R&D Investor Briefing

December 5, 2017
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Introduction and Highlights

Professor Andrew Cuthbertson AO
R&D Director and Chief Scientist
Agenda

• Welcome                                        Mark Dehring
• Introduction and Highlights                   Andrew Cuthbertson
• Research                                       Andrew Nash
• Early Development                              Charmaine Gittleson
• Immunoglobulins, Haemophilia and Specialty Products  
  – Clinical Development                       Bill Mezzanotte
  – Commercial Opportunities                   Bill Campbell
• Q&A                                           

– Break –

• Transplant and Breakthrough Medicines (CSL112)  
  – Clinical Development                       Bill Mezzanotte
  – Commercial Opportunities                   Bill Campbell
• Summary                                       Andrew Cuthbertson
• Q&A                                           

Commitment to Research and Development

- **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

- R&D investment ~10-11% global revenue
### Key Past Launches from R&D Portfolio

<table>
<thead>
<tr>
<th>Year</th>
<th>Ig</th>
<th>Specialty</th>
<th>Haem</th>
<th>Vaccines</th>
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<tr>
<td>2006</td>
<td>VIVAGLOBIN®</td>
<td>ZEMAIRA® (US)</td>
<td>VONCENTO® (EU)</td>
<td>GARDASIL®</td>
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<td>2007</td>
<td>RHOPHYLAC®</td>
<td>BERIPLEX® (EU)</td>
<td>IDELVION®</td>
<td>AFLURIA®</td>
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<td>BERINERT® (US)</td>
<td>AFSTYL®</td>
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<td>FLUAD® US</td>
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<td>2011</td>
<td>CIDP (EU)</td>
<td>KCENTRA® (US)</td>
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<td>2012</td>
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<td>RESPREEZA® (EU)</td>
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<tr>
<td>2013</td>
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<td>HAEGARDA® (US)</td>
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<td>2017</td>
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Leveraging Global Capabilities

>1,500 scientists globally
# R&D Portfolio – December 2016

## Life Cycle Management

<table>
<thead>
<tr>
<th>Phases</th>
<th>Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>PCC New Indications</td>
<td>HIZENTRA® CIDP</td>
</tr>
<tr>
<td>C1-INH New Indications</td>
<td>PRIVIGEN® CIDP US</td>
</tr>
<tr>
<td>Fibrinogen New Forms</td>
<td>PRIVIGEN® Japan</td>
</tr>
<tr>
<td>Haptoglobin /Hemopexin</td>
<td>KCENTRA® Japan</td>
</tr>
<tr>
<td>Influenza Vaccine</td>
<td>RESPREEZA® EU/US</td>
</tr>
<tr>
<td>Immunoglobulins</td>
<td>Haemophilia</td>
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<tr>
<td>Specialty Products</td>
<td>Influenza Vaccine</td>
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## Market Development

<table>
<thead>
<tr>
<th>New Indications</th>
<th>US, EU, Japan</th>
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<tbody>
<tr>
<td>PCC New Indications</td>
<td>HIZENTRA® CIDP</td>
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<td>Fibrinogen New Forms</td>
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<td>Influenza Vaccine</td>
<td>RESPREEZA® EU/US</td>
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## 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
CSL Behring Protein Therapeutics Platform

- Breakthrough Medicines
- Immunoglobulins
- Specialty Products
- Haemophilia Products

- Plasma Fractionation
- Recombinant Technology

Protein Science

Global
Progress Through Stage Gates in 2017

Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP | Transplant

*Partnered Projects
<table>
<thead>
<tr>
<th>Life Cycle Management / Market Development</th>
<th>RESEARCH</th>
<th>PRE-CLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>PHASE III</th>
<th>REGISTRATION</th>
<th>COMMERCIAL / PHASE IV</th>
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<tbody>
<tr>
<td>Clinical Applications</td>
<td>C1-INH New Indications</td>
<td>HIZENTRA® IIM</td>
<td>CSL964 AAT GvHD</td>
<td>PRIVIGEN® CIDP US</td>
<td>PRIVIGEN® CIDP Japan</td>
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<td></td>
<td>Fibrinogen New Formulations</td>
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<td>HIZENTRA® CIDP</td>
<td>KCENTRA® Japan</td>
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<td>Haptoglobin/ Hemopexin</td>
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<td>HAEGARDA® EU</td>
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<td>CSL640 rIX-FP subct</td>
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<td>HAEGARDA® US</td>
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<td>New Product Development</td>
<td>CSL730 rFc Multimer</td>
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<td>PRIVIGEN® CIDP Japan</td>
<td>AFLURIA® QIV 65+ US, UK</td>
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<td>CSL626 D’D3 LA rVIII</td>
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<td>FLUAD® TIV 65+ US, UK</td>
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<td>CSL334 IL-13R* ASLAN</td>
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<td>FLUCELAX® QIV 4+ US</td>
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<td></td>
<td>CSL311 Anti-BC</td>
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<td>AFLURIA® QIV 5-17 US</td>
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<td>P. gingivalis/POD* OH-CRC</td>
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Core Capabilities: Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP | Transplant

*Partnered Projects
Research Portfolio and Technologies

Dr Andrew Nash
Senior Vice President, Research
Research Organisation & Portfolio

- Coordinated global project portfolio

- Hub (Bio21, Parkville) & spoke model
- Bio21 expansion to be completed Feb 2018
- Research capabilities: plasma & recombinant proteins, gene and cell-based therapies
Recombinant Fc Multimer – CSL730

**Fab region**
- Immune deficiencies

**Fc region**
- Autoimmune conditions

Recombinant multimerised Fc

Improved target binding
Recombinant Fc Multimer – CSL730

CSL / Momenta Collaboration

• First-in-class recombinant Fc multimer targeting Fcγ receptors

• Exclusive Research Collaboration and License Agreement
  – Development and commercialisation of the Fc multimer M230/CSL730
  – Research & development of additional Fc multimers

• Momenta has elected to co-fund development of CSL730
Recombinant Fc Multimer – CSL730

- Non-clinical safety toxicity data supports commencement of FIH studies
- Phase I study (healthy volunteers) planned to commence Q1 2018
- Phase Ib proof of mechanism study anticipated for 2019
Calimmune Technology

- Acquisition of California based biotechnology company
  - Performance based milestones

- Gene / cell based therapy, rare genetic disorders
  - *ex vivo* Lenti virus transduction of hematopoietic stem cells (HSC’s)

- Calimmune differentiating technology:

**Cytegrity** Lentivirus Manufacturing
- stable & scalable GMP compliant system

**Select** In Vivo Selection Tool
- drives engraftment with lower intensity conditioning
- significantly reduced burden on patient
Calimmune – CAL-H Program

Sickle Cell Disease

• Group of disorders caused by abnormal beta-globin gene resulting in sickled red cells
• Average life expectancy in the developed world is 40 – 60yrs
• High unmet need
• Total SCD patients: 155,000 (US + 5EU)

- CAL-H program aims to provide sufficient functional globin gene to prevent sickling

- Cytegrity™ lenti-backbone + Select+™ technology + SIN-LV γ-globin construct (sGbG™)

- 7SK shRNA
- HPRT shRNA
- β pro
- γ-globin exons
- LCR

- Normal red blood cells
- Abnormal, sickled red blood cells (sickle cells)
- Cross-section of RBC
Calimmune – CAL-H Program

- Range of further opportunities beyond SCD
Early Development Portfolio

Dr Charmaine Gittleson
Chief Medical Officer
### Early Development Portfolio

- Portfolio of preclinical and early-mid stage clinical opportunities consistent with CSL commercial objectives
- Delivery of high quality candidates for clinical development

<table>
<thead>
<tr>
<th></th>
<th>Research</th>
<th>Product Dev / Tox</th>
<th>Phase I</th>
<th>Phase II</th>
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<tr>
<td>CSL312 (anti-FXIIa)</td>
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<tr>
<td>CSL324 (anti-G-CSFR)</td>
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<td>CSL346 (anti-VEGF-B)</td>
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<td>CSL730 (rFC multimer)</td>
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CSL312 – HAE and Thrombosis

- Targeting FXIIa represents a novel approach to the treatment of hereditary angioedema and contact activated thrombosis
- Efficacy in multiple animal models and translational studies

\[ FXI \rightarrow FXIa \quad \rightarrow \text{thrombin} \quad \rightarrow \text{thrombin} \]

\[ PK \rightarrow KAL^* \quad \rightarrow \text{HK} \rightarrow \text{BK} \rightarrow \text{BR2} \quad \rightarrow \text{C1qr,s} \rightarrow \text{C1qr,s} \]

Haemostasis

Thrombosis

HAE

Transplant

Auto-activation

23
CSL312 – HAE and Thrombosis

Phase I (dosing complete Nov 2017)
Normal Healthy Volunteers
• Safety/PK/PD

Safe, well tolerated
GO

Phase II (2018/19)
Patients with HAE

Phase Ib (~2019)
Proof of mechanism in thrombosis

First in Human Phase I study
- Single doses administered
- Confirmed CSL312 safe and well tolerated with good bioavailability
CSL324 Anti-G-CSF Receptor Antibody

- White blood cells (neutrophils) – contribute to protective mechanism against infections
- Neutrophil numbers and activity under control of Granulocyte Colony Stimulating Factor (G-CSF)
- Excessive activated neutrophils, in absence of infection, cause chronic severe inflammatory diseases
- Blocking G-CSF could decrease unwanted effects of excessive neutrophils, possibly ameliorate chronic inflammatory diseases
First in Human Phase I study
- Single and multiple doses administered; dosing completed
- Confirmed CSL324 can block receptors and lower neutrophil counts
Free fatty acids (FFA) in diet support normal energy requirements in skeletal muscle, heart and kidney.

VEGF-B controls FFA movement into tissues.

Excess fatty acid uptake causes:
- Reduced glucose utilisation, insulin resistance and diabetic complications
- Toxic fat accumulation in vital organs (liver, kidney)

Blocking VEGF-B action may help prevent or treat effects of excess FFA.

**CSL346 Anti-VEGF-B Antibody**
CSL346 Anti-VEGF-B Antibody

Phase I
- Normal Healthy Volunteers
  - Safety/PK/PD
  - Started November 2017

Phase Ib
- Patients with metabolic disorders
  - Proof of mechanism
  - Study anticipated for 2019

Safe, well tolerated
GO
Central receptor (Beta Common) involved in stimulating immune modulating cells

Increased activation in Auto-immunity, Allergy and Inflammation

Blocking Beta Common (CSL311) and down regulating cells may ameliorate disease

CSL311 blocks activity of GM-CSF, IL-3 and IL-5

CSL311 inhibits activity of myeloid cells from normal and diseased tissue

FIH targeted for calendar year 2019
Immunoglobulins, Haemophilia and Specialty Products

Dr Bill Mezzanotte
Senior Vice President, Clinical Development
Immunoglobulins

- Maintaining leadership position through focus on:
  - New Indications
  - Geographic expansion
  - Delivery options

- Key Focus:
  - HIZENTRA®
  - PRIVIGEN®
Impact of Ig (IV & SC) in Rare Diseases

- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)
- Immune & Inflammatory Myositis (IIM)
- Systemic Sclerosis & other diseases
- Primary Immunodeficiency
- Secondary Immunodeficiency

- Immunoglobulins
Impact of Ig (IV & SC) in Rare Diseases

- Primary Immunodeficiency
- Secondary Immunodeficiency
- Systemic Sclerosis & other diseases
- Chronic Inflammatory Demyelinating Polyneuropathy
PATH: SC Ig (HIZENTRA®) Provides Effective Prophylaxis for CIDP Patients

- PATH study the largest controlled CIDP study ever performed
- Investigated multiple doses
- Disease control demonstrated in patients previously treated with IVIG

van Schaik et al; Lancet Neurology – Nov 17
IV and SC Ig are Effective Treatments for CIDP

- In the PRIMA trial
  - 61% of patients responded to PRIVIGEN®; 50% after the first dose
  - Almost 50% of IVIG-naïve patients responded to PRIVIGEN®

- In the PATH study
  - 81% patients on high dose and 67% on low dose of HIZENTRA® remained relapse free (after initial PRIVIGEN® stabilisation)
  - All efficacy outcomes showed clinically relevant improvements

- PRIVIGEN® & HIZENTRA®:
  - Improve multiple measures of CIDP disease activity
  - Are well tolerated by patients with CIDP
Milestones in Ig Development for CIDP

- **2012**: PRIMA study shows efficacy of PRIVIGEN® for CIDP
- **2013**: PRIVIGEN® for CIDP approved in EU
- **2014**: PRIVIGEN® for CIDP approved in EU
- **2015**: PATH study confirms efficacy of PRIVIGEN® for CIDP
- **2016**: PRIVIGEN® for CIDP: FDA approval Sept 13
- **2017**: PATH study confirms efficacy of HIZENTRA® for CIDP
- **2018**: HIZENTRA® for CIDP
  - Expected Approval
    - FDA / EU 1H 2018
    - Japan 2H 2018
Impact of Ig (IV & SC) in Rare Diseases

- Proposed Ig IIM with Unique Study Design to start 2018
- Health Authority (FDA, EMEA, PMDA) interactions 1Q 2018
Specialty Products

Leveraging high quality broad product portfolio through:
- New markets
- Novel indications
- Novel modes of administration

Key Focus:
- HAEGARDA®/BERINERT®
- KCENTRA®/BERIPLEX®
- ZEMAIRA®/RESPREEZA®
Hereditary Angioedema (HAE)

- Hereditary angioedema (HAE) is a disorder that results in recurrent attacks of severe swelling.
- All body sites are associated with impairment and patients are impacted during and between attacks.
- Most severe are laryngeal attacks which can require emergency interventions to protect the airway.
Demonstrating the Unique Benefit of HAEGARDA®

- Approval in US & Canada; approval pending EU
Commercial Market Overview

Mr Bill Campbell
Executive Vice President & Chief Commercial Officer
Targeted Protein Therapeutic Market

Total Global Market Value:
~$27.6B

- Haemophilia: $10.8B
- Immunoglobulin: $9.3B
- Albumin: $3.9B
- Specialty: $3.6B

CSL Portfolio

CSL Total FY17 $5,811M

- Immunoglobulin: $2,774M
- Specialty: $1,174M
- Haemophilia: $1,023M
- Albumin: $840M
Commercial / R&D Partnership

- Integrated strategy teams
- Coordinated New Product Development / Market preparation
- Disciplined launch preparation & execution

Multiple high value product launches:
- 2013  KCENTRA®
- 2016  IDELVION® & AFSTYLA®
- 2017  HAEGARDA®
- 2018  HIZENTRA® CIDP (pending approval)

Foundational products plus new launches will continue to fuel significant growth
CSL’s Global Performance

- CSL FY17 Sales $2,774 M
- Significant growth opportunity
  - Per capita use varies widely
  - Core areas PID / SID
  - Neurology
  - New indications
- Continued acceptance, growth & patient benefits of SCIG
Immunoglobulins: Category Leadership

GROW
the current business
- Maximise PID / SID opportunity
- Leverage broad portfolio
- Enhance product offerings

EXPAND
our presence in neurology
- Replicate our approach to build market leading segments
- Build on PRIVIGEN® experience in CIDP
- Launch HIZENTRA® in CIDP

INNOVATE
and protect the franchise
- Novel delivery devices
- New indications eg IIM, SSc
- rFc multimer
HIZENTRA®: Innovator, Market Leader

- 7 years and 51 countries
- 90,000 patient-years, 4.8M exposures worldwide
- Convenient self-administration
- Individualised therapy
- Most prescribed SCIG worldwide
CIDP – Growing Area of Focus

Global IG volume by indication

- ~23% of all IG usage globally
- Growing market segment
- Many unmet needs remain

Sources: Data on File – US, 5EU, Japan.
HIZENTRA® addresses unmet needs in CIDP therapy

Unmet Needs

**IVIG improves CIDP symptoms but many patients experience “wear off” with IVIG therapy**

**IVIG therapy difficult for patients with poor venous access**

**Many patients on IVIG suffer from systemic effects like nausea and headache**

**Majority of patients receive IVIG at infusion centers**

- Steady state IG levels for continuous control
- Hizentra therapy does not require venous access
- 4 fold lower systemic AE rates than IVIG
- Increased independence and flexibility (time/site/frequency)

**HIZENTRA® was preferred by 3X as many patients as IVIG**
Global Market

- Highly competitive Haem A market space
- Rapid transition of Haem B category
- Major advancements in patient care
- 75% of patients with bleeding disorders are under/untreated

Sources: Company annual reports/financial schedules, based on 2017 data, MRB Global Coagulation Factors Concentrate Market 2016, CSL Actuals FY17.
Coagulation Portfolio

<table>
<thead>
<tr>
<th>Haemophilia A</th>
<th>Haemophilia B</th>
<th>VWD</th>
<th>Other</th>
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<tbody>
<tr>
<td>AFSTYLA®</td>
<td>Cidelvion®</td>
<td>HUMATE-P®</td>
<td>RiaSTAP®</td>
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<tr>
<td>Antihemophilic Factor (Recombinant), Single Chain</td>
<td>Antihemophilic Factor (Recombinant)</td>
<td>Antihemophilic Factor/von Willebrand Factor Complex (Human)</td>
<td>Fibrinogen Concentrate (Human)</td>
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<td>Helixate®</td>
<td>Mononine®</td>
<td>VONCENTO®</td>
<td>Corifact®</td>
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<tr>
<td>Antihemophilic Factor (Recombinant)</td>
<td>Monoclonal Antibody Purified, Antihemophilic Factor (Human)</td>
<td>(Human Coagulation Factor VIII Von Willebrand Factor Complex)</td>
<td>Factor XIII Concentrate (Human)</td>
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<td>Monoclote-P®</td>
<td>Beriate® P</td>
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<td>STIN</td>
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<tr>
<td>Factor VIII Pasteurized, Monoclonal Antibody Purified, Antihemophilic Factor (Human)</td>
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<td>(desamopressin acetate): Neal</td>
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Transforming Care of Haemophilia B Patients

#1 “Switch to” brand providing highest factor levels for the longest period of time

<table>
<thead>
<tr>
<th>1st Haemophilia therapy with up to 14-day dosing</th>
<th>Long-lasting protection with high trough levels</th>
<th>Excellent efficacy</th>
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</thead>
<tbody>
<tr>
<td><strong>UP TO 14-DAY DOSING</strong></td>
<td><strong>14 DAYS ABOVE 13% WITH 75 IU/KG</strong></td>
<td><strong>ZERO BLEEDS MEDIAN AsBR</strong></td>
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<tr>
<td>Greater freedom from infusions</td>
<td>Ability to live a more normal life</td>
<td>Protection from bleeds</td>
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“All my IDELVION® patients were on prophylaxis previously with BeneFIX… they were very interested in having less frequent infusions.”
– Hematologist, HTC

“I mean, it’s very impressive. Once we get to 21%, you know the patient is very well-protected. Seven-day dosing – there’s nothing not to like about this.”
– HTC MD

“This is not something I would associate with another FIX. It’s higher than Alprolix, and, from a physician’s perspective the most important thing is that a patient not bleed.”
– Hematologist, MD

“About half of my Alprolix patients have switched to IDELVION® now. I expect more will do the same.”
– Hematologist, MD
Transition to New Products in Haemophilia B

- Demand exceptionally strong
  - Capturing ~2/3 of patient switches
- Ongoing launch
  - Launched in 12 countries
  - First hemophilia product in Japan
  - France, Spain, Greece, Poland, Portugal, Israel, Canada, Australia, New Zealand and others still to come
- Extension Study
  - Clinically meaningful efficacy using 21 day regimen
## Accelerating AFSTYLA® Adoption

Proven long-lasting bleed protection with a unique single-chain design

<table>
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<tr>
<th>Feature</th>
<th>Description</th>
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<tr>
<td>Higher binding affinity to vWF</td>
<td>3X HIGHER COMPARED TO OCTOCOG ALFA</td>
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<tr>
<td>Long-lasting protection with high trough levels</td>
<td>ABOVE 1.9% WITH 2X/WEEK DOSING</td>
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<tr>
<td>Excellent efficacy</td>
<td>ZERO BLEEDS MEDIAN AsBR</td>
</tr>
<tr>
<td>Individualised dosing</td>
<td>2X WEEKLY AVAILABLE</td>
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<tr>
<td>Extended time in circulation</td>
<td>Ability to live a more normal life</td>
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<td>Protection from bleeds</td>
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<td></td>
<td>Flexible dosing – 2x or 3x weekly</td>
</tr>
</tbody>
</table>
CSL’s Global Performance

- Specialty portfolio growth FY17 +20%
  - KCENTRA® / BERIPLEX® +35%; BERINERT® +31%
- HAEGARDA® US launch & rapid acceptance
- Often under or misdiagnosed

CSL FY17
Sales $1,174 M
Continued Growth Opportunities for Kcentra®

**US Anti-Coagulation Market**

- COUMADIN/WARFARIN: 46%
- XARELTO: 25%
- ELIQUIS: 25%
- SAVALSA: 0%
- PRADAXA: 4%

**US Demand (IU)**

- 2014/15: 94
- 2015/16: 119
- 2016/17: 170

**Japan**

- Launch Sep 2017
- Fast formulary acceptance
  - Over 300 hospitals

**Sources:** IMS Health NPA data, Sept 2017; Decision Resource Group Claims data, Mar 2017; Internal data (Japan)
Specialty Products – HAEGARDA®

- Product launched July 2017
- 7 year orphan exclusivity
- 95% reduction in HAE attacks
- >99% reduction in the need for rescue medication
- First and only subcutaneous formulation
- Strong patient, physician and provider engagement
<table>
<thead>
<tr>
<th>“I haven’t had a single attack since starting the HAEGARDA® study in 2015!”</th>
<th>“This is the <strong>longest period in my life having gone without a single attack</strong> since my very first one at age 13.”</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I choose not to suffer, and HAEGARDA® gives me that choice.”</td>
<td>“I feel like I am finally a <strong>participant in my own life!</strong>”</td>
</tr>
<tr>
<td>“The patient is just giddy.”</td>
<td>“It is, hands down, the easiest medication I’ve had to administer that <strong>ACTUALLY works.</strong>”</td>
</tr>
</tbody>
</table>
Transplant and Breakthrough Medicines (CSL112)

Dr Bill Mezzanotte
Senior Vice President, Clinical Development
Transplant

• Developing CSL and other novel therapies with potential to improve transplant outcomes:
  – Significant unmet need

• Key Focus:
  – C1 inhibitor (C1-INH) / BERINERT®
  – Alpha1 anti-trypsin (AAT) / ZEMAIRA®
  – Anti-IL-6 / clazakizumab*
  – CSL312 (anti-FXIIa mAb)
  – CSL324 (anti-G-CSFR mAb)

*Partnered project
Solid Organ Transplant (SOT): Unmet Medical Need

Before Transplantation
- Patient & Donor
  - Organ Availability and Patient-Donor Matching
    - Donor-specific antibody reduction; increased access to transplantation

Donor Organs
- Improving organ utilisation and reducing ischemic injury prior to transplant

During Transplantation
- Patient
  - Ischemia-Reperfusion Injury and Consequences
    - Reducing IR-related injury and its consequences – e.g. Primary Graft Dysfunction (PGD) & Delayed Graft Function (DGF)

After Transplantation
- Patient
  - Transplant Rejection
    - Improving Treatment & Prevention of Antibody Mediated Rejection

More Viable Organs Available
Graft Survival
Solid Organ Transplant (SOT): Unmet Medical Need

<table>
<thead>
<tr>
<th>Before Transplantation</th>
<th>During Transplantation</th>
<th>After Transplantation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient &amp; Donor</strong></td>
<td><strong>Donor Organs</strong></td>
<td><strong>Patient</strong></td>
</tr>
<tr>
<td><strong>Organ Availability and Patient-Donor Matching</strong></td>
<td><strong>Organ Viability and Donor Management</strong></td>
<td><strong>Ischemia-Reperfusion Injury and Consequences</strong></td>
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<tr>
<td>Donor-specific antibody reduction; increased access to transplantation</td>
<td>Improving organ utilisation and reducing ischemic injury prior to transplant</td>
<td>Reducing IR-related injury and its consequences – e.g. Primary Graft Dysfunction (PGD) &amp; Delayed Graft Function (DGF)</td>
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<td><strong>More Viable Organs Available</strong></td>
<td><strong>Graft Survival</strong></td>
<td><strong>Transplant Rejection</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improving Treatment &amp; Prevention of Antibody Mediated Rejection</td>
</tr>
</tbody>
</table>
Antibody Mediated Rejection (AMR) in Kidney Transplantation

The kidney is the most commonly transplanted solid organ

- AMR occurs in up to 5-10% of transplants acutely and up to 30% chronically
- AMR is marked by declining renal function and is associated with lower graft survival
- Patients with donor-specific antibodies are denied transplant due to the risk for AMR

Long Term C1 INH Administration Stabilises Graft Function in AMR Patients Unresponsive to Standard of Care

In a pilot study 6 patients with AMR, unresponsive to standard of care, were treated with C1 INH and had improved renal function (estimated Glomerular Filtration Rate, eGFR) at 6 months.

Viglietti et al., Am J of Transplantation 2016
CSL842 C1-INH to prevent recurrent AMR: Randomised, Placebo-controlled Withdrawal

Part 1: 12 Weeks  Part 2: 26 Weeks  3.5 Years

IVIg + C1 INH open label  C1 INH  Placebo

Responders Randomised  1° endpoint  2° endpoint

Loss of Response**  Graft Survival

**occurrence of any of the following
- Decline in renal function (eGFR)
- Allograft failure
- Subject death
Complement Dependent & Independent Pathways Involved in AMR

Potential Benefits of Anti-IL6 therapy in AMR:

- Reducing DSA production
- Reducing DSA mediated injury to allograft
- Pilot study demonstrated blocking IL-6 stabilises renal function and prolongs graft survival*

*Choi et al Am J Transplantation 2017
Vitaeris and CSL Strategic Collaboration

- Vitaeris Inc.
  - clazakizumab (anti-IL6 mAb) in clinical development
  - Successful FDA Type C Meeting
- Anticipated dosing in AMR patients in 2018
- CSL – Vitaeris Strategic Collaboration
  - Collaboration and purchase option agreement to expedite the development of clazakizumab
  - Exclusive Option to acquire company at later date with data readout
  - CSL with Board Observer & Director seats, Member of Scientific Advisory Board
**Unmet Medical Need in Graft versus Host Disease (GvHD)**

- **Incidence and mortality**
  - Hematopoietic Stem Cell Transplant (HSCT) is a common effective therapy for many life-threatening malignant and non-malignant diseases
    - Autologous – Patient’s own cells
    - Allogenic – Donor cells
  - ~50-60% of Allogeneic HSCT develop acute Graft versus Host Disease (GvHD) despite prophylaxis
  - GvHD is a common cause of morbidity & mortality in HSCT
    - Therapies are often ineffective or cause severe immunosuppression
    - Survival is 30% for Grade III and 10% for Grade IV
  - Pathophysiology of GvHD in HSCT may be addressed by immunomodulatory effects of Alpha 1 Anti Trypsin (AAT)
Clinical Data:
Treatment of Steroid-Refractory GvHD with AAT

• ZEMAIRA® (AAT) - Mangenau, ASBMT 2016
  – 40 Patients with Steroid refractory aGVHD
  – Open label AAT - 60mg/kg twice weekly x 4 weeks
  – Overall response rate (ORR) - 65%
    • 35% Complete Response
  – Sustained responses - 73% at Day 60
  – Well tolerated with low rates of infection

• Proposed AAT GvHD Study
  – Anticipated study start in 2018
  – Final design pending ongoing regulatory discussions
Transplant

Breakthrough Medicines

Immunoglobulins

Specialty Products

Haemophilia Products

Transplant

• Developing CSL and other novel therapies with potential to improve transplant outcomes:
  – Significant unmet need

• Key Focus:
  – C1 inhibitor (C1-INH) / BERINERT®
  – Alpha1 anti-trypsin (AAT) / ZEMAIRA®
  – Anti-IL-6 / clazakizumab*
  – CSL312 (anti-FXIIa mAb)
  – CSL324 (anti-G-CSFR mAb)

*Partnered project
Breakthrough Medicines

- Leveraging clinical and technical insight in developing novel protein-based therapies:
  - Significant unmet need
  - Multiple indications

- Key Focus:
  - CSL112 (ApoA-I)
  - CSL312 (anti-FXIIa mAb)
  - CSL324 (anti-G-CSFR mAb)
  - CSL346 (anti-VEGF-B mAb)
  - CSL311 (anti-BC mAb)
Cardiovascular Disease (CVD) - High Unmet Medical Need

- CVD remains leading cause of death globally
- In the US alone, 800,000 acute MIs occur each year
- Survivors remain at high risk for early recurrent CV events
- Among high-risk populations:
  - 14% recurrence in year one
  - of these ~70% within first 90 days
- Reducing the risk of early recurrent events represents a significant unmet need
Cholesterol Efflux With CSL112 (apolipoprotein A-I)

Apolipoprotein A-I (ApoA-I) is the primary component of HDL ("good cholesterol") and responsible for cholesterol efflux capacity (CEC)
- HDL levels & CEC are inversely correlated with atherosclerotic heart disease

CSL112:
- purified ApoA-I from human plasma
- increases CEC, particularly ABCA1-dependent CEC
- unique compound
CSL112 Hypothesis

- CSL112 will be safe and well tolerated
- CSL112 will enhance cholesterol efflux capacity (CEC)
- CSL112 will acutely stabilise atherosclerotic plaques and prevent subsequent major adverse cardiovascular events (MACE) in the early, highest risk period (unique treatment period)
CSL112: Clinical Path to Phase III – Safety & Mechanism of Action

Phase I Single Ascending Dose (SAD)
- Normal Healthy Volunteers
- N=57; Single Site: AUS
- STATUS: Completed 2011

Phase I Multiple Ascending Dose (MAD)
- Normal Healthy Volunteers
- N=36; Single Site: AUS
- STATUS: Completed 2011

Phase Ila
- Stable coronary artery disease
- Safety, PK, PD
- N=44; Multicenter: US
- STATUS: Completed 2011

Phase IIb Dose-ranging (AEGIS-I)
- AMI target population
- Safety, MOA, pop PK
- N=1,258 (PBO, 2g, 6g; weekly x 4)
- 145 sites: NA, Europe, AUS, IS
- STATUS: Completed 2015-16

Moderate RI PK/safety (Phase I)
- Moderate RI vs. normal renal
- Safety, PK, PD
- N=32 (2.6g SD)
- Specialty sites (4-6 Europe)
- STATUS: Completed 2015-16

Moderate RI safety (Phase Ila)
- AMI target population
- Safety, pop PK, MOA
- N=83 (6 g; weekly x 4)
- 31 sites (US, IS, GER, HUN, NL)
- STATUS: Completed 2016-17

Phase III Pivotal Trial (AEGIS-II)
- AMI target population
- CV outcomes efficacy (MACE) and safety
- Multicenter: ~40 countries; ~1000 sites; ~17,400 patients
- STATUS: Start planned 2018
No Safety Concerns in Patients with Moderate Renal Impairment

Low incidence of renal events across CSL112 and placebo

Safety data are consistent across:

- Degree of renal impairment: (eGFR 30- <45 ml/min) versus (eGFR 45 - <60ml/min)
- Presence or absence of antidiabetic therapy

Results support including patients with moderate renal impairment into Phase III (AEGIS II)

<table>
<thead>
<tr>
<th></th>
<th>Number of subjects with data</th>
<th>Number of subjects with events, n (%) n’</th>
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<tbody>
<tr>
<td><strong>Renal SAEs</strong></td>
<td></td>
<td></td>
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<tr>
<td>CSL112 6g (N=52)</td>
<td>52</td>
<td>1 (1.9%) 1</td>
</tr>
<tr>
<td>Placebo (N=28)</td>
<td>28</td>
<td>4 (14.3%) 5</td>
</tr>
<tr>
<td><strong>Acute Kidney Injury (AKI) Events</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSL112 6g (N=52)</td>
<td>50</td>
<td>2 ( 4.0%) 2</td>
</tr>
<tr>
<td>Placebo (N=28)</td>
<td>28</td>
<td>4 (14.3%) 4</td>
</tr>
</tbody>
</table>
CSL112 raises Cholesterol Efflux to a similar extent in Patients with and without Moderate Renal Impairment

- At the end of infusion time points, the relative increases in CEC and ABCA1 dependent CEC were similar in both studies.
- These efflux results are encouraging as patients with moderate renal impairment tend to experience a greater number of MACE events.
Phase III (AEGIS-II): Study Design

- Enriched Study Population: Multi-vessel coronary artery disease and at least one of the following:
  - Age >65
  - History of MI
  - Diabetes mellitus
  - Peripheral artery disease (PAD)
- Registry data confirms enriched AEGIS-II population is associated with high early recurrent event rate and supports our trial assumptions
Phase III (AEGIS-II)

Designed with Health Authority Input

Designed with International Trialists
CSL112 Program Timeline

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<tbody>
<tr>
<td>CSL112 CMC - Supply</td>
<td>AEGIS-I</td>
<td>MOD RI Phase II</td>
<td>Phase III (AEGIS II) Outcomes Study</td>
<td>Futility #1 Mar ‘20</td>
<td>Futility #2 Oct ‘20</td>
<td>Interim Efficacy Apr‘21</td>
<td>BLA</td>
</tr>
</tbody>
</table>
Breakthrough Medicines Commercial Opportunities

Mr Bill Campbell
Executive Vice President & Chief Commercial Officer
CSL112 to Address High Unmet Medical Need

- CVD remains leading cause of death globally
- In the US alone, 800,000 acute MIs occur each year
- Survivors remain at high risk for early recurrent CV events:
  - Among high-risk populations:
    - 14% in year one
    - of these ~70% within first 90 days
- Reducing the risk of early recurrent events represents a significant unmet need
AEGIS-II Population – High Early Recurrent Event Rate

US AMI Registry/Symphony Health Claims Database
N=75,758 (AEGIS-II eligible); 2012-2015

Breakthrough Medicines

Patients with vascular death, MI or stroke %

Days from AMI Admission

0% 2% 4% 6% 8% 10% 12% 14% 16%

Acute

Sub-Acute

Chronic

“Uncontested sub-acute market space”

CSL 112

Statins PCSK9i’s

0 30 60 90 120 150 180 210 240 270 300 330 360 390
Significant Opportunity in Sub Acute Space

- Acute MI Discharges per year (US & EU5): 1.2M
- High Risk Patients and other exclusion (AEGIS II population): 380-520K
- Hospital coverage & utilisation: 230-320k
- CSL112 patient population: 200-270k
CSL112 Strategic Commercial Activities

- **Phase III Plan**: Integrating clinical, regulatory and payer input
- **Real World Evidence**: Validating with customised database
- **Value Proposition & Pricing**: Engaging hospitals and payers
- **Education & Prelaunch**: Developing the market
Seqirus R&D

Professor Andrew Cuthbertson AO
R&D Director and Chief Scientist
Highlights of 2017

- **FLUAD™**
  - Approved in UK, strong recommendation for people 65yr and older
  - Holly Springs approved by FDA as a MF59 manufacturing and FLUAD fill-finish site

- **aQIV**
  - Submission for paediatric indication USA (end December)

- **AFLURIA® QIV**
  - 5 years+
    - Approved USA
    - Submitted Australia, Canada, Argentina, Sth Korea
  - 6 months to 4 years
    - Pivotal trial completed – confirms improved safety profile of product
    - Submitted USA, AUS

- **FLUCELVAX® QIV**
  - FDA approval and first commercial manufacture of H3N2 using cell-based seed
  - Manufactured volumes more than quadrupled to 21m doses
Planned Milestones During 2018

**Phase III**
- **Fluad™ QIV 65yrs+ Safety & Immuno complete**

**Registration & Launch**
- **Fluad™ QIV 6m-23m Approval USA**

**Post Registration**
- **Fluad™ TIV 65yrs+ Approval AUS**
- **Afluria® QIV 5yrs+ Approval AUS, CAN**
- **Afluria® QIV 6m-4yrs Approval USA, AUS**
- **Afluria® QIV 5yrs+ Submitted Canada, Argentina**

- **aH5N1c prepandemic Submitted USA**

NB: plan to increase QIVc volumes by further 20%
<table>
<thead>
<tr>
<th>Life Cycle Management / Market Development</th>
<th>RESEARCH</th>
<th>PRE-CLINICAL</th>
<th>PHASE I</th>
<th>PHASE II</th>
<th>PHASE III</th>
<th>REGISTRATION</th>
<th>COMMERCIAL / PHASE IV</th>
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<tbody>
<tr>
<td></td>
<td>Clinical Applications</td>
<td>C1-INH New Indications</td>
<td></td>
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<td>PRIVIGEN® Japan</td>
<td>HIZENTRA® CIDP</td>
<td>PRIVIGEN® CIDP US</td>
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<td>Fibrinogen New Formulations</td>
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<td>HIZENTRA® IIM</td>
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<td>KCENTRA® Japan</td>
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<td>Haptoglobin/ Hemopexin</td>
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<td>HAEGARDA®</td>
<td>AFLURIA® QIV</td>
<td>HAEGARDA® US</td>
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<td>CSL640 rIX-FP subct</td>
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<td></td>
<td>C1-INH</td>
<td>FLUAD® TIV 65+ US, UK</td>
<td>FLUCELAX® QIV 4+ US</td>
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<td>CSL964 AAT GvHD</td>
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<td>AFLURIA® QIV 5-17 US</td>
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<tr>
<td>New Product Development</td>
<td>Emerging Technologies</td>
<td>CSL730 rFc Multimer</td>
<td></td>
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<td>clazakizumab* Transplant</td>
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<td>IDELVION®</td>
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<td>Novel Strategies</td>
<td>CSL626 D’D3 LA rVIII</td>
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<td>Mavri GM-CSFR-AZ*</td>
<td>pdFVIII Ruide</td>
<td>AFSTYLA®</td>
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<td></td>
<td>Discovery Projects</td>
<td>CSL334 IL-13R* ASLAN</td>
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<td>Clinical Applications</td>
<td>CSL311 Anti-BC</td>
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<td>CSL312 Anti-FXIIa</td>
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<td>P. gingivalis/POD* OH-CRC</td>
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<td>CSL346 Anti-VEGF-B</td>
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**Core Capabilities:** Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP | Transplant

*Partnered Projects*
# Expected Progress in Next 12 Months

<table>
<thead>
<tr>
<th>New Product Opportunity</th>
<th>Research</th>
<th>Product Dev. &amp; GLP Toxicology</th>
<th>Phase I (FIH)</th>
<th>Phase II</th>
<th>Phase III</th>
<th>Registration &amp; Launch</th>
<th>Post Registration</th>
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<tbody>
<tr>
<td>1</td>
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<td>Enter Product Dev. &amp; GLP Tox.</td>
<td>Enter Phase I</td>
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<td>Enter Post Registration</td>
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<td>2</td>
<td>CSL730 rFC Multimer</td>
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<td>HIZENTRA® IIM</td>
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<td>CSL112 ApoA-I</td>
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<td>3</td>
<td>Novel Strategies</td>
<td>Clinical Applications</td>
<td>Clinical Applications</td>
<td>Discovery Projects</td>
<td>HAEGARDA® EU</td>
<td>pdFVIII Ruide</td>
<td>FLUAD® QIV 6m-23m US</td>
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<tr>
<td>4</td>
<td>Core Capabilities: Immunoglobulins</td>
<td>Haemophilia</td>
<td>Specialty Products</td>
<td>Breakthrough Medicines</td>
<td>Vaccines &amp; IP</td>
<td>Transplant</td>
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*Partnered project
### Significant Target Launch Dates

<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
<th>2020-2023</th>
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<tbody>
<tr>
<td>2017</td>
<td>PRIVIGEN® CIDP US</td>
<td>HIZENTRA® CIDP US/EU</td>
<td>PRIVIGEN® CIDP Japan</td>
<td>Hizentra® IIM</td>
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<td></td>
<td>AFSTYLA® EU/Japan</td>
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<td>CSL830 HAEGARDA® US</td>
<td>CSL830 EU</td>
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<td>KCENTRA® Japan</td>
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<tr>
<td>2018</td>
<td>AFLURIA® QIV 5-17yr US</td>
<td>AFLURIA® QIV 6m-4yr US</td>
<td>AFLURIA® QIV 6m-5yr AUS</td>
<td>CSL12 ApoA-I</td>
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<td>AFLURIA® QIV 5-17yr AUS</td>
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<td>2019</td>
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<td>QIV EU</td>
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<td>2020-2023</td>
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**Core Capabilities:** Immunoglobulins | Haemophilia | Specialty Products | Breakthrough Medicines | Vaccines & IP | Transplant

*Partnered Projects
### 2017 Highlights

#### Immunoglobulins
- PRIVIGEN® CIDP approved in US
- HIZENTRA® CIDP accepted for review by US FDA and EMA
- Momenta collaboration to develop CSL730 (rFC Multimer)

#### Specialty Products
- HAEGARDA® results in 95% reduction in HAE attacks and >99% reduction in rescue mediation and new standard of care for HAE
- HAEGARDA® registered and launched in the US

#### Haemophilia
- IDELVION® dosage extension study supports 21 day regimen
- AFSTYLA® registered in EU, Japan and Australia

#### Transplant
- CSL842 (C1INH) Phase III study in kidney AMR commenced
- Strategic collaboration and option agreement with Vitaeris to develop clazakizumab (anti-IL6 MAb) as a therapeutic option for AMR

#### Breakthrough Medicines
- Data supports decision to proceed to CSL112 (Apo A-1) Phase III study (AEGIS-II)
- CSL346 (anti-VEGF-B) Phase I study commenced
- Completion of CSL312 (anti-FXIIa) HAE Phase I study
- Acquisition of Calimmune platform gene therapy technology and CAL-H SCD program

#### Licensing & Vaccines
- AFLURIA® QIV registered in US in 5+ yrs; 6mnths-4yrs trial completed
- FLUAD® registered in UK, strong recommendation for people 65yr and older
Further Information

Presentation Playback
A webcast of the presentation can be accessed in the investors section of the CSL website.
Contact: maria.pikos@csl.com.au

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