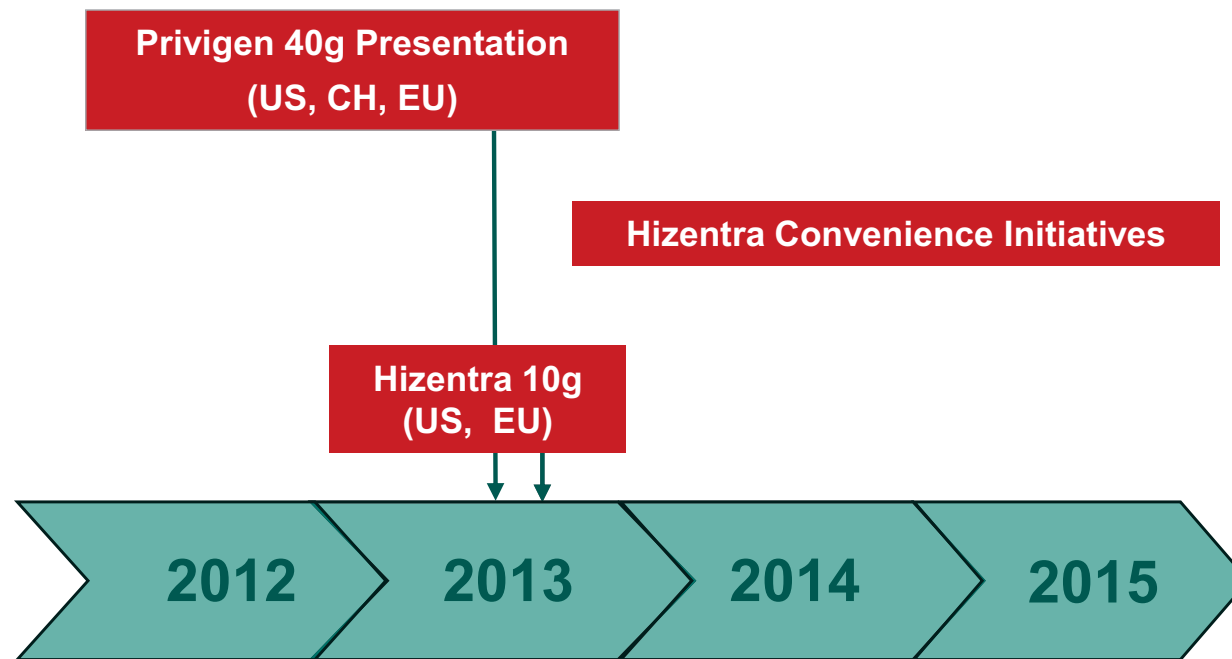
- Privigen[®] currently registered in 55 countries
- Hizentra[®] currently registered in 33 countries
- Continue global launches for Privigen[®] and Hizentra[®]

Expand into Neurology



- Strengthen presence in neurological segment
- Launch Privigen[®] in CIDP in the EU
- Develop Hizentra[®] in CIDP in the US, the EU and RoW

Increase Convenience



- Increase dosing flexibility
- Differentiate through convenience launches:
 - 10 g vial Hizentra[®]
 - 40 g vial Privigen[®]
 - Ongoing convenience initiatives



Sanitize your hands



Clean surface



Inspect each vial of Hizentra



Prepare syringe



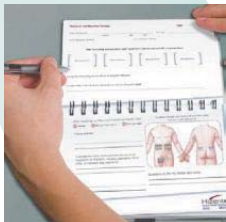
Prepare syringe (continued)



Prepare syringe (continued)



Gather your supplies



Write in your journal



Start infusion



Insert Sub-Q needle(s)



Prepare injection site(s)

Hizentra[®]
Immune Globulin Subcutaneous (Human) 20% Liquid

Infusion Steps

4 preparation steps per vial

➔ Reducing number of vials increases convenience

The only registered CMV immunoglobulin in the US indicated for the prevention of CMV disease associated with transplantation

Center for Disease Control¹:

- CMV is the most common viral infection that infants are born with in the United States
- About 1 in 150 children is born with congenital CMV infection
- About 1 in 750 children in the US is born with or develops permanent problems due to congenital CMV infection

Potential Opportunity

Assuming Screening at week 23 95% screening uptake

Number of Patients: 25 thousand

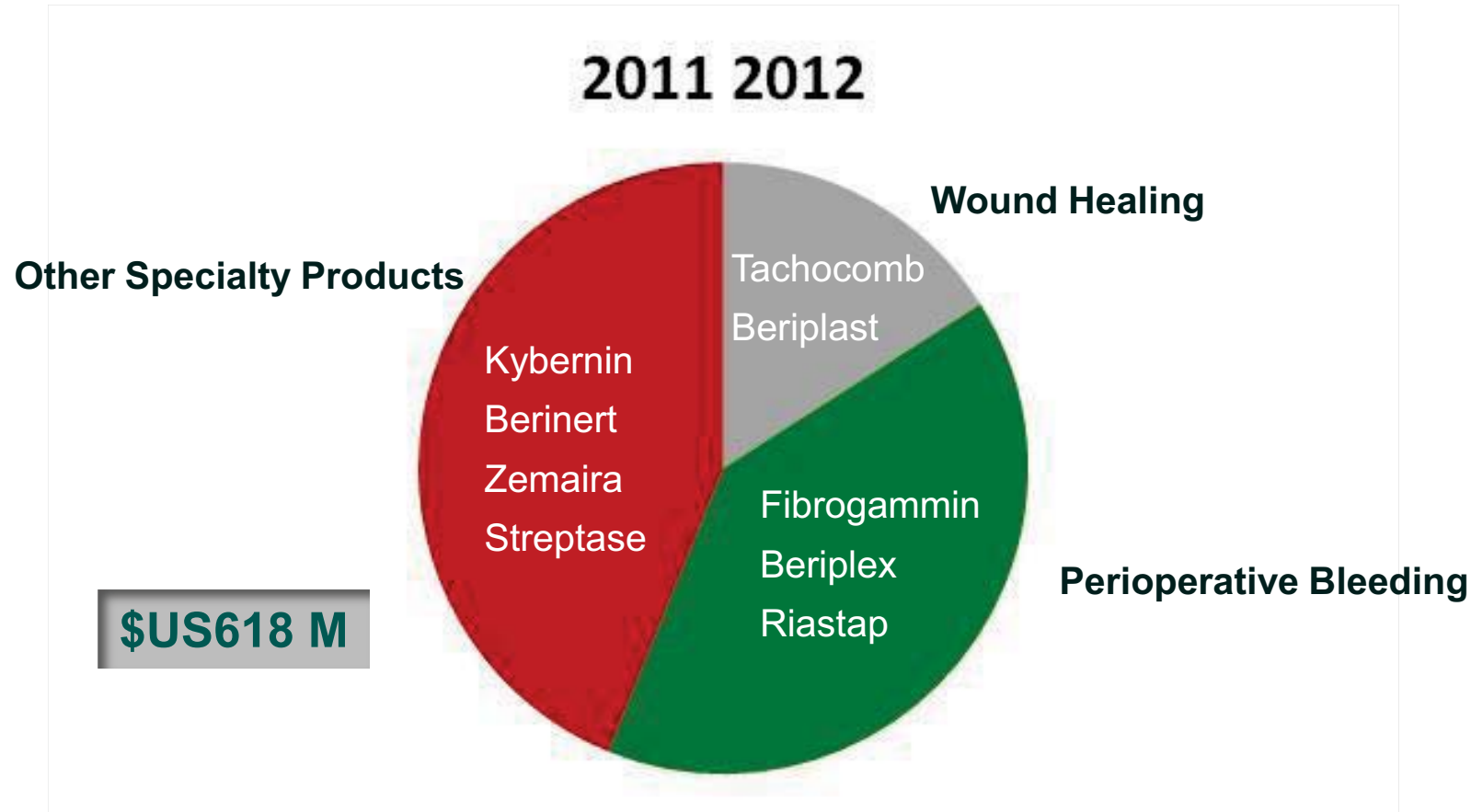
Total market (volume): ~ 1,000 kg

Total U.S. Market: ~ \$US 300-500 M

1) <http://www.cdc.gov/cmvtrends-stats.html>

Specialty Products

Specialty Products



- Increase clinical data set
- Add indications
- Expand regionally

In the US 3.8 M patients are on warfarin¹ with a major bleeding rate of 3.1-3.6%² per year

- In US launch in warfarin reversal indication
- US surgical indication: Patients requiring emergency surgery needing urgent reversal of warfarin
- Understand the use in Factor Xa inhibitor reversal
- Include in perioperative bleeding management algorithm

1) IMS data July 2012

2) Connolly et al NJEM 2009, Patel et al NEJM 2011, Granger et al NEJM 2011

Blood Products vs. Concentrates



FFP

Fibrinogen concentration at $\approx 2.3\text{g} / \text{L}$
Not virus inactivated
Frozen, requires time (<50 minutes) to thaw



Red Blood Cells

Need to be matched to blood type
Not virus inactivated



Platelets

Short shelf life (5 days)
Risk of bacterial contamination



Cryo

- Frozen, require time to thaw
- Pooled from 10 bags of FFP in the blood bank
- Average Fibrinogen concentration $\approx 6\text{g} / \text{L}$

Confidex®

RIASTAP®
Fibrinogen Concentrate

Corifact®
Factor XIII Concentrate (Human)



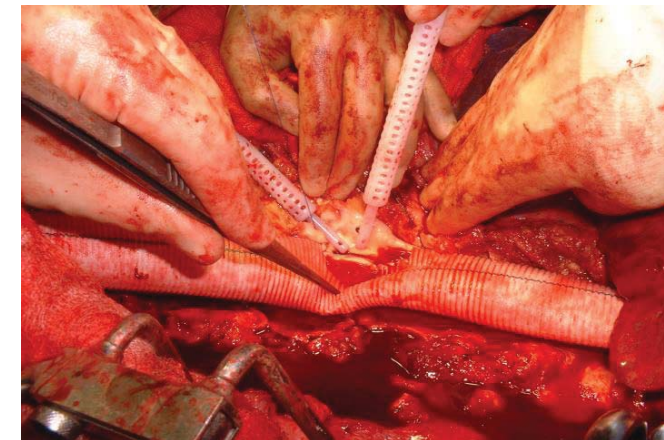
Concentrated, virus inactivated, room temperature storage, Fibrinogen concentration $20\text{g} / \text{L}$



Fibrinogen[®]



- Obtain WEU & US acquired label
- Initiate acquired label expansion
- Generate, publish & communicate data



Bring to Europe

Pivotal trial objective: Zemaira slows the progression of emphysema

Demonstration of a clinical outcome (disease modification)

- Publish data in 2013:
 - American Thoracic Society
 - European Respiratory Society
- Recognition in treatment guidelines
- Demonstrate economic benefit
- Reimbursement
- Enhanced testing & diagnosis



Beriner treats the fundamental cause of HAE symptoms by providing C1-INH deficient patients with the missing human protein¹.

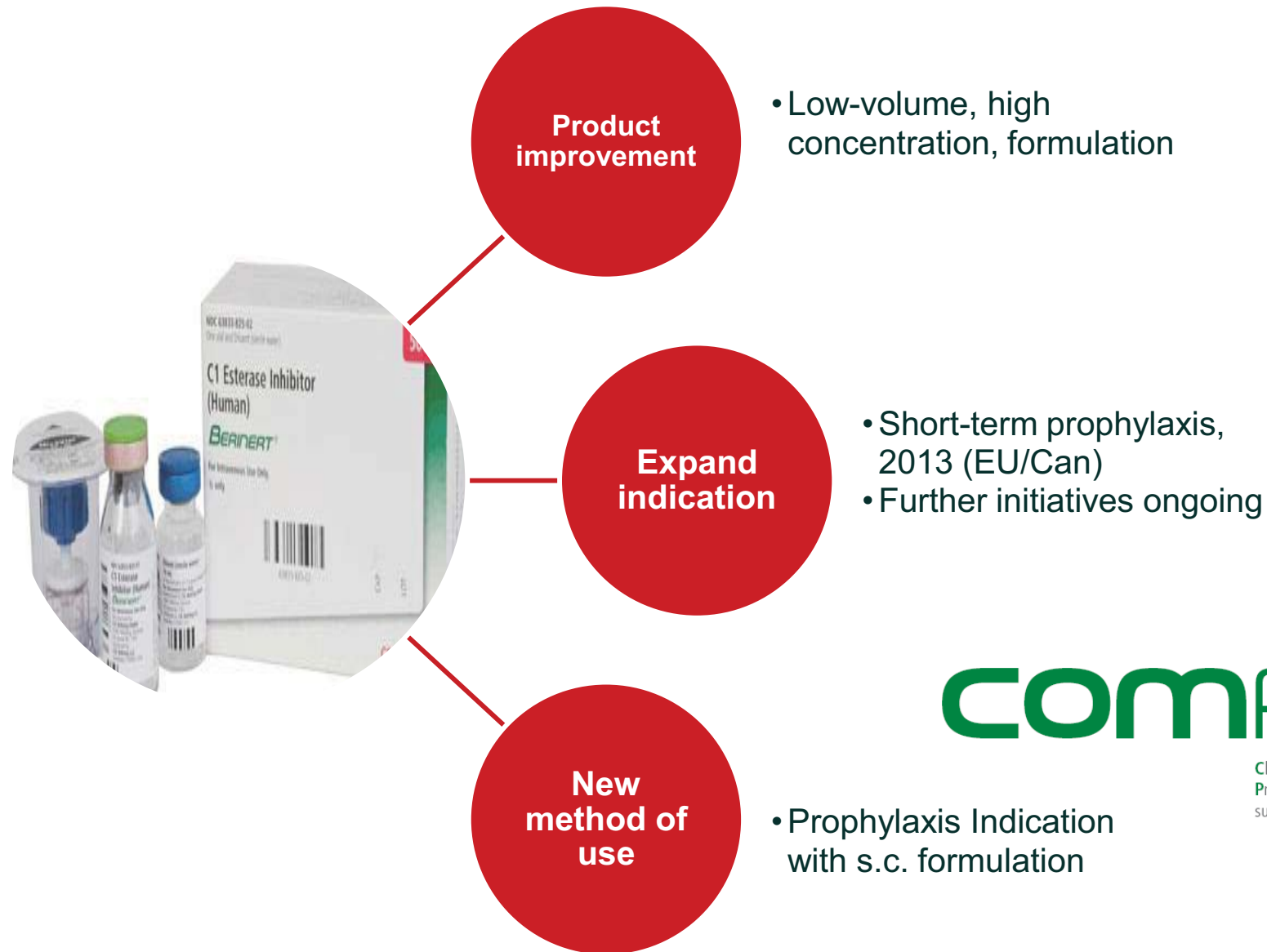
Beriner has demonstrated that it provides fast relief of pain and swelling within 30 minutes²

- Obtain Prophylaxis indication
 - Increase convenience with s.c. treatment option
- Continue geographical expansion
- Continuous Life Cycle Management to improve product profile

1) Agostini et al. J Allergy Clin Immunol. 2004

2) Craig et al. J Allergy Clin Immunol 2009

Berinert[®] - Current Life Cycle Activities



COMPACT

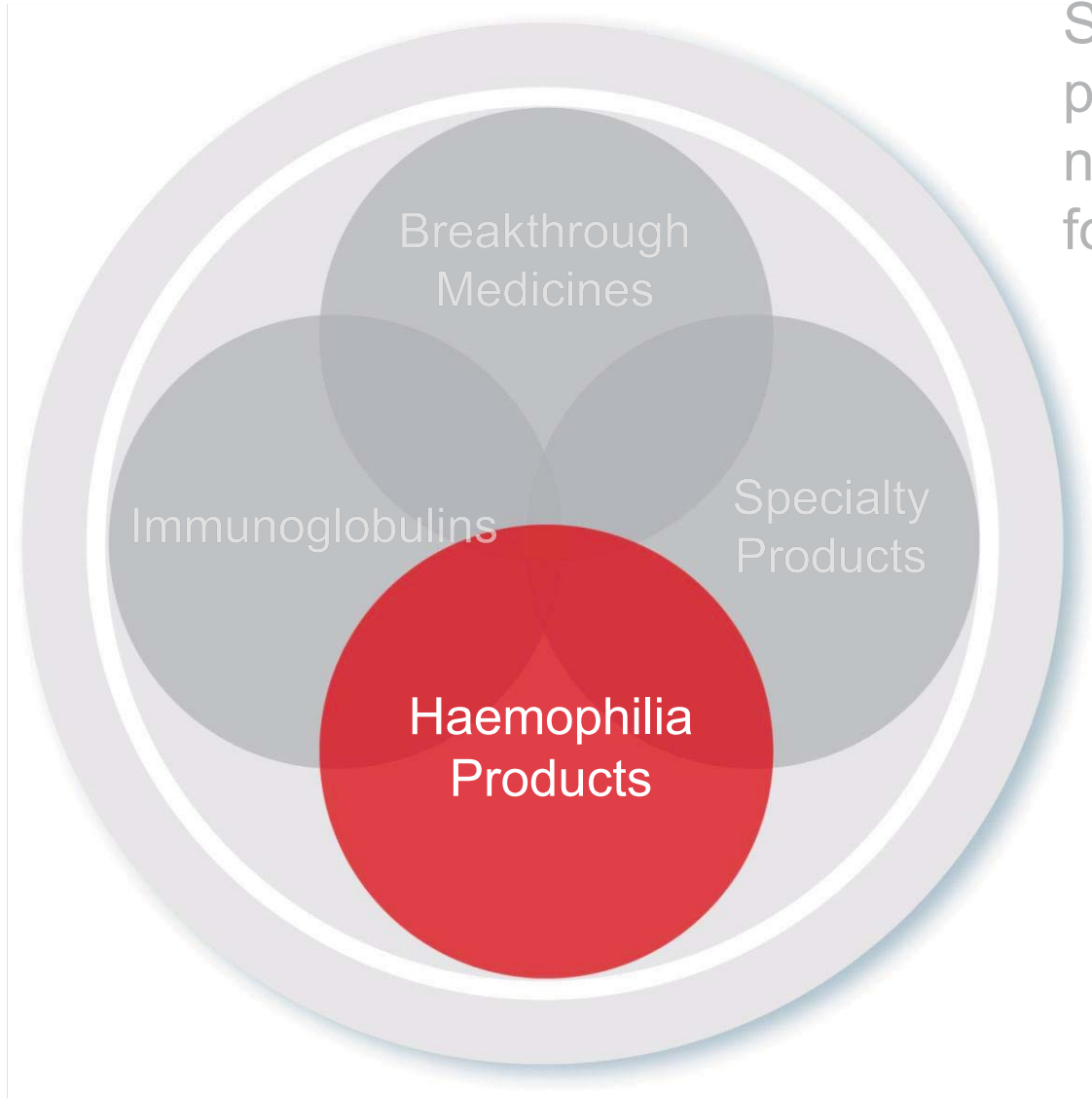
Clinical Studies for **O**ptimal Management in Preventing **A**ngioedema with low-volume subcutaneous **C**1-inhibitor Replacement **T**herapy

Q&A

Break

Haemophilia Products

Haemophilia



Supporting and enhancing plasma products and developing novel recombinant portfolio with focus on:

- Scientific and product innovation
- Patient benefit

Key Focus

- Long acting rIX-FP
- Long acting rVIIa-FP
- rVIII-Single Chain
- Research into long acting rVWF-FP

Innovation to Drive Growth

- Patient convenience primary driver of innovation
 - Albumin fusion technology
 - rIX-FP, rVIIa-FP, rVWF-FP
- Factor VIII
 - biobetter rVIII-SingleChain

Scientific Edge

Improved half life, extended dosing interval

rAlbumin as fusion platform

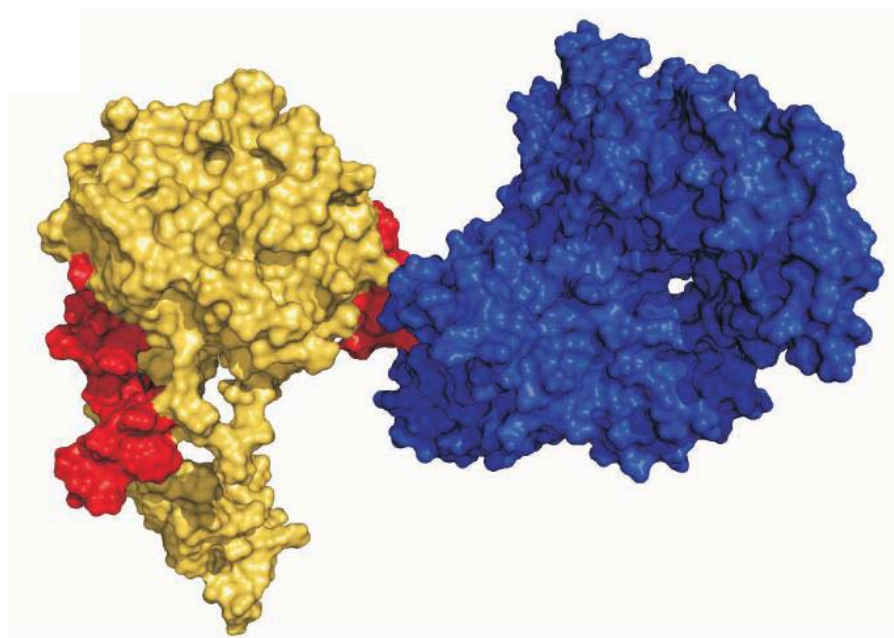
Precise engineering of specially designed linker

High VWF affinity

Improved molecular stability

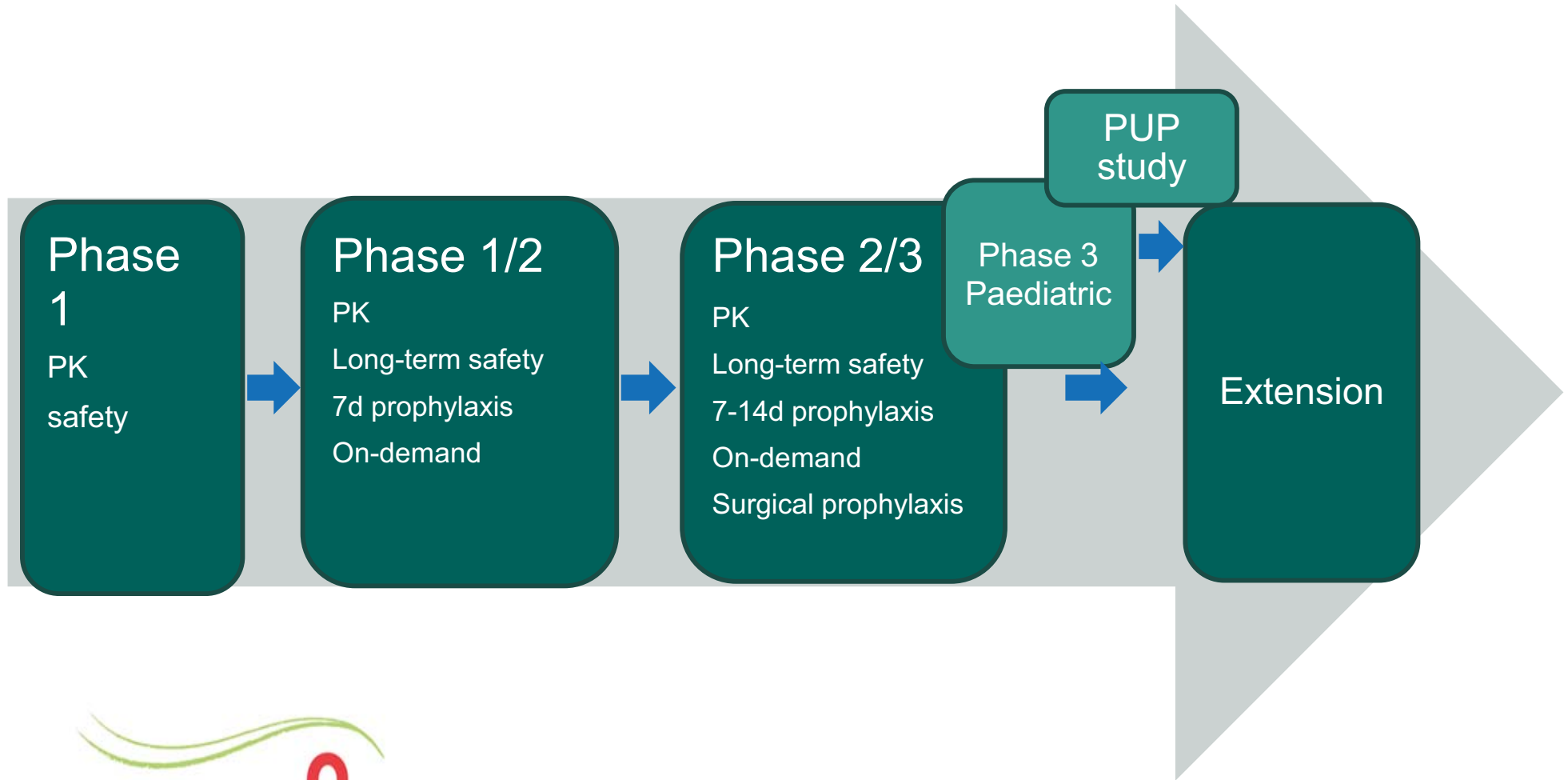
Opportunity for Extended Dosing Interval

rIX-FP (CSL654)



PROLONG **9** FP

rIX-FP (CSL654) Clinical Program

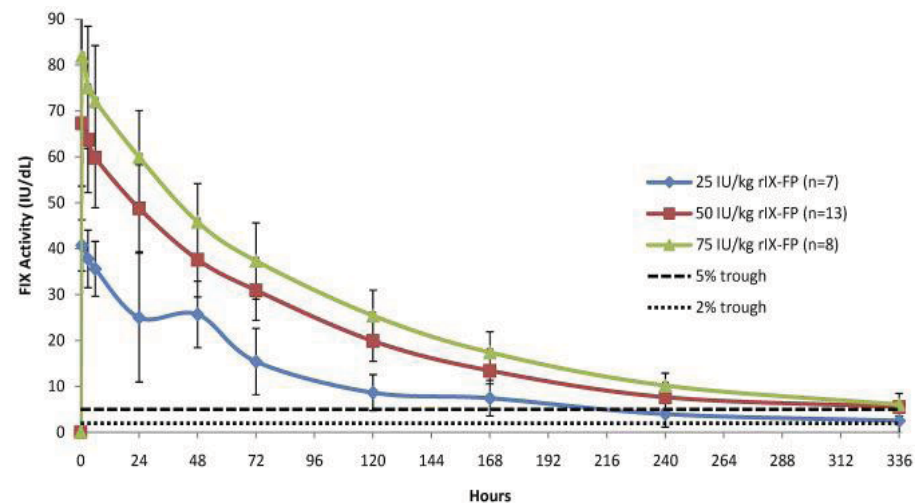
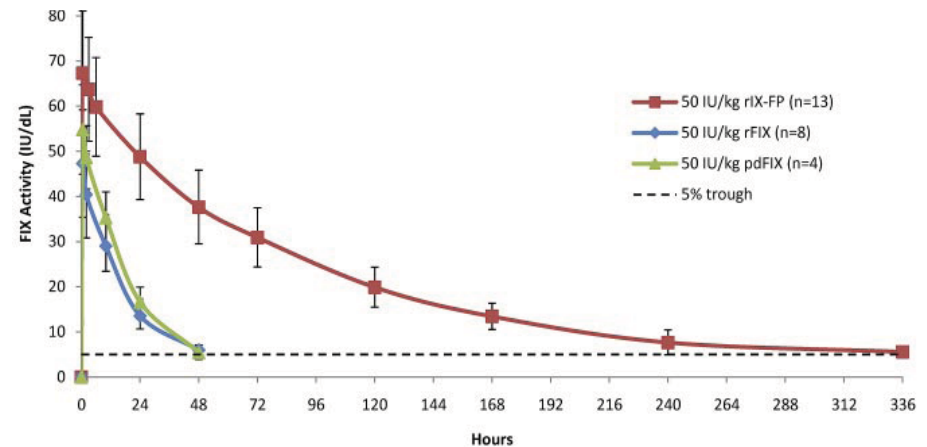


Safety and pharmacokinetics of a novel recombinant fusion protein linking coagulation factor IX with albumin (rIX-FP) in hemophilia B patients

Elena Santagostino, Claude Negrier, Robert Klamroth, Andreas Tiede, Ingrid Pabinger-Fasching, Christine Voigt, Iris Jacobs and Massimo Morfini

Compared with in market rFIX

- 5.3-fold longer half-life (92hrs)
- ~ 45% higher incremental recovery
- ~7-fold larger AUC
- ~7-fold slower clearance



Efficacy of rIX-FP in Phase 1/2 Trial

- 13 subjects treated weekly for up to 48 weeks
 - previously on prophylaxis → no increase in weekly FIX consumption
 - switched from on-demand to weekly prophylaxis → >90% reduction in bleeding rate
- Subjects treated on-demand (85 bleeds)
 - 88% of episodes controlled by a single injection (the rest by only one additional injection)



rIX-FP (CSL654) Safety Data

- Excellent safety profile in completed studies
 - Well tolerated
 - No inhibitors
 - No adverse events related to CSL654

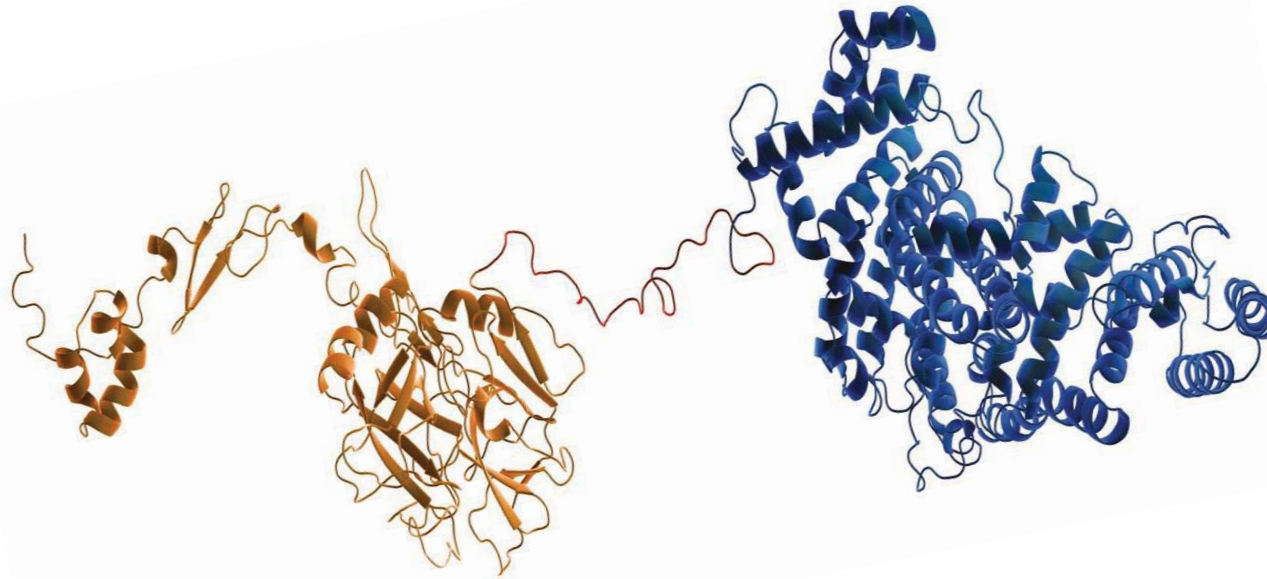


rIX-FP (CSL654) Further Development

- Enrolment of Phase 2/3 study due to be completed early 2013
- Paediatric study has commenced
- Prolonged half life → exploring treatment intervals longer than every second week



rVIIa-FP (CSL689)



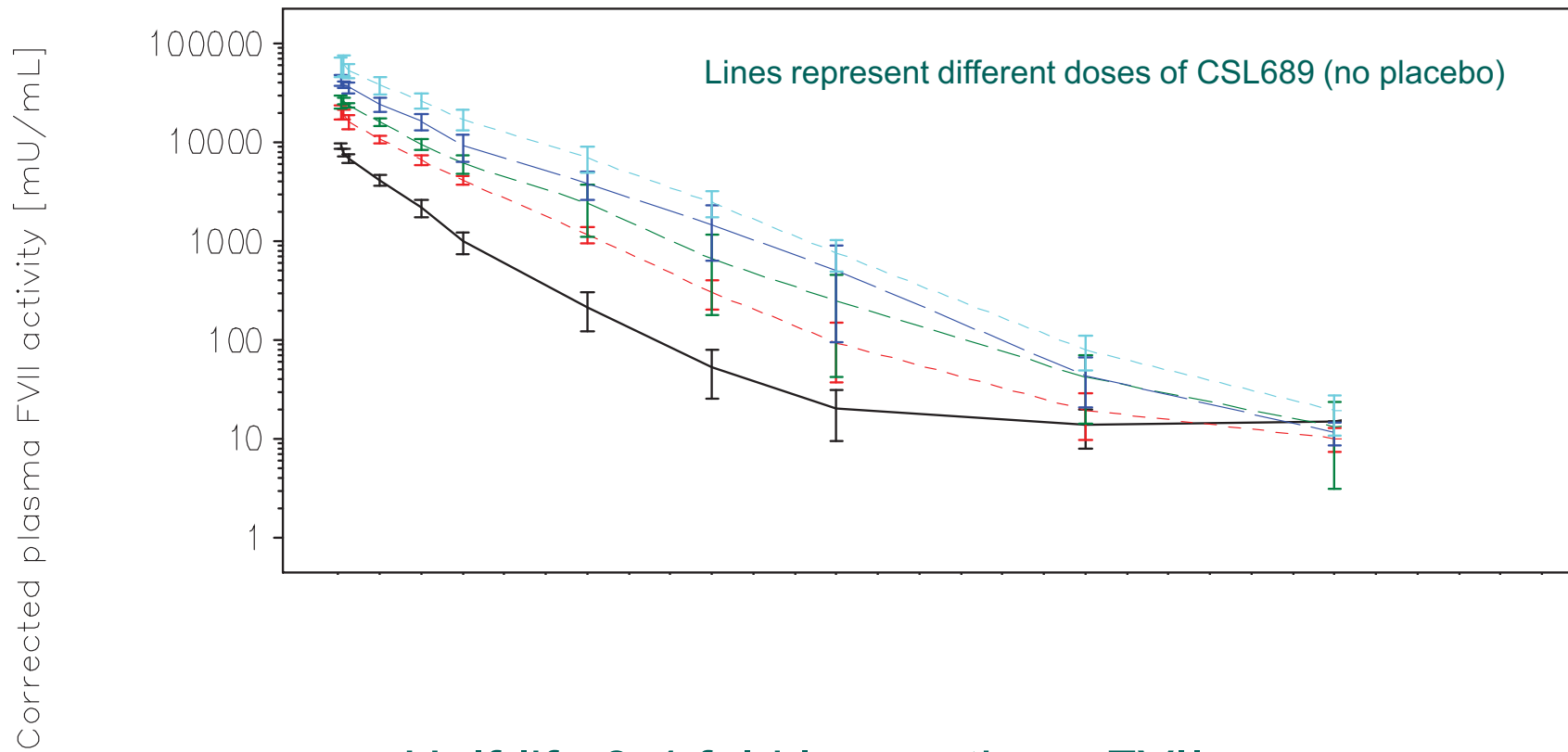
PROLONG **7** FP

Development of rVIIa-FP (CSL689)

- Phase 1 in 40 healthy volunteers
 - First-in-man dose escalation study in healthy volunteers completed
 - No SAEs, one related mild AE
- Pivotal Phase 2/3 Trial in Hemophilia A & B patients with Inhibitors
 - Dose finding, Safety and Efficacy on-demand therapy
 - Completed discussions with PEI
 - Briefing documents to FDA / EMA



Phase 1 Study of rVIIa-FP in Healthy Volunteers



Half-life 3-4 fold longer than rFVIIa

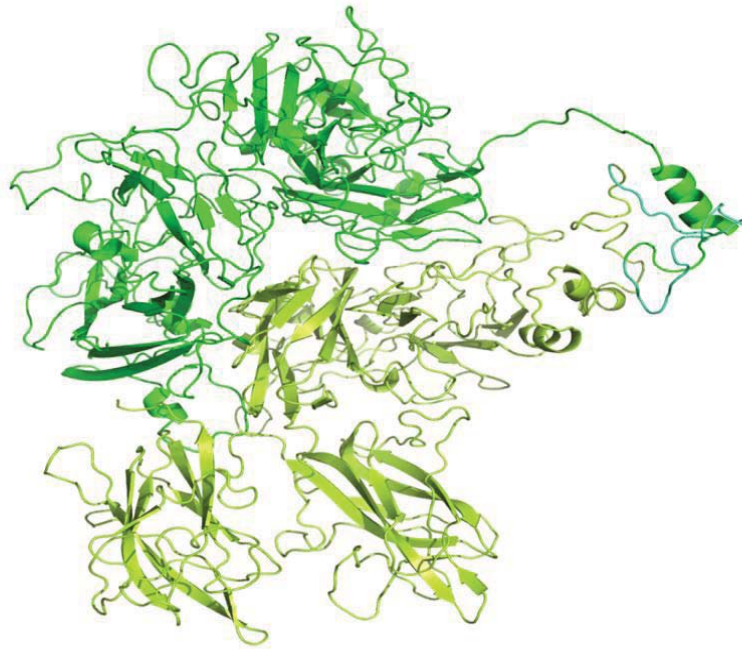


Potential of rVIIa-FP (CSL689)

- For patients with inhibitors
 - Single dose for treatment of bleeding
 - Prevention of bleeding in patients undergoing surgery
 - Prophylaxis
- Other indications
 - Congenital Factor VII deficiency
 - Acquired hemophilia
 - Glanzmann's thrombasthenia



rVIII-SingleChain (CSL627)



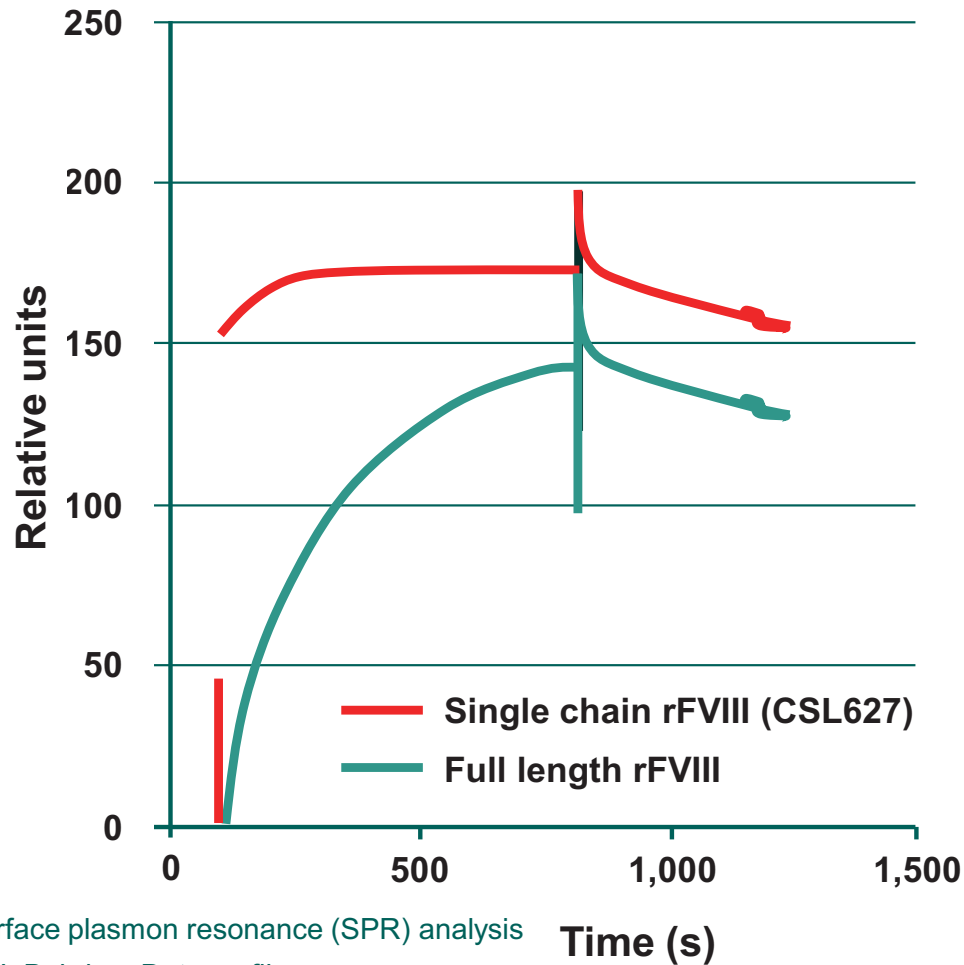
rVIII-SingleChain: approach for improved FVIII

- FVIII's physiological partner in plasma is von Willebrand factor (vWF)
 - FVIII/vWF complex is important role in the physiological activity and clearance of FVIII
 - *Aim - improve binding to VWF*
- FVIII is an unstable molecule in the manufacturing environment
 - Potential for dissociation and loss of procoagulant activity of FVIII
 - *Aim - improve molecular stability*



rVIII-SingleChain: high affinity for vWF

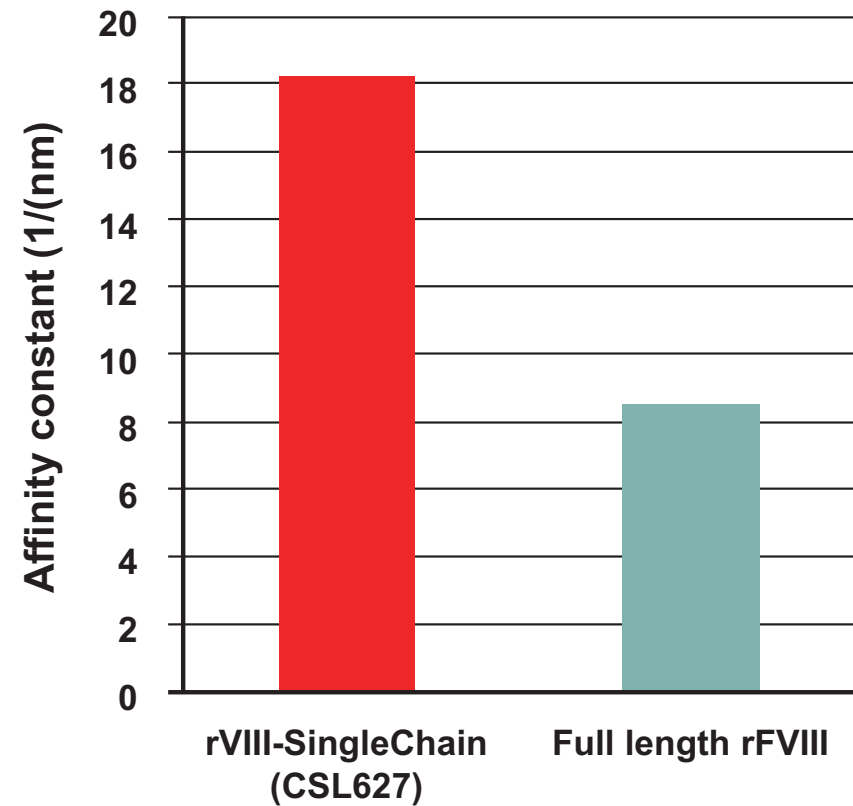
Binding to plasma-derived (pd) VWF



Surface plasmon resonance (SPR) analysis

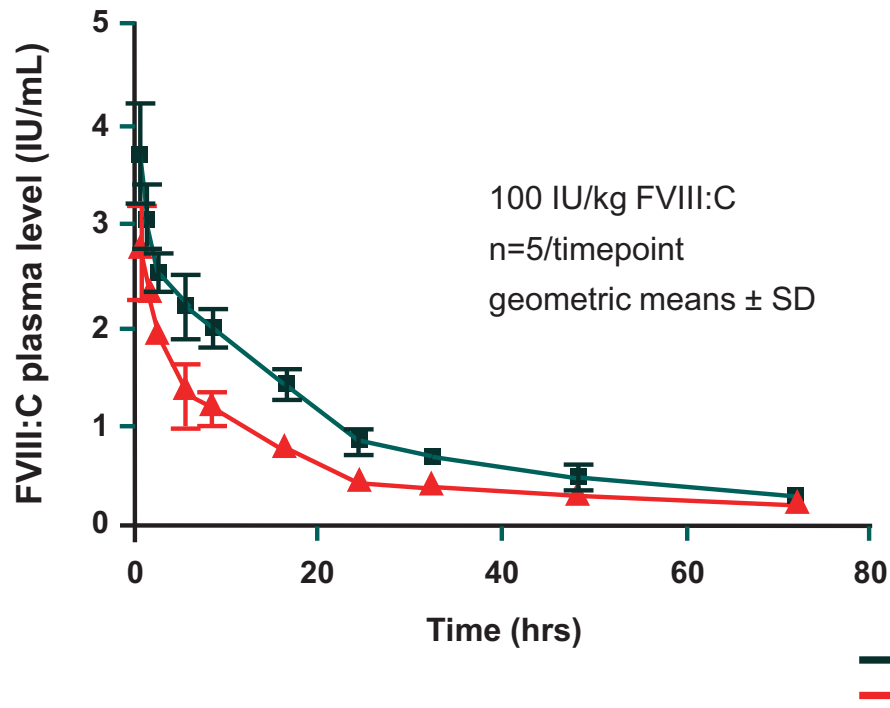
CSL Behring. Data on file

Comparison of VWF affinity constants

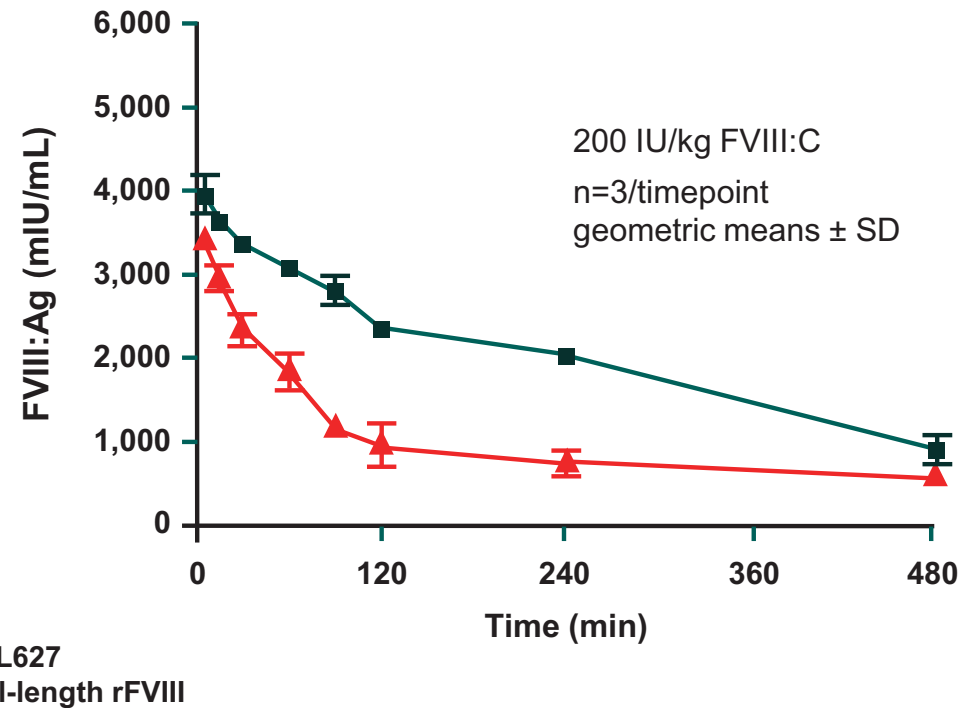


rVIII-SingleChain : PK profiles in rodents

PK in haemophilia A mice

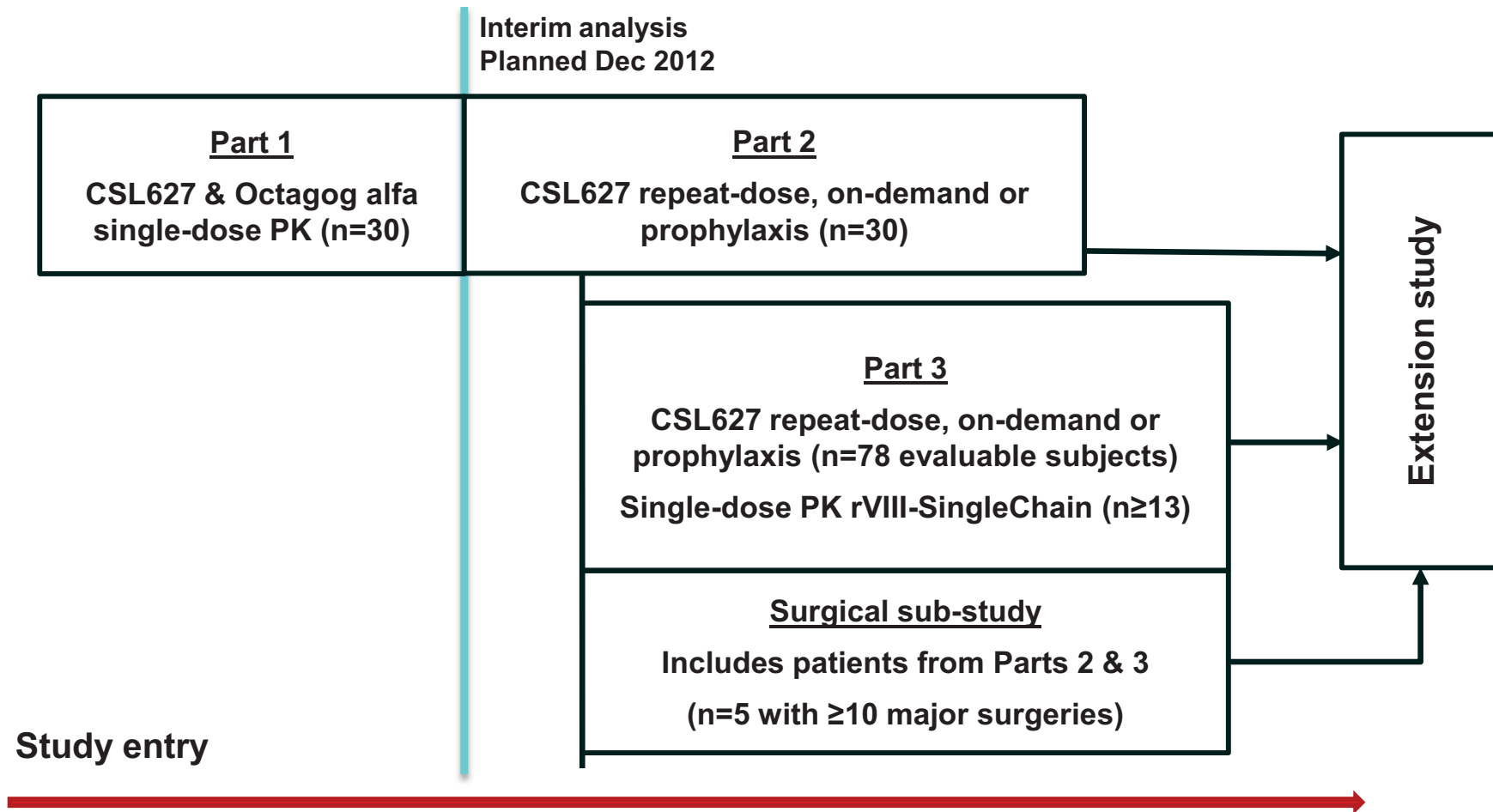


PK in rats



CSL627 has ~ 50% increase in terminal half-life compared to full-length rFVIII

rVIII-SingleChain Phase 1/3 Study Design



- Part 1 due to complete enrolment 2012
- Part 3 to commence early 2013

Recombinant Coagulation Portfolio Summary

Target Launch Dates

2015

CSL654 (rIX-FP)

- Pivotal Phase II/III study commenced
- Phase I data demonstrate >5x half life extension
- Orphan drug status granted by US FDA

2016

CSL627 (rVIII-SingleChain)

- Phase I/III trial commenced
- Early clinical data support potential half life extension

2017+

CSL689 (rVIIa-FP)

- Initial pharmacokinetic data shows a 3-4x half life extension
- Orphan drug status granted by US FDA

CSL650 (rVWF-FP)

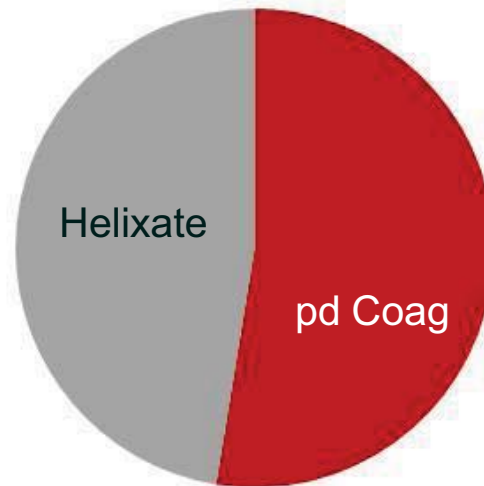
- Candidate pre-clinical molecule shows a 5x half life extension

Commercial Opportunities and Activities

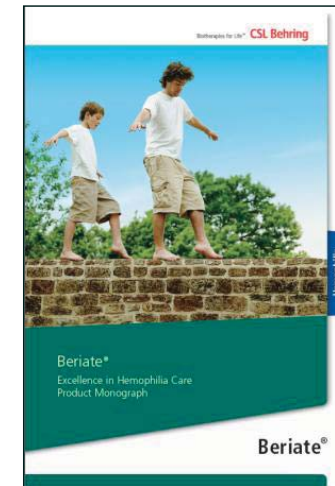
Coagulation Sales



2011 2012



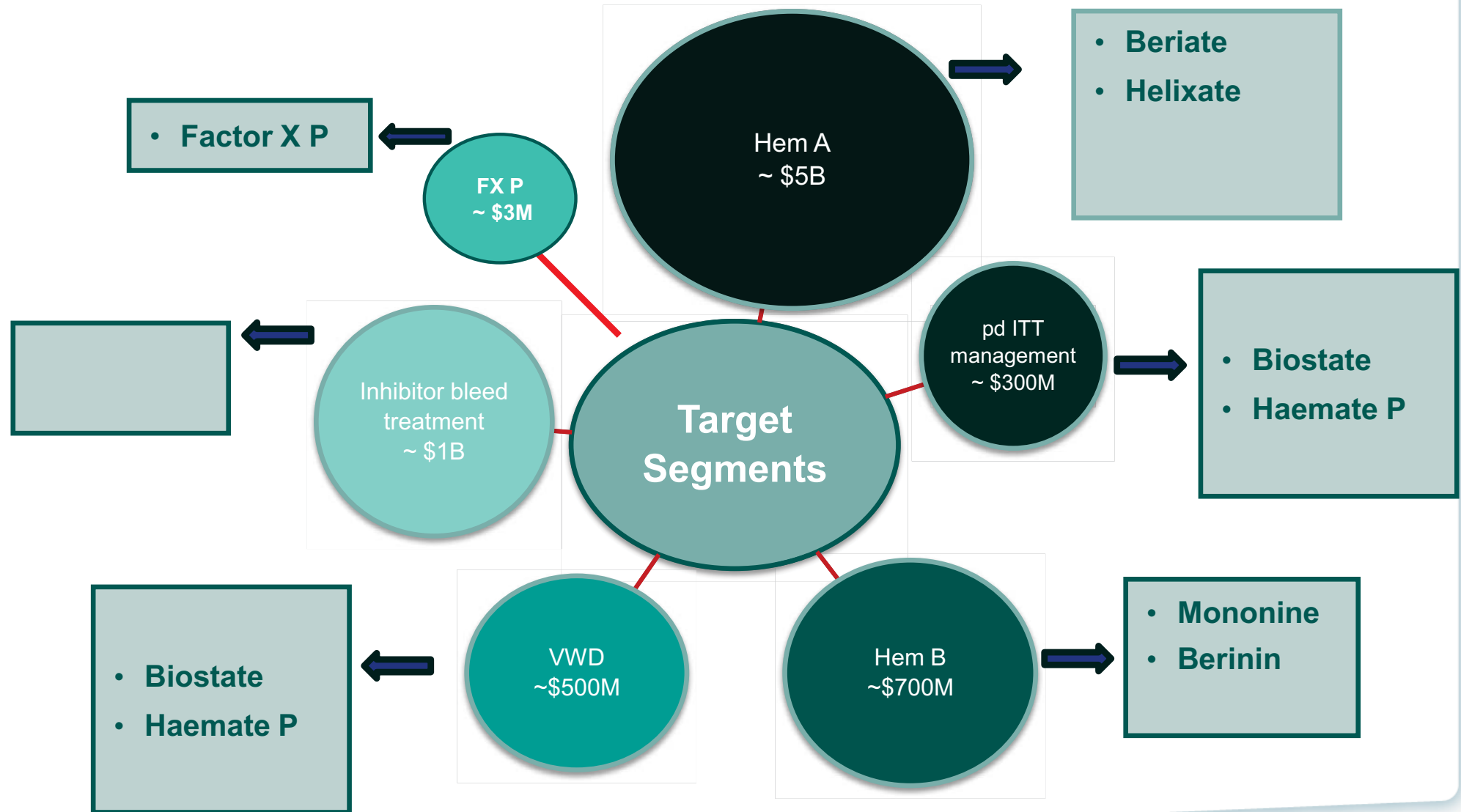
\$US1,058M



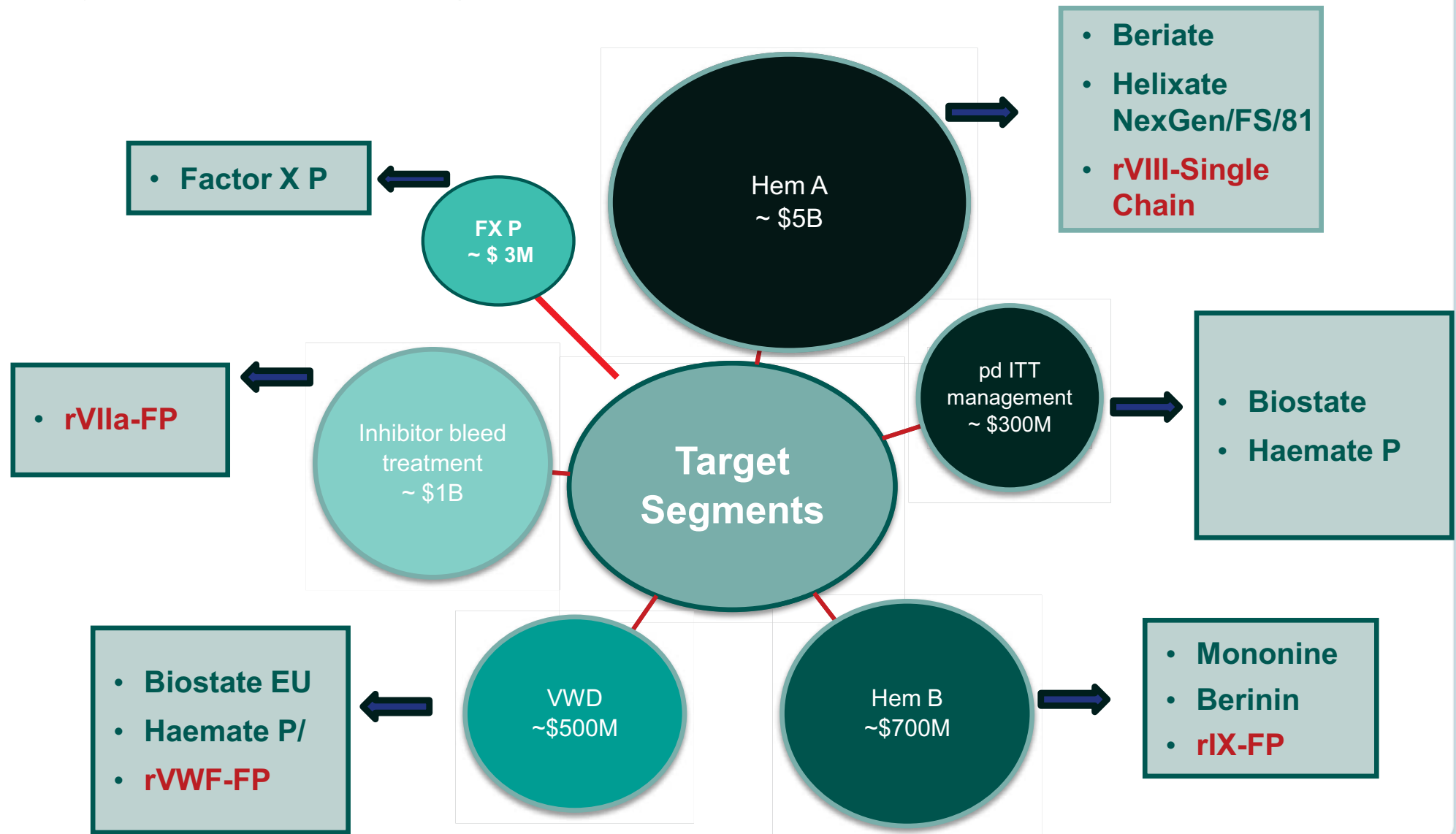
- Launch rIX-FP in 2015
- Launch rVIII-SingleChain as bio-better in 2016
- Grow pd FVIII

Coagulation: Total Market Size

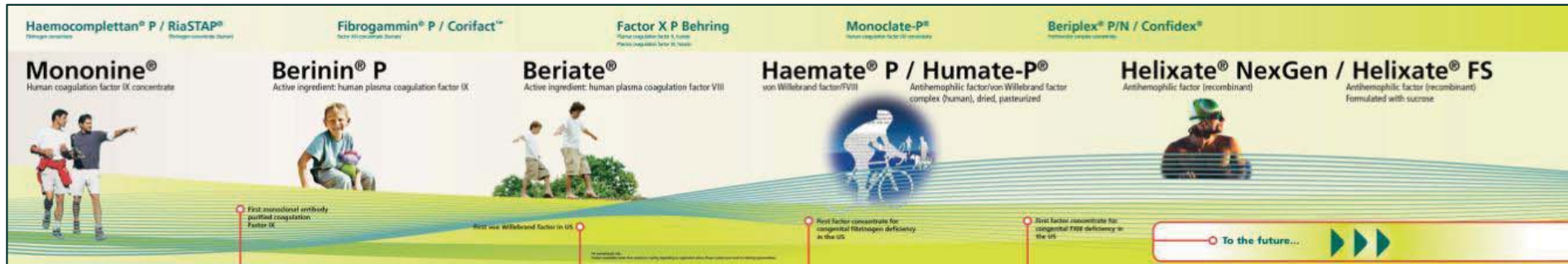
Key Market Segments and Products



Coagulation: Key Market Segments and Products.



Recombinant Coagulation Portfolio



- Differentiate recombinant albumin fusion platform and launch rIX-FP
- Differentiate and launch rVIII-SingleChain
- Strong support for Helixate and growth of rVIII-SingleChain

rIX-FP (CSL654) & rVIIa-FP (CSL689)

Scientific Edge

Improved half
life, extended
dosing
interval

Recombinant
Albumin as
fusion
partner

Specifically
designed
linker



rIX-FP: The Scientific Edge

Phase 1 data	rIX-FP ¹ (CSL Behring – Albumin Fusion)	rFIX- PEGylated ²	rFIX-Fc fusion ³
Half life extension vs rFIX	x 5.3	x 5	~ x3



- Half life supports dosing every 2+ weeks

1 Santagostino et al, Blood. 2012; 120 (12): 2405 – 2411

2 Negrier et al., Blood 2011, 118(10): 2695-2701

3 Shapiro et al., Blood 2012, 119(3): 666-672

rVIIa-FP: The Scientific Edge

T/2 extension	rVIIa-FP (CSL Behring-Albumin Fusion) <i>Phase 1 being analysed</i>
Half life vs rFVIIa	x 3-4



- The only half life extension technology currently in clinical development which enhances the duration of effect of *native* rFVIIa
- Half life supports single dose management of bleeding events and may enable prophylactic use

rVIII-SingleChain (CSL627)

Commercial Edge

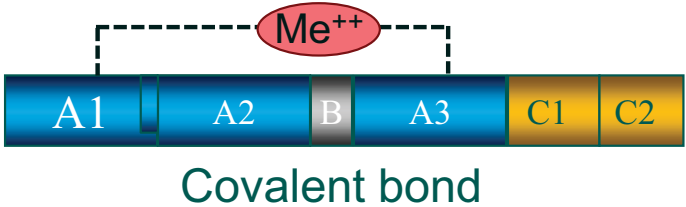
Scientific Edge

Improved financial contribution

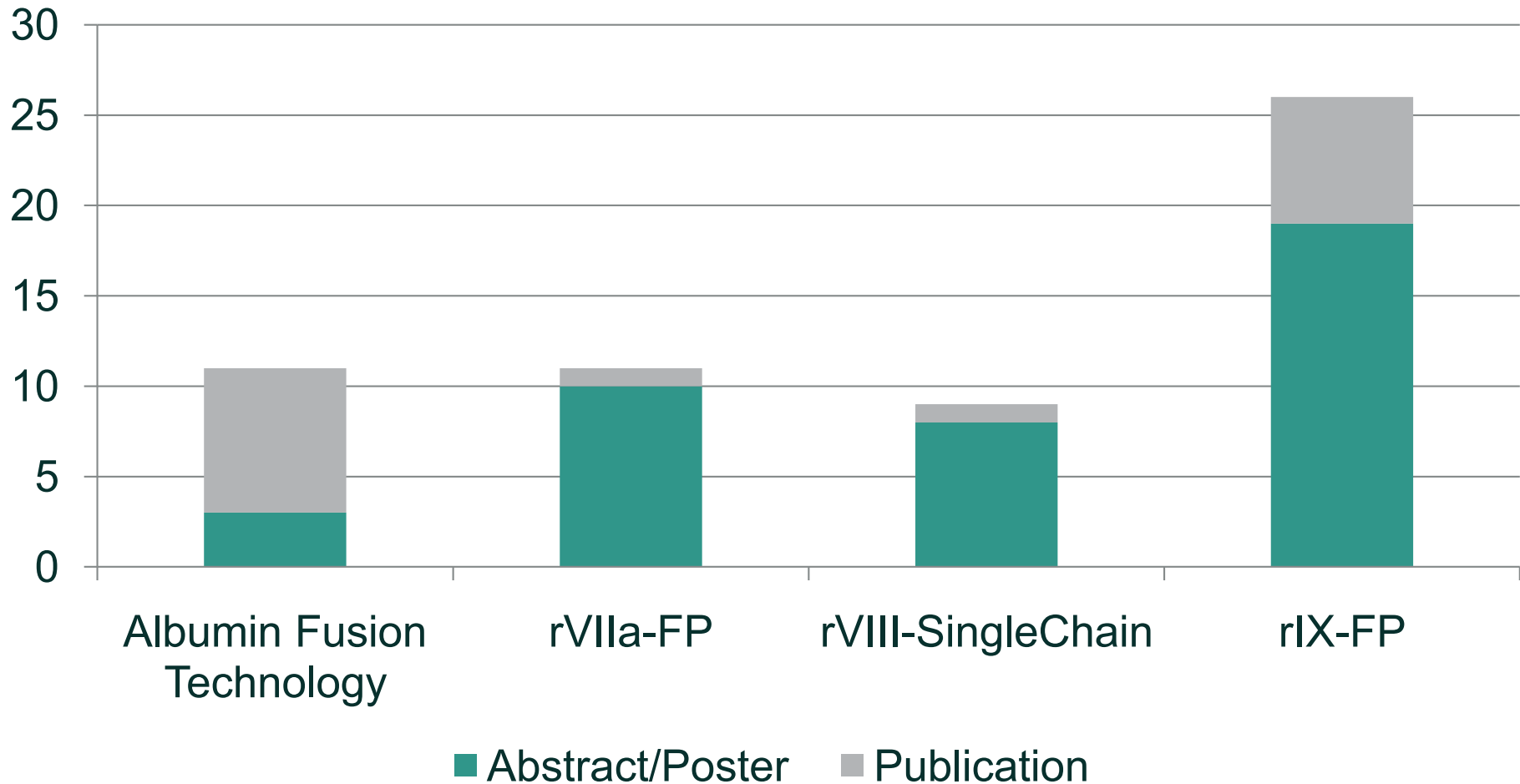
High VWF affinity

Improved molecular stability

Opportunity for Extended Dosing Interval

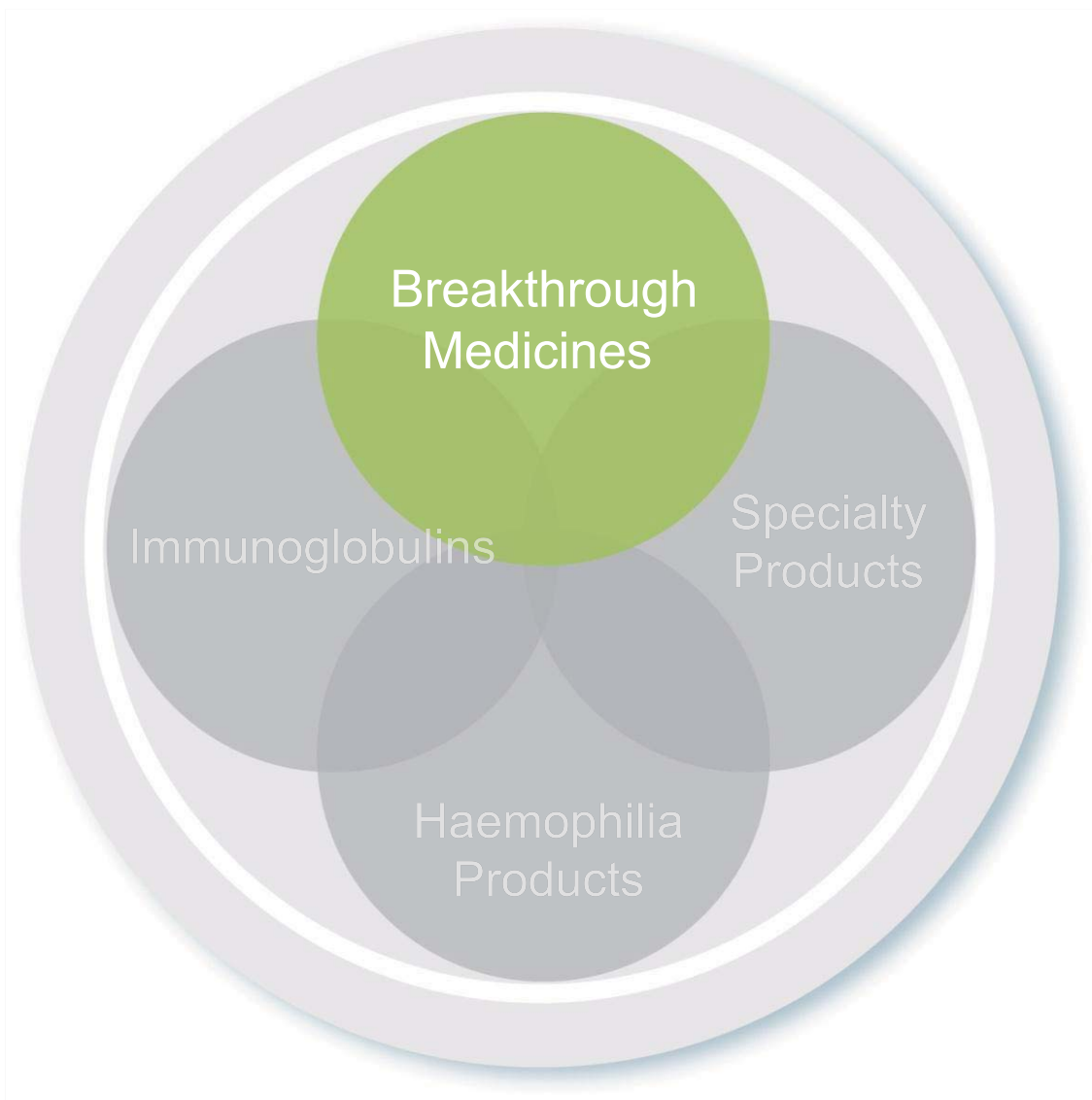


Presenting Data: Active Scientific Presence



Breakthrough Medicines

Breakthrough Medicines



Leveraging clinical and technical insight in developing novel protein-based therapies

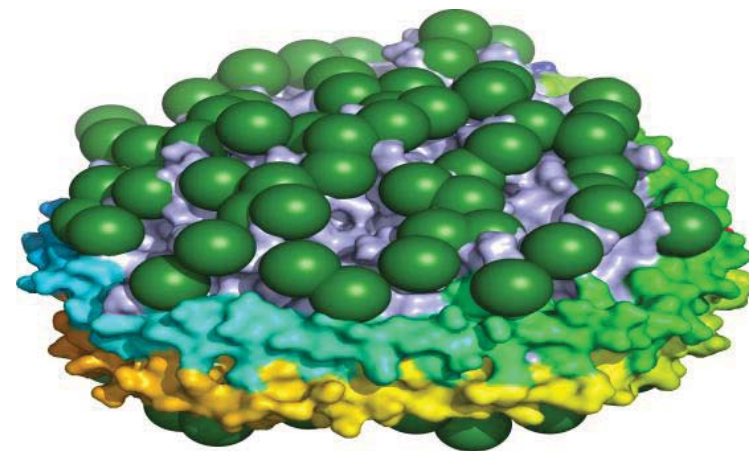
- Significant unmet need
- Multiple indications

Key Focus

- CSL112 (Apo AI)
- CSL362 (anti-IL-3R mAb)
- CSL346 (anti-VEGF-B mAb)

CSL112 (Apolipoprotein A-I)

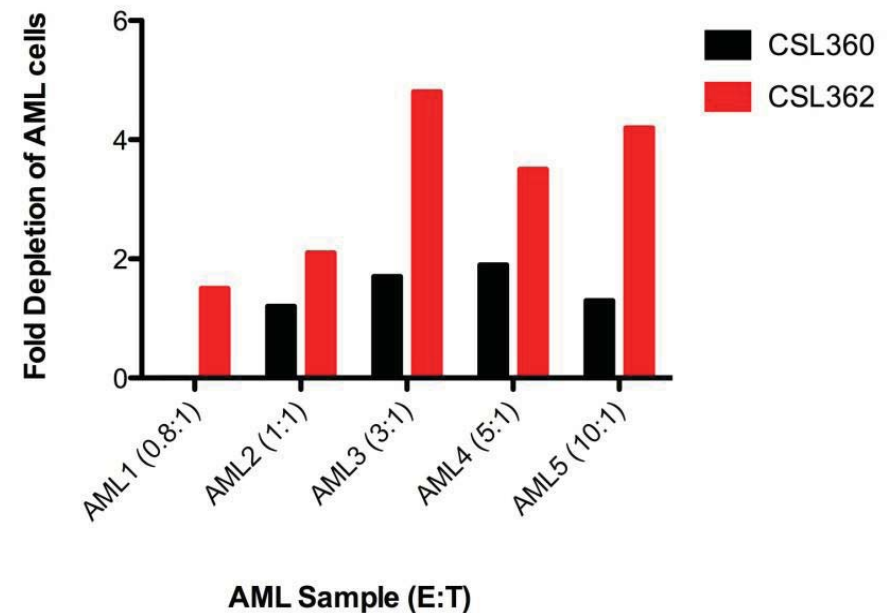
- CSL112 is natural apolipoprotein A-I (apoA-I) the chief protein component of HDL
- Rapidly and robustly enhances capacity of plasma to promote cholesterol efflux
- Global Phase 2b development program to initiate mid-2013
- Potential to address significant gap in acute coronary syndrome



CSL362 (anti-IL-3R α mAb)

- Initial indication: Acute myeloid leukaemia
- Enhanced recruitment of tumour killing NK cells
- Targeting patients in remission with high risk of relapse
- Phase I trial in progress at 4 sites
- Other high quality opportunities in autoimmunity eg. SLE

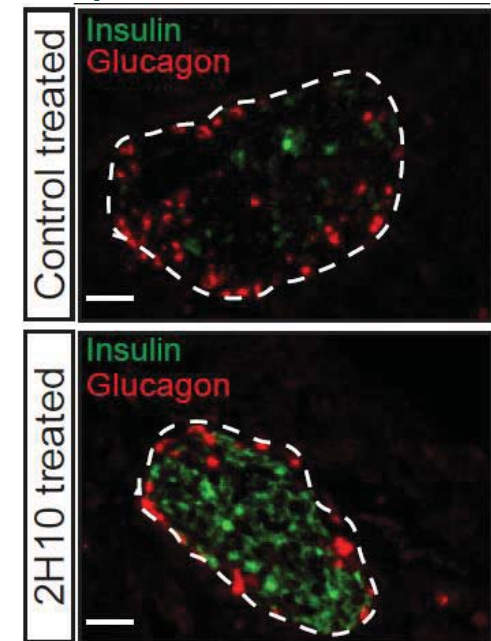
CSL362 - Improved killing of patient leukaemia cells with autologous NK cells



CSL346 (anti-VEGF-B mAb)

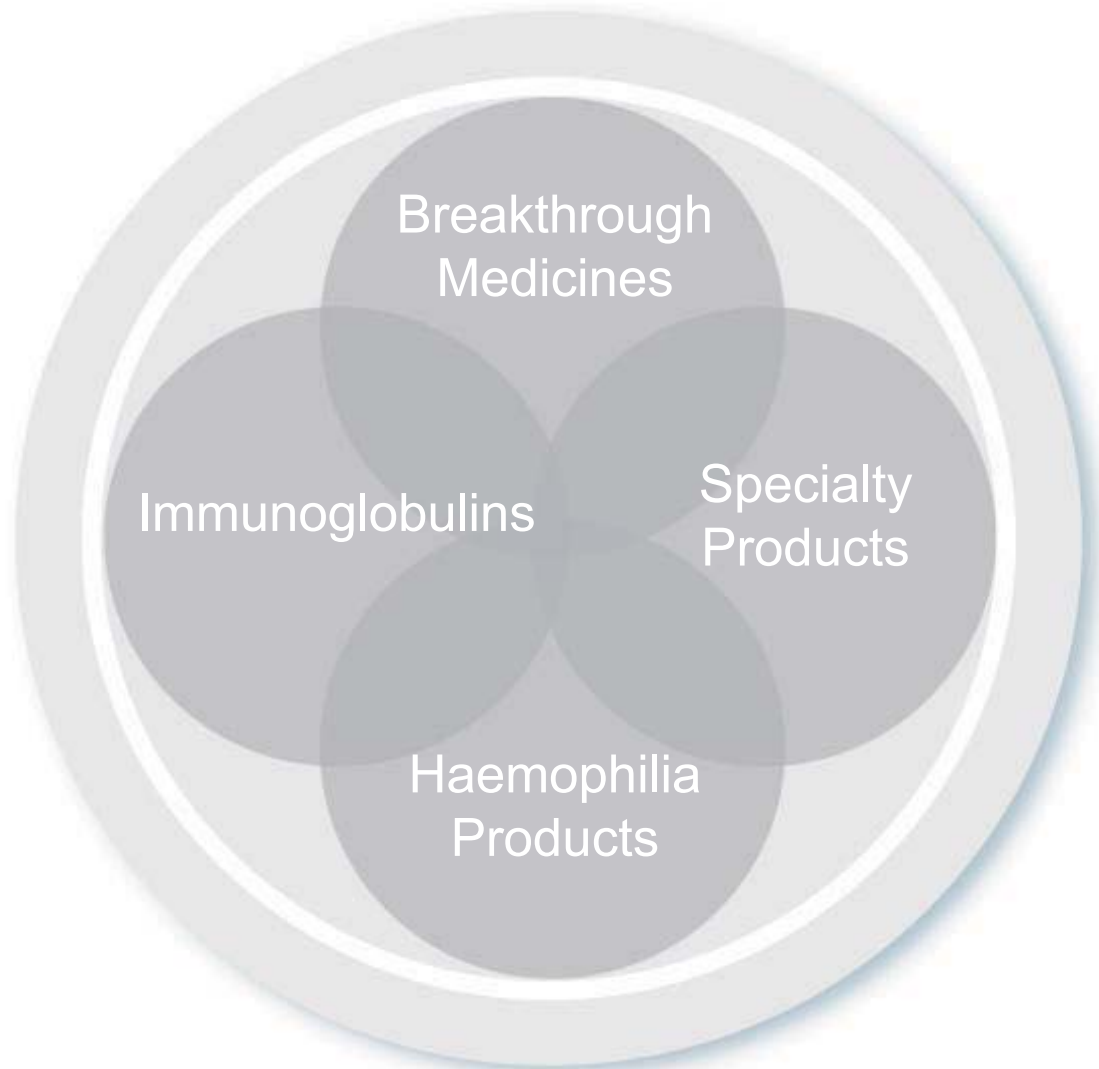
- Type 2 Diabetes
 - Fat accumulation within tissues leads to insulin resistance and failure to control blood glucose
 - Most patients progress to insulin dependence
- VEGF-B controls fat uptake into tissues
 - Blockade of VEGF-B signalling in rodents prevents insulin resistance and preserves islet cell function
- Humanised mAb in development
 - single agent and in combination with existing therapies

CSL346 treatment preserves β cell insulin production in diabetic mice



Licensing and Collaborations

Licensing

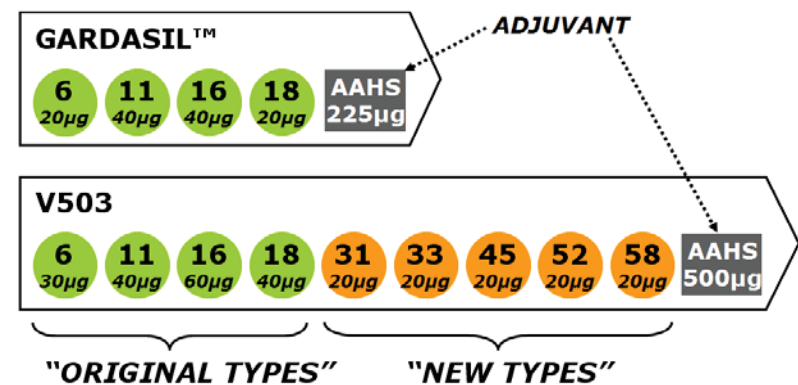


Optimising value of IP Portfolio and assets

- Partner high opportunity products
 - GARDASIL[®]
 - Mavrilimumab (GM-CSFR α - Medi/AZ)
 - Periodontal disease (Sanofi)
- Continue broad licensing strategy for ISCOMATRIX[®] adjuvant

GARDASIL®

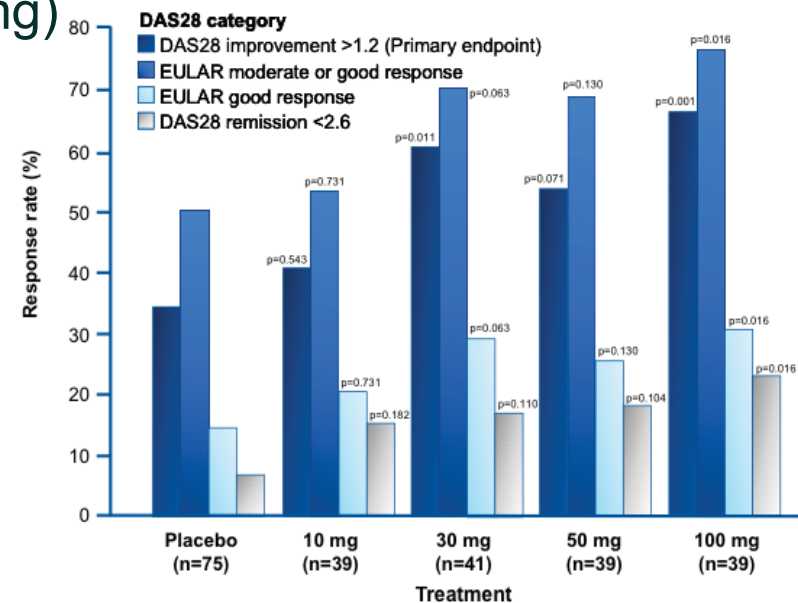
- Impact of Australian HPV Vaccination Program
 - 93% reduction in genital warts in females less than 21 years
- Adolescent male funding
 - Extension to Australian NIP to include 12-13 yr males, with 2 year catch up for Year 9 males, from 2013
- Long term protection
 - No break through disease 6 yrs post immunisation
- V503: 9-Valent HPV Vaccine
 - Merck's 2nd generation HPV vaccine
 - Anticipated global filing Dec 2013 for 2015 launch



Mavrilimumab (GM-CSFR α)

Phase II EARTH Study completed

- 264 subjects with moderate-to-severe RA
- bi-weekly dosing for 12 weeks (10, 30, 50, 100mg)
- Primary endpoint
 - DAS28-CRP decrease >1.2 at wk12
- Secondary endpoints
 - DAS28-CRP remission
 - ACR20/50/70 & HAQ-DI
 - Safety profile



Outcomes

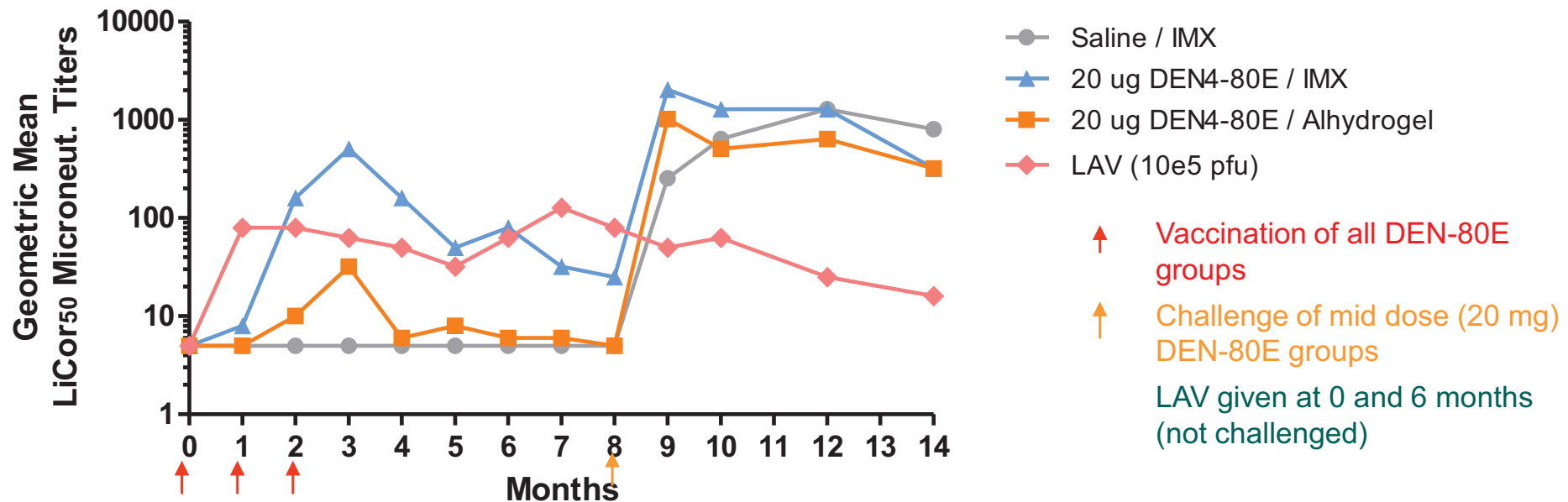
- rapid (2 weeks) and significant clinical effect compared with placebo
- excellent safety profile over 3 months of dosing

Current clinical activity

- Two ongoing Phase II studies
 - mavrilimumab in subjects with moderate to severe RA (NCT01706926)
 - mavrilimumab vs. anti-TNF in subjects with RA (NCT01715896)

ISCOMATRIX[®] Adjuvant Partnering Activities

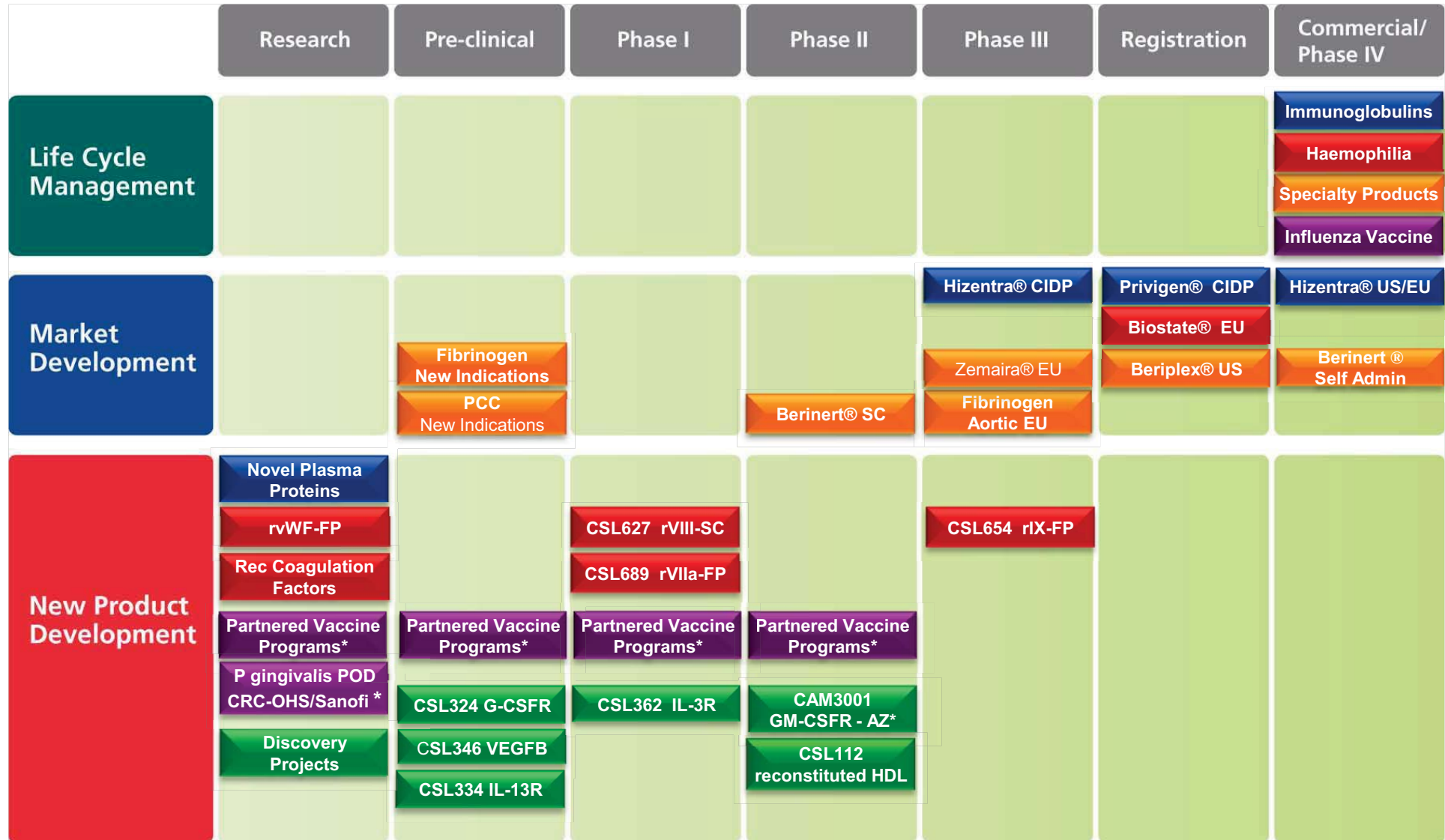
- Major partners continue to advance vaccine development programs
- Merck Research Laboratories initiated Dengue clinical study
 - Strong neutralising antibodies against all 4 serotypes in NHPs even at low antigen doses



Summary

Global R&D Portfolio

December 2012



Core Capabilities

Immunoglobulins

Haemophilia

Specialty Products

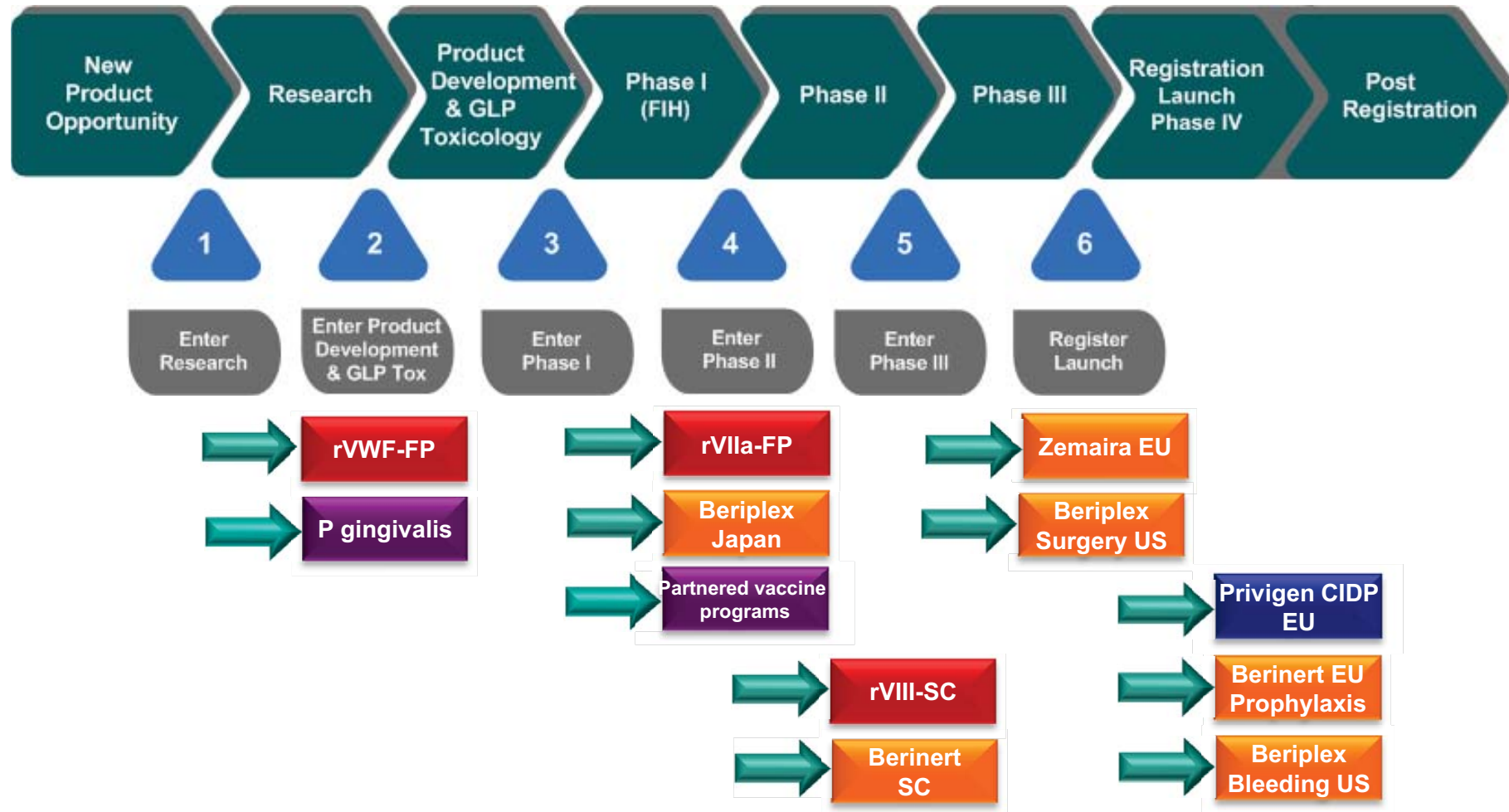
Breakthrough Medicines

Vaccines & IP

*Partnered Projects

#LCM includes direct post marketing commitments as well as pathogen safety, capacity expansions, yield improvements, new packages and sizes for all registered products

Expected Progress in next 12 Months



Significant Short-Midterm Target Launch Dates

2013	2014	2015	2016	2017
		CSL654 rIX-FP	CSL627 rFVIII	CSL689 rVIIa-FP
Beriplex® US Bleeding	Beriplex® US Surgical	Berinert® SubCut EU Fibrinogen EU Aortic Surgery Zemaira® EU	Berinert® SubCut US	
Privigen® CIDP EU	Hizentra® Japan		Hizentra® CIDP	

Core Capabilities Immunoglobulins Haemophilia Specialty Products Breakthrough Medicines Vaccines & IP

*Partnered Projects

*Calendar Years

Q&A

For website and printed version

Mavrilimumab



MedImmune

Safety profile - Most Common Adverse events (≥3%)

Adverse event	Placebo (n=79)	Mavrilimumab, n (%)				
		Total (n=160)	10 mg (n=39)	30 mg (n=41)	50 mg (n=40)	100 mg (n=40)
DLCO change ≥20%	4 (5.1)	19 (11.9)	10 (25.6)	3 (7.3)	3 (7.5)	3 (7.5)
Nasopharyngitis	2 (2.5)	10 (6.3)	1 (2.6)	4 (9.8)	1 (2.5)	4 (10.0)
Upper respiratory tract Infection	4 (5.1)	6 (3.8)	2 (5.1)	1 (2.4)	1 (2.5)	2 (5.0)
Rheumatoid arthritis	2 (2.5)	5 (3.1)	2 (5.1)	1 (2.4)	2 (5.0)	0 (0.0)
Alanine Aminotransferase Increased	0 (0.0)	4 (2.5)	0 (0.0)	2 (4.9)	1 (2.5)	1 (2.5)
Pharyngitis	0 (0.0)	4 (2.5)	0 (0.0)	1 (2.4)	2 (5.0)	1 (2.5)
Transaminases increased	0 (0.0)	4 (2.5)	1 (2.6)	1 (2.4)	1 (2.5)	1 (2.5)
Hepatic enzyme increased	2 (2.5)	2 (1.3)	1 (2.6)	0 (0.0)	0 (0.0)	1 (2.5)
Hypercholesterolemia	1 (1.3)	3 (1.9)	1 (2.6)	1 (2.4)	1 (2.5)	0 (0.0)
Influenza	1 (1.3)	3 (1.9)	1 (2.6)	0 (0.0)	2 (5.0)	0 (0.0)
Neutropenia	0 (0.0)	3 (1.9)	0 (0.0)	2 (4.9)	1 (2.5)	0 (0.0)
Oral herpes	0 (0.0)	3 (1.9)	1 (2.6)	2 (4.9)	0 (0.0)	0 (0.0)

Safety profile – serious adverse events

Serious adverse event	Placebo (n=79)	Mavrilimumab n (%)				
		Total (n=160)	10 mg (n=39)	30 mg (n=41)	50 mg (n=40)	100 mg (n=40)
Total number of SAEs	1 (1.3)	4 (2.5)	2 (5.1)	2 (4.9)	0 (0.0)	0 (0.0)
Humerus fracture	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)
Patella fracture	0 (0.0)	1 (0.6)	0 (0.0)	1 (2.4)	0 (0.0)	0 (0.0)
RA	1 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Intervertebral disc disorder	0 (0.0)	1 (0.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)
Abortion spontaneous	0 (0.0)	1 (0.6)	1 (2.6)	0 (0.0)	0 (0.0)	0 (0.0)

- None of the SAEs were considered treatment related
- 1 subject receiving placebo discontinued from study because of worsening RA
- No deaths reported during the study