

# CSL Limited

Capital Markets Day

16 October, 2023

For persona

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#### Agenda

9:00 – 9:15	Registration/Coffee	
	Welcome	Mark Dehring
	Strategic Overview	Paul McKenzie
	CSL Seqirus	Ken Lim
	CSL Vifor	Hervé Gisserot
	Q&A	
10:40 – 11:00	Break	
	CSL Behring	Andy Schmeltz
	Q&A	
12:30 – 13:30	Lunch	
	Information & Digital	Mark Hill
	Finance & Sustainability	Joy Linton
	Research & Development	Bill Mezzanotte
	Q&A	
	Concluding Remarks	Paul McKenzie
16:00 – 18:00	Refreshments – Marble Bar	CSL Team



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# Strategic Overview

Paul McKenzie CEO & Managing Director

#### Leading Positions in Large, Growing Markets



#### Global #1

in plasma protein therapies ~\$38 billion industry

Global #2 in influenza vaccines ~\$7 billion industry

**Global #1** in iron ~\$5 billion industry



serving patients and people in **100+** countries

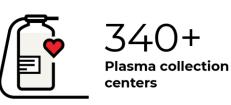


\$13.31B in annual revenue

32,000 employees worldwide



\$5.1B CSL R&D Investment over the last 5 years





\$5.7B capital expenditures in the last 5 years

#### **Positioned for Annual Double-Digit Earnings Growth**



- Significant unmet need
- Durable products driven by continued innovation and embedded know how



#### **Robust R&D Portfolio**

- Near-to-mid-term launches
- Longer-term opportunities across platforms and therapeutic areas



#### Yield & capacity expansion

- Yield enhancement across plasma and manufacturing platforms
- Investing in Ig and cell capacity



## Disciplined capital allocation for growth

- R&D, CapEx and value-creating BD
- Partnerships across the value chain with leading companies



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### **CSL Behring**

Biotherapies & Rare Disease



Vaccines

#### **CSL Vifor**

Iron Deficiency & Nephrology

#### **Strategic Focus Areas**

Drive **top-line growth** across our core franchises 2

Realise COGS efficiencies, driving CSL Behring gross margin to pre-pandemic levels and beyond 3

Deliver our **R&D pipeline** within our investment envelope 4

Invest in new digital technologies to drive business performance 5

Attract, engage, develop and retain **next** generation leaders

#### **Management Team**



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Andy Schmeltz EVP, CSL Behring United States



**Stephen Marlow** SVP and General Manager CSL Seqirus

Australia



Hervé Gisserot SVP and General Manager CSL Vifor

Switzerland



**Bill Mezzanotte** EVP, Head Research & Development United States



Ken Lim EVP, Chief Strategy Officer Australia



**Joy Linton Chief Financial** Officer Australia

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**Mark Hill** Chief Digital Information Officer

United States



**Elizabeth Walker** 

EVP, Chief Human **Resources** Officer

United States



**Kate Priestman** 

Chief Corporate & External Affairs Officer

United Kingdom



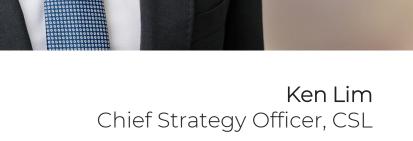
**Greg Boss** 

EVP Legal and General Counsel United States

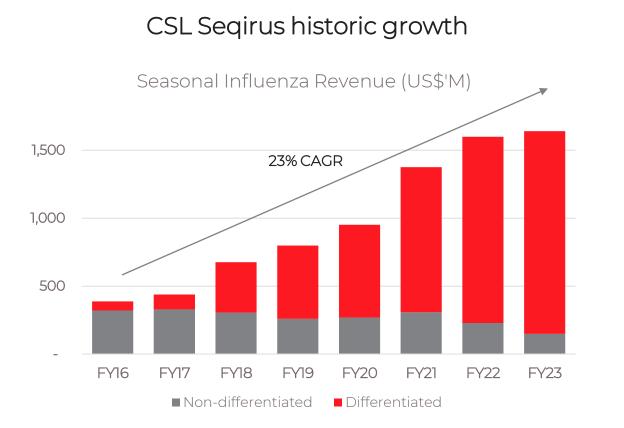


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# **CSL Seqirus**



# CSL Seqirus growth linked directly to differentiation strategy and core capabilities





#### **CSL Seqirus**

#### CSL Seqirus's focus within its 4 strategic pillars drives its near and long-term success

#### 1. CONTINUED GROWTH IN INFLUENZA



Opportunities in both new and existing markets to increase our global footprint

#### 3. GROW BEYOND INFLUENZA



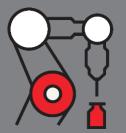
Leverage core competence of respiratory vaccines

#### 2. BROADEN OUR PANDEMIC BUSINESS



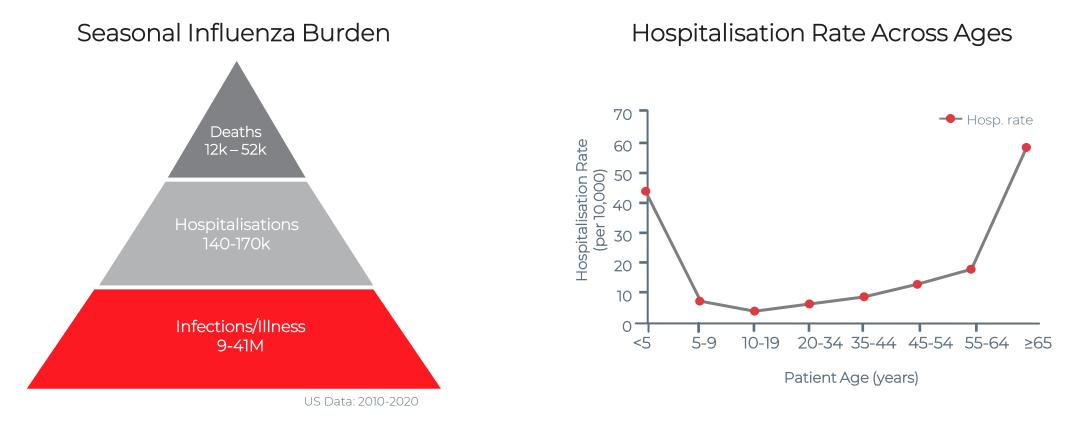
Multi-pathogen pandemic capability

4. INVEST IN SCALABLE MANUFACTURING TECHNOLOGY



Common technologies and yield investments to underpin our growth

# Influenza still has significant unmet need, particularly in paediatric and older adult populations



https://www.cdc.gov/flu/about/burden/ Accessed 8/8/23 Glezen WP, et al. Am Rev Respir Dis. 1987;136(3):550-555.

Putri, Wayan C.W.S. et al , Economic burden of seasonal influenza in the United States , Vaccine. 2018 Jun 22;36(27):3960-3966. Found at: https://pubmed.ncbi.nlm.nih.gov/29801998/ (Accessed September 2020

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# In influenza, Seqirus will grow the market through differentiation despite lower immunisation rates





Influenza Vaccine Doses Distributed in the United States, By Season

and water water

Millions of Doses Reset

#### Expectations

- Immunisation rates will return over time
- Annualisation of COVID-19 boosters will reduce vaccine fatigue
- CSL Seqirus growth will outpace the market through differentiation and advocacy efforts

Current Northern Hemisphere 2023/24 season to date (early, in progress)

- On track to our pre-season commitments
- Flawless supply season
- Positioned to support in-season opportunities if they arise
- N.B. we're still early in the season

Source: www.cdc.gov



#### **CSL Seqirus focused on continuous innovation to** reduce the burden of influenza

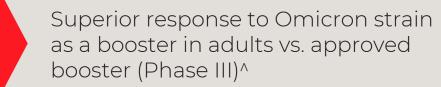
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#### sa-mRNA technology differentiates

CSL Seqirus COVID-19 vaccine candidate

#### Differentiators of sa-mRNA Technology



Lower dose of mRNA

#### Duration of protection up to 12 months

Links to online publications:

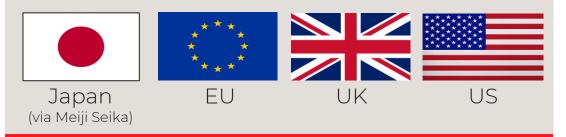
https://www.medrxiv.org/content/10.1101/2023.07.13.23292597v1.full.pdf

https://ir.arcturusrx.com/news-releases/news-release-details/study-shows-novel-sa-mrnavaccines-offer-robust-broad-enduring

#### Accelerating to market

- Licensing and collaboration agreement with Arcturus Therapeutics Inc.
- Finalising clinical programs
- Studying emerging variants
- Regulatory submissions

#### Global Launches Anticipated in 2024 - 2026



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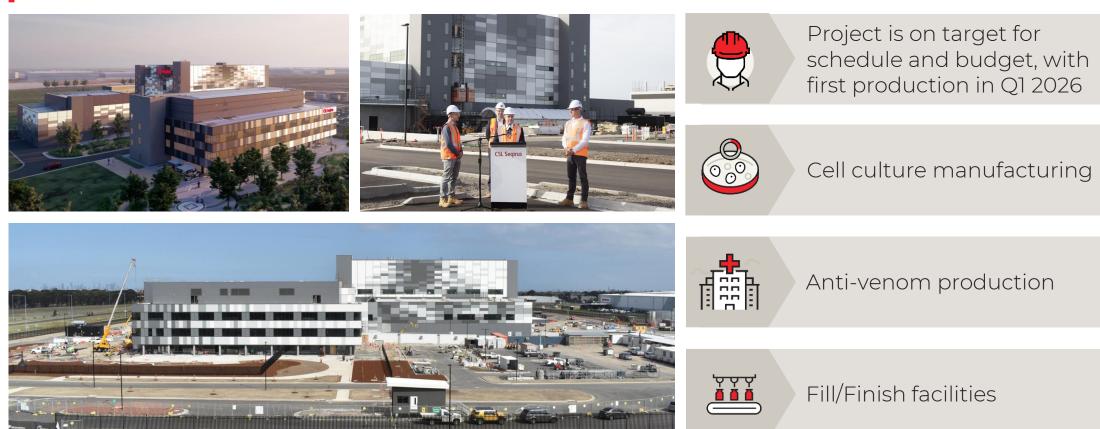
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Leverage core comp

#### New Flu Cell Culture facility in Australia to meet growing demand and pandemic protection





#### **Key Takeaways**

- CSL Seqirus is well positioned to continue its success in influenza:
  - Capacity development well advanced to support aQIVc launch
- Continuous innovation will enable CSL Seqirus to outpace market growth:
  - aQIVc setting new standard of care
  - sa-mRNA
- sa-mRNA technology will differentiate CSL Seqirus vaccine in COVID-19





Hervé Gisserot General Manager, CSL Vifor

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#### FY23 – a solid result with 11 months contribution<sup>1</sup>

Fe

Nephrology

Non-Dialysis

. Veltassa

O TAVNEOS<sup>™ 5</sup>

(Ex-US)

Rayaldee

calcifediol 1 353285 N

(avacopan)

Dialysis

MIRCERA 53

Retacrit<sup>®</sup> 4

epoetin alfa-epbx

**VELPHORO** 

KORSUVA<sup>®</sup> 7

(difelikefalin) Injection

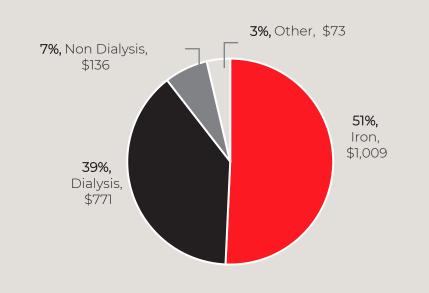
KAPRUVIA<sup>™</sup> (difelikefalin) Injection

Pfizer Oncology

#### ~14% revenue growth<sup>2</sup> EPS accretive Integration and cost synergies on track

#### FY23 Revenue By Therapy Group \$m<sup>1</sup>





**Maltofer**®

2. Eleven months FY22 pre CSL ownership and unaudited versus eleven months FY23 at constant currency

venofer

3. Licensed from F. Hoffman-La Roche AG., 4. Licensed from Pfizer Inc., 5. Licensed from ChemoCentryx, Inc., 6. Licensed from OPKO Health, Inc., 7. Licensed from Cara Therapeutics, Inc.

In Market products

Iron Therapy

ferinject

# CSL Vifor's strategic framework will set the foundations to drive sustainable, profitable growth

Maximize Ferinject® / Injectafer® growth opportunities



Unlock revenue upside in Patient Blood Management across CSL



Deliver successful launches and pipeline progress to strengthen renal disease position



Lean and efficient operations to compete in the new environment

# Iron market: Unique conditions enabling us to drive long-term value

Market development	Continued market growth due to untapped potential	$\bigcirc$
Follow-on Competition	• Limited number of follow-on products	$\oslash$
Innovation	No breakthrough innovation	$\bigcirc$
Pricing dynamics	Strong price competition	?

1. Kassebaum NJ. The Global Burden of Anaemia. Hematol Oncol Clin North Am. 2016;30(2):247-308

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#### **Relentless focus on Ferinject<sup>®</sup> / Injectafer<sup>®</sup> growth**

ylnc	GROWTH				
use (	NEW COMPETITIVE LANDSCAPE	GEOGRAPHIC & MARKET EXPANSION	LCM & SCIENTIFIC EXCELLENCE		
For personal	<ul> <li>Tendering excellence</li> <li>Non-clinical differentiation</li> <li>Cost of goods improvement</li> </ul>	<ul> <li>New launch markets</li> <li>New indications</li> <li>Maximizing value of partnerships</li> </ul>	<ul> <li>Investment in RWE/RWD</li> <li>New presentations / formulation</li> <li>Non-Biologic Complex Drug characterisation</li> </ul>		

#### SIGNIFICANT UNTAPPED MARKET POTENTIAL

RWE = Real World Evidence; RWD = Real World Data

# Patient Blood Management addresses a global health issue

#### Critical need to reduce whole blood transfusions

- Avoidable adverse outcomes
- Wastage of scarce blood supply
- Inefficient healthcare spend

#### Due to:

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- Insufficient screening of iron deficiency
- Suboptimal intra-operative haemostasis

#### Patient Blood Management

Evidence-based approach to preserve patient's own blood

#### **Three Pillars of PBM**



02

**Detect** & manage anaemia/iron deficiency

Minimize blood loss



**Optimize** patient tolerance of post-op anaemia

#### Benefits

#### For patients:

- Improved outcomes
- Increased safety
- **Reduced risk** of complications and infections

#### For Health Systems:

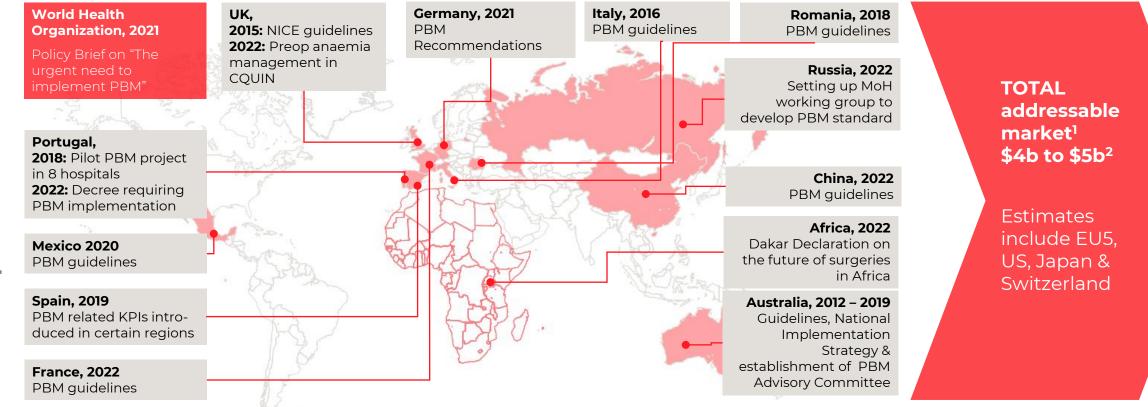
- Preserve blood for high-value usage
- Decrease overall cost of care
- Improve Quality Indicators & KPIs



#### **Repeated Demonstrations of Patient & Health System Benefits when PBM is fully implemented**

$\geq$		Benefits for health systems		Benefits for patients			
		Decrease overall cost of	Decrease overall cost of care		Improved patient outcomes Mortality Infection AMI/stroke		
USe	Western Australia Patient Blood Management Program <sup>1</sup>	<b>\$18.1 m</b> blood product cost savings over the six-year study period	Activity based cost savings between ~ <b>\$80 m - \$100 m</b>	28%	21%	31%	15%
a						In-Hospital Adv. Events*	Length of stay
For person	N=400,998 admissions Jan 2010 through December 2017 at two integrated hospital campuses	<b>22% reduction</b> in allogenic transfusions	Savings of <b>\$7 m</b> in transfusion related costs			1.5%	15%
	Across 5 John Hopkins Hospitals <sup>3</sup>	<b>49% reduction</b> in RBC transfusions orders	Savings of <b>\$2.1 m</b> in blood acquisition costs – ROI 400%				
	University Hospital of Zurich <sup>4</sup> N=213,882 patients discharged between 2012 and 2017 were included in this retrospective study	<b>40%</b> reduction in RBC transfusions	Savings of <b>\$12.44 m</b> in blood acquisition costs over 4 years				

#### **Countries calling on PBM implementation leading to addressable market of \$4-5B across range of specialties**



1. Consisting therapeutic areas where we can address PBM in Pillar 1, Pillar 2 and Pillar 3. Areas of potential significant growth include Cardiothoracic Surgery, Orthopaedic Surgery, Major Vascular Surgery, Oncologic Surgery, Gynecologic & Obstetric Surgery, Transplant Surgery and possibly Trauma

2. Internal calculation. Potential PBM market size estimate based on number of addressable patients. Market sizing estimate assumes price erosion across all classes

#### CSL is uniquely positioned in PBM to translate evidencebased medicine into evidence-based practice

	Pre-surgery	During surgery	Post-surgery		
Benefits of PBM	Diagnosing & treating iron-deficiency (anaemia) Optimizing hemoglobin and erythropoiesis to avoid complication during and post surgery	<b>Optimizing coagulation</b> Using factor concentrates to minimize need for allogenic blood products	Ensuring optimal & fast recovery Managing anaemia & iron- deficiency and post-operative bleeding & clot stability		
CSL Portfolio	Image: Second symplect       Image: Second symplect         Image: Second symple	KCENTRA       Forthrombin Complex         Prothrombin Complex       Forthrombin Concentrate         Beriplex       Forthrombin Complex         Human Prothrombin Complex       Forthrombin Complex         Correiforct       Forthrombin Complex	ferinject       Retacrit         epoetin alfa-epbx         injectafer         ferric carboxymaltose injection		

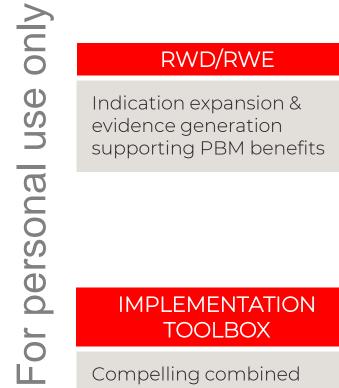
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Factor XIII Concentrate (Human)

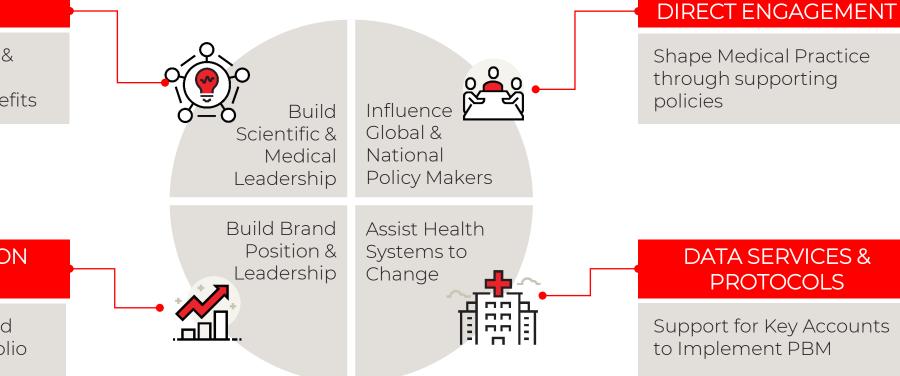
1. Rights for PBM currently reside with Pfizer (licensor) – asset is part of VFMCRP (distribution limited to US dialysis and non-hospital market)

Factor XIII Concentrate (Human)

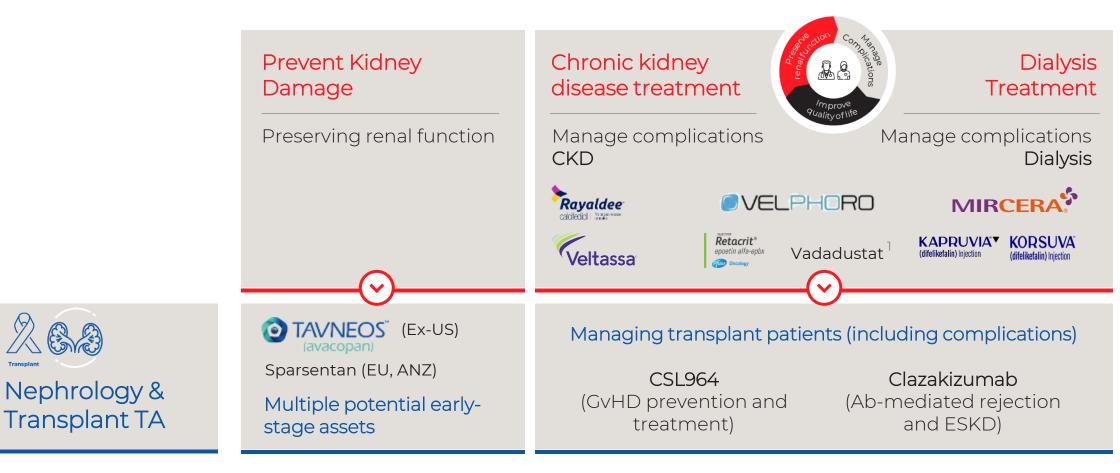
# Realising the market opportunity through integrated Go to Market operating model



Compelling combined Behring & Vifor Portfolio Offering



# Strengthen renal disease position along the full spectrum of kidney disease



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1. Currently in regulatory assessment by the U.S. FDA. Based on standard NDA resubmission review timelines, our partner Akebia Therapeutics expects a letter from the FDA acknowledging that the resubmission is complete, classifying the resubmission, and setting the PDUFA date at the end of October 2024.

# CSL Vifor key value catalysts will drive growth into the medium - long term

#### Near-term

- Ferinject<sup>®</sup> reimbursement in China
- Injectafer<sup>®</sup> Heart Failure US launch
- Launches Kapruvia<sup>®</sup> / Korsuva<sup>®</sup>, Tavneos<sup>®</sup> & Sparsentan
- Collaboration with Behring / Seqirus

#### Mid-term

- Maximize strategic partnerships
- PBM revenue upside
- CSL 300

#### Long-term

R&D Opportunities

- Nephrology/Transplant pipeline
- BD opportunities

#### Cost Synergies

#### Indications / Geographic expansion

1. CUA = Calcific Uremic Arteriolopathy

2. PAD-ESKD = Peripheral Arterial Disease - End Stage Kidney Disease



# Thank You / Questions

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# **CSL Behring**

Andy Schmeltz EVP, CSL Behring

#### **CSL Behring: Driving Sustainable, Profitable Growth**

Working together from Donor to Patient

PLASMA COLLECTION COMMERCIALISATION MANUFACTURING order for CSL Behring to produce sufficient life-saving treatments. Nuestra misión es recolectar plasma humano en forma segura, eficiente y conforme a las normativas a fin de que CSL Behring desarrolle suficientes tratamientos que salvan vidas. (F) DONOR.

#### **CSL Behring: Driving Sustainable, Profitable Growth**

Working together from Donor to Patient

PLASMA COLLECTION MANUFACTURING Grow Plasma (F) Volume Reduce Plasma Acquisition Cost



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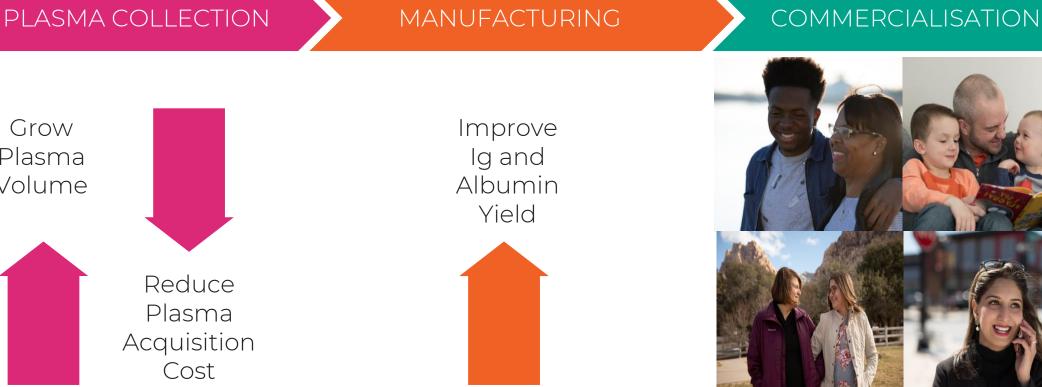
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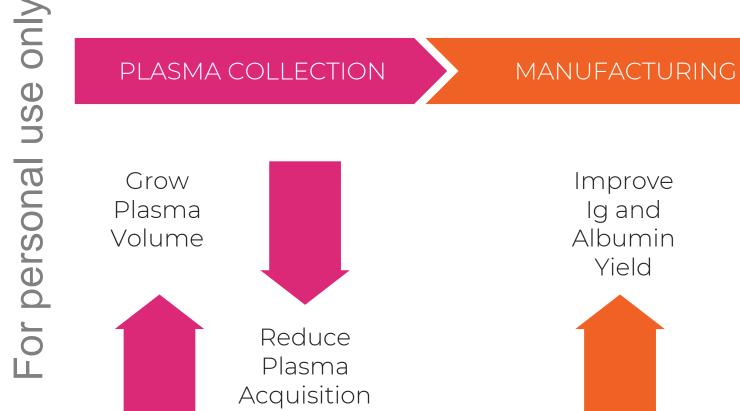
#### **CSL Behring: Driving Sustainable, Profitable Growth**

Working together from Donor to Patient

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Working together from Donor to Patient



Cost



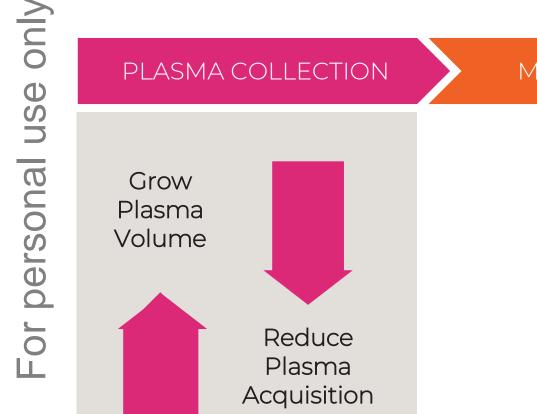


Grow Key Medicines and Deliver Successful Launches

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Working together from Donor to Patient



Cost

MANUFACTURING

Improve lg and Albumin Yield



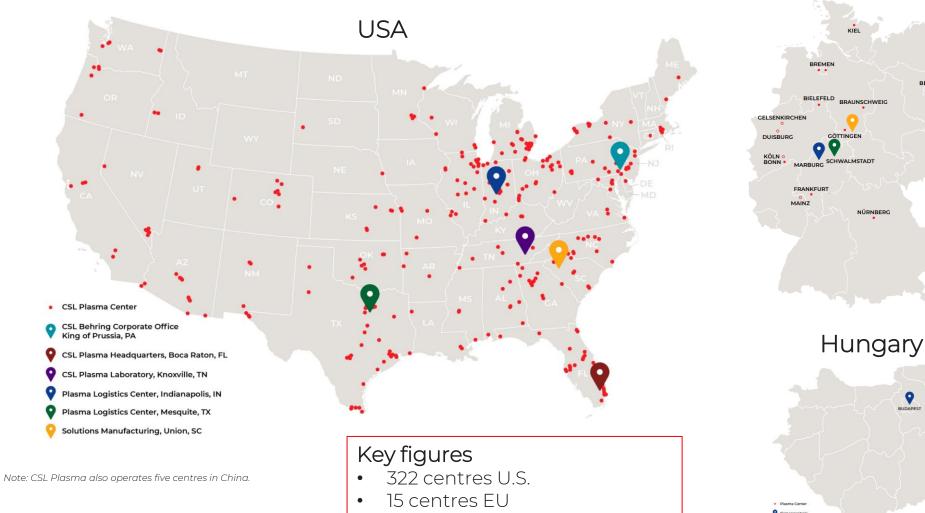
Grow Key Medicines and Deliver Successful Launches

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### **Snapshot of CSL Plasma's Industry-Leading Collection Network**





•



Germany

BERLIN

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Disema Conto

Plasma Center Lease Sign

Plasma Logistic Cente Head Quarte

### **Global Plasma Collections Back on Track**

-22% in FY21 | +24% in FY22 | +31% in FY23

Plasma Collections (Litres) 341-23 341-20 AU0:23  $\sum_{n=1}^{n} \sum_{i=1}^{n} \sum_{j=1}^{n} \sum_{i=1}^{n} \sum_{i$ FY23 FY21 **FY22** FY24

40 Driven by Our Promise

Source: Global Donor Management Systems

### Leading the Way in Plasma Growth & Efficiency





### Multiple Levers to Support Collections Growth, Enabled by Digital Transformation

- Optimize mix of qualified and new donors
- Focus on donor and market segmentation
- Leverage personalized messaging and incentives

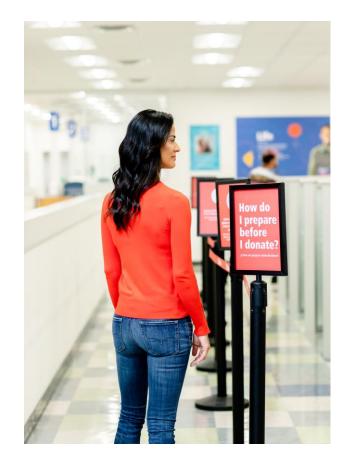


#### FREQUENCY

- Deliver best-in-class service
- Apply **technology** to guide fee setting
- Personalize experience via app

#### NEW LAPSED DONORS

- Increase awareness across different media
- Drive first-time donation with differentiated fees
- Digitize pre-registration and appointments



### **Clear Path to Driving Cost Per Litre (CPL) Efficiencies**

# COVID disruption led to

Higher donor fees to drive collections

Lower centre output and unfavourable cost absorption

Higher labor wage rates

However, we have turned the corner. Further CPL reductions over coming 4 years

#### 1-3 YEARS

**01** Optimizing Fee Structures

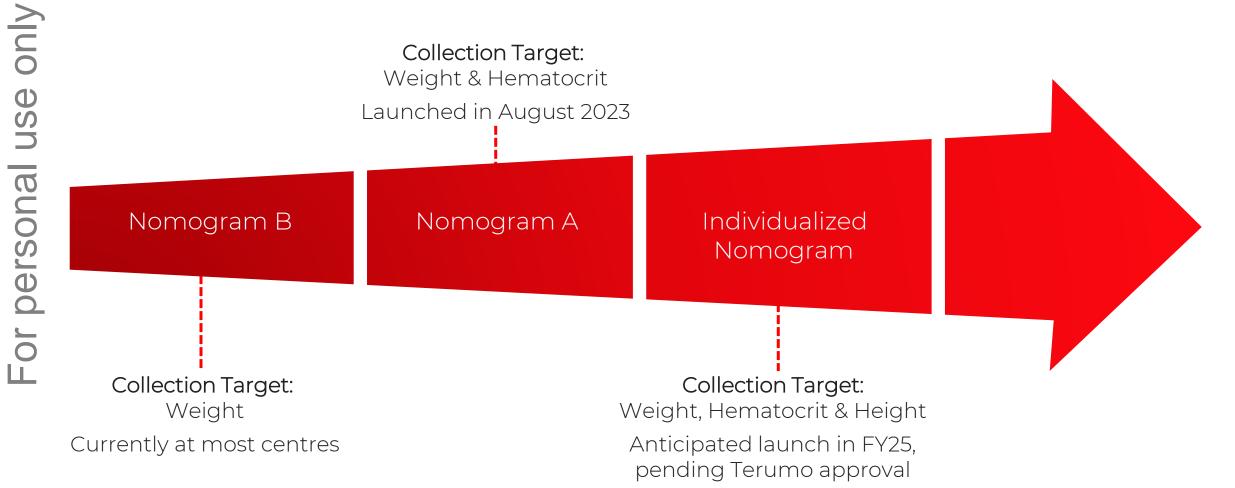
**02** Focus on centre-level Labor Productivity

**03** Continued Rollout of Rika Plasma Donation System 2 - 4 Years

Individualized **04** Nomogram

Improved Centre **05** Productivity and Cost Absorption

### **U.S. FDA Nomogram: Important Lever to Optimize Donations and Drive Plasma Yield**



USe

### **Benefits of Rika Plasma Donation System**

Currently deployed in ~15 centres Roll-out schedule to be agreed with Terumo by December 2023

#### Donor Experience

Fewer donor deferrals; reduced donation time by ~30%



#### Donor Safety

Improper collection volume due to employee error reduced by 85%



#### Sustainable Growth

Individualized Nomogram will improve average donation yield by ~10%



#### Sustainability

Reduced biohazard disposable waste by 10-15%





### Leading the Way in Plasma Growth & Efficiency



- Digital Transformation
- Rika Plasma Donation System
- Nomogram A & I



- Enhanced Scheduling
- Donor Fee Strategy
- Fleet Optimization

Working together from Donor to Patient



### **Global Manufacturing Presence**



Bern, Switzerland

- Core products: immunoglobulins & albumin
- Specialty products: anti-D-hyperimmune



Broadmeadows, Australia

- Core products: immunoglobulins & albumin
- Specialty products: coagulation factors, critical care, CSL312
- Toll plasma services for Australia, New Zealand, Hong Kong, Malaysia & Taiwan



Marburg, Germany

- Core products: Human Albumin Behring, coagulation factors, critical care
- Specialty products: hyperimmunes



Kankakee, Illinois, U.S.

• Core products: albumin, fractionation for intermediate pastes

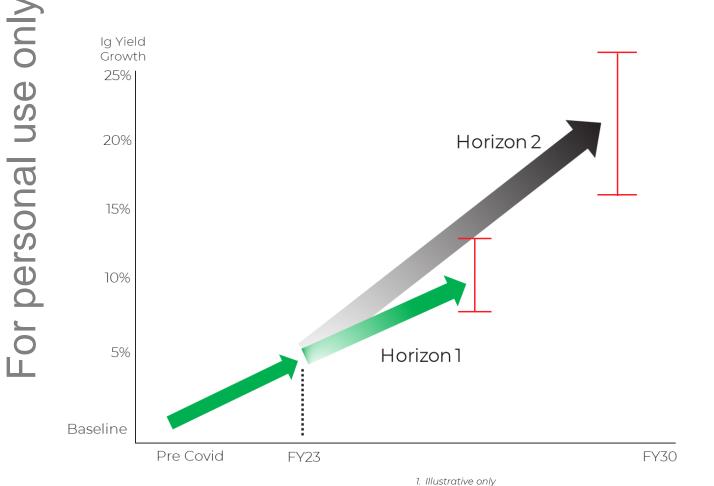
Specialty products: alphal-proteinase inhibitor



#### Wuhan, China

• Core products: albumin, immunoglobulins

### Ig Yield Maximisation Strategy<sup>1</sup>





#### Yield Improvements

#### Horizon 1

- Process changes within regulatory filing
- Data analytics and plasma allocation
- Operational excellence

#### Horizon 2

- Proprietary process improvements with some manufacturing retooling
- Will require regulatory approval
- Targeted at litres producing Ig & Albumin only
- Pilot work underway

Subject to the success and timing of research and development activities and the decisions of regulatory authorities

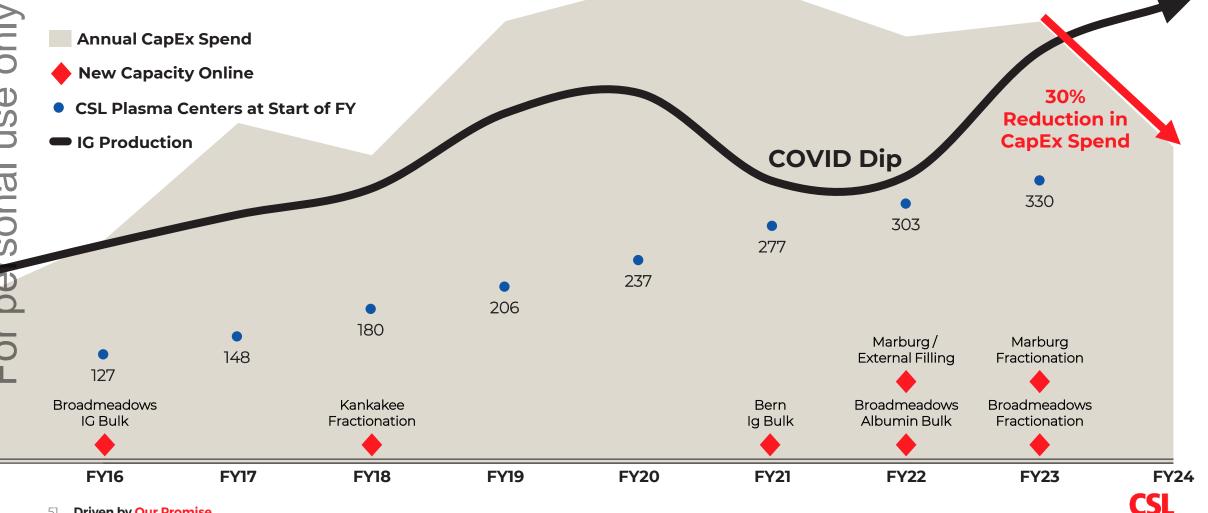
### **Operational Excellence**

CSL Operating System Delivering Value Across Six Areas

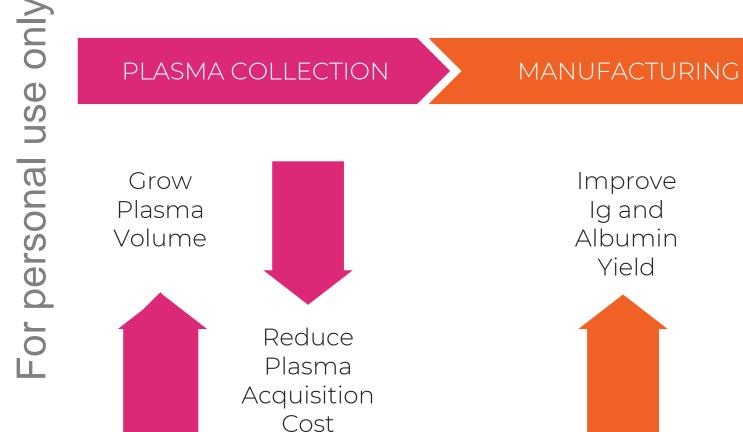
**Productivity** Reliability Quality **Sustainability** Service Engagement Example Value Reduction in cycle Increase level of On Reduction in Reduction in More efficient Increase in time and increased Time In Full schedule **Repeat Deviations** inventory environmental Delivery to markets adherence & write offs footprint capacity

### **CapEx Investments are Providing Capacity for Growth**

CSL expects CapEx investment needs to reduce as major projects are now coming online



Working together from Donor to Patient

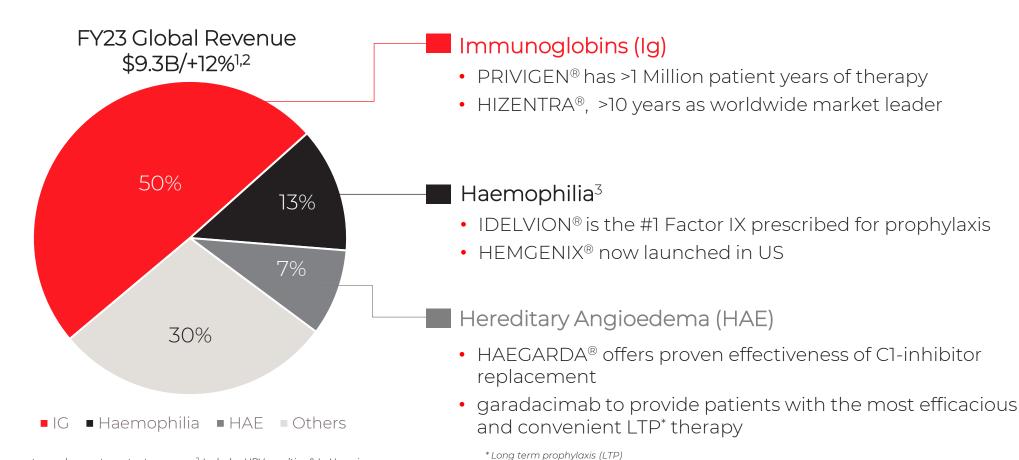


COMMERCIALISATION

Grow Key Medicines and Deliver Successful Launches



### Strong CSL Behring Portfolio with Compelling Growth Drivers



#### Source:

<sup>1</sup> FY23 Growth percentages shown at constant currency <sup>2</sup> Includes HPV royalties & Ig Hyperimmunes
 <sup>3</sup> Haemophilia includes Afstyla (Hem-A), Idelvion (Hem-B), Hemgenix (Hem-B), and other coagulation products.

### Ig Usage Trends by Country Shows Significant **Opportunity, Particularly Beyond US and Australia**

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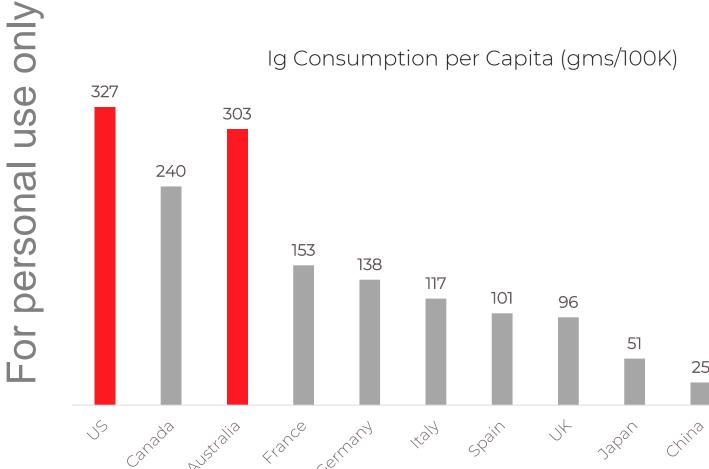
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- US, Australia and ٠ Canada are the leading countries for per capita Ig utilization
- Disease prevalence is ٠ consistent globally
- Clear opportunity to ٠ grow lg subject to adequate supply

# Behring Ig Growth Opportunities Span Current and New Indications

5%

# IVIG SCIG

1%

7 Major Markets: Ig Market Volume by Indication (FY23)

■ PID ■ SID ■ CIDP ■ ITP ■ MG ■ All Others

19%

Abbreviations: primary immunodeficiency (PID), secondary immune deficiency (SID), chronic immune thrombocytopenic purpura (ITP), chronic inflammatory demyelinating polyneuropathy (CIDP), myasthenia gravis (MG)

- Ig demand across core indications continues to grow:
  - Ig replacement in PID, SID
  - Ig as an immunomodulator in MG, CIDP, ITP
- Multiple levers to sustain and expand leadership:
  - Real-world experience (RWE) and data generation
  - Launch of HIZENTRA pre-filled syringe offerings; 5ml, 10ml, 20ml, 50ml
  - Exploring multiple additional indications including dermatomyositis (DM)





### **PRIVIGEN®** and **HIZENTRA®** : Compelling Offerings for Patients



- Standard of care IVIg with proven protection through reliable Ig restoration
- 15+ years in PID and ITP; 10+ years in CIDP
- Demonstrated to improve motor function in CIDP:
  - Supported by PRIMA and PATH studies
- > 1.1M patient years' experience across indications

Hizentra®

- Market leading SCIg offering personalized treatment options to patients
- Recommended for CIDP maintenance treatment in Peripheral Nerve Society (PNS) treatment guidelines<sup>1</sup>

(Human)

20% Liquid

- Proven long-term protection with 5+ years of RWE in CIDP
- Expanding into dermatomyositis (DM) as the first-and-only SCIg

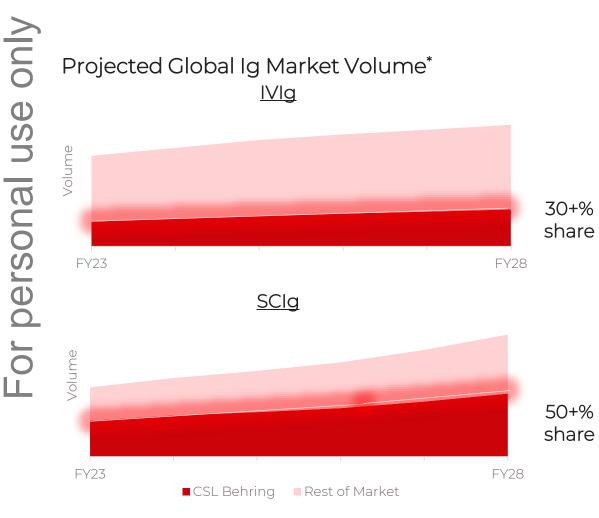
**Privigen**<sup>®</sup>



Abbreviations: primary immunodeficiency (PI), chronic immune thrombocytopenic purpura (ITP), chronic inflammatory demyelinating polyneuropathy (CIDP)

<sup>&</sup>lt;sup>1</sup>Van den Bergh PYK, van Doorn PA, Hadden RDM, et al. European Academy of Neurology/Peripheral Nerve Society guideline on diagnosis and treatment of chronic inflammatory demyelinating polyradiculoneuropathy: Report of a joint Task Force—Second revision. Eur J Neurol. 2021;1-28. https://doi.org/10.1111/ene.14959.

### **Behring Ig Portfolio to Outpace Market Growth**

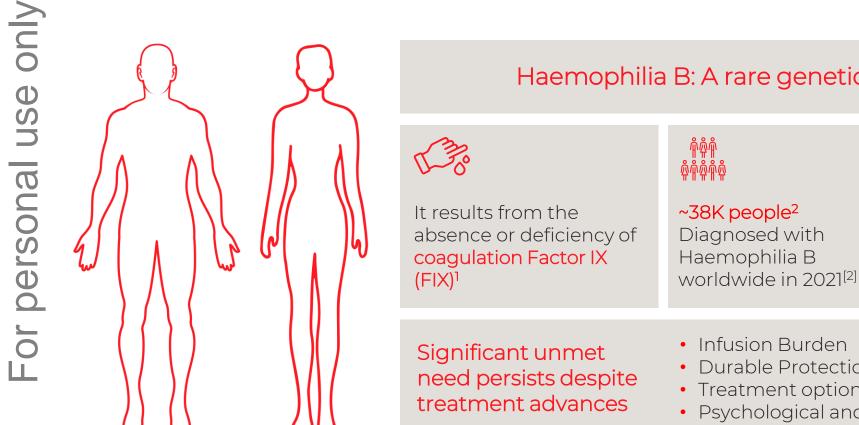




- Improving Ig market supply, strong underlying demand and improved diagnosis rates in PID
- PRIVIGEN® (IVIg) and HIZENTRA® (SCIG) leadership in core indications while expanding to new areas of unmet need

### Haemophilia B

Disease Overview and Unmet Needs



Haemophilia B: A rare genetic bleeding disorder

~20K people Treated with Factor IX therapies

ӎ҄ѽ҉ҋ

- Infusion Burden
- Durable Protection/ Stable FIX level
- Treatment options for patients with inhibitors
- Psychological and Social Impact

[1] National Bleeding Disorders Foundation [2] WFH Annual Survey 2021 PdFIX: Plasma-derived Factor IX; SArFIX: Short-acting recombinant Factor IX; LArFIX: Long-acting recombinant Factor IX

### **IDELVION®** and **HEMGENIX®**: Leading Through Innovation

#### Idelvion

Coaqulation Factor IX (Recombinanti), Albumin Fusion Protein

- Well established standard of care
- Provides highest factor levels for the longest period of time of any FIX replacement therapy
- Offers personalized dosing options of up to 21days\*
- Safe and well tolerated with low incidence of adverse reactions

#### Hemgenix®

Provides greater bleed protection vs prophy

etranacogene dezaparvovec-drlb

- 63% patients reported zero bleeds in the 7 to 18-month period following infusion<sup>[1]</sup>
- Eliminates routine prophylaxis
  - 96% of people discontinued Factor IX prophylaxis and remained prophy-free <sup>[1]</sup>
- Sustains FIX levels projected to last 15+ years for majority of patients<sup>[2]</sup>
- Safe and well tolerated with no treatment related SAE's

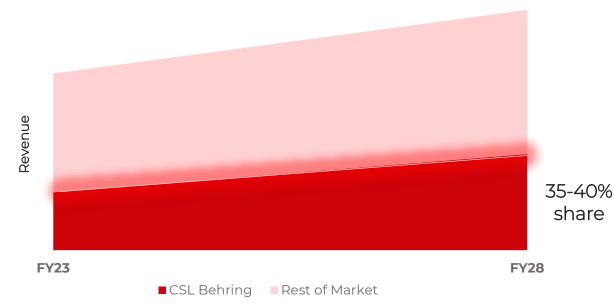
[1] HOPE-B trial [2] Jinesh Shah, factor IX activity following etranacogene dezaparvovec gene therapy in the treatment of haemophilia B Hongseok Kim, Krupa Sivamurthy, Paul E. Monahan & Michael Fries (2023) Comprehensive analysis and prediction of long-term durability of, Current Medical Research and Opinion, 39:2, 227-237, DOI: 10.1080/03007995.2022.2133492Add durability modelling publication reference

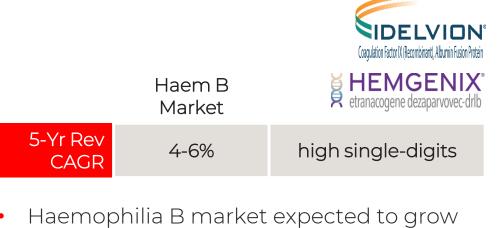
\*Where 21-day dosing is approved

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### Behring Haemophilia B Portfolio to Outpace Market Growth

Projected Global Haemophilia B Market Revenue\*





- Haemophilia B market expected to grow due the launch of advanced therapies including gene therapy (GT)
- Targeting the right patients for IDELVION® and HEMGENIX® will maximize success for CSL Haemophilia B portfolio

### Hereditary Angioedema (HAE)

Disease Overview and Unmet Needs

 HAE results from missing or low levels of a protein called C1 esterase inhibitor (C1-INH) and can cause attacks of swelling, and often pain, in specific parts of the body.

 Laryngeal attacks that block the airway are potentially life threatening

	Hereditary Angloedema: A rare genetic disorder			
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	1/40,000-50,000 ~12K treated patients in major markets	50% Chance of passing it on to a child	>50% increase in patients getting prophylaxis treatment between 2016 and 2023	
S	Significant unmet need persists despite treatment advances	<ul> <li>Delayed diagnosis</li> <li>Treatment burden</li> <li>Lack of immediate acting prophylaxis treatments</li> <li>Psychological and Social Impact</li> </ul>		

Psychological and Social Impact

Prophy patient share

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### **HAEGARDA<sup>®</sup> and Garadacimab**

Best in Class Prophylactic Efficacy



- Addresses the root cause of HAE by replacing missing or dysfunctional C1-INH
- Reduces the median frequency of HAE attacks by 95%\*
- Reduces the median frequency of rescue medication by >99%\*
- 99% of US patient days were attack free for up to 2.7 yrs.+

#### Garadacimab

- First Factor XIIa therapy for HAE prevention working at the top of the cascade
- One dose, once a month, in less than 15 seconds via prefilled pen
- >99% median reduction in attacks and rescue medication use per month vs placebo\*
- >62% of patients (12 years of age +) were completely attack-free over 6-months\*

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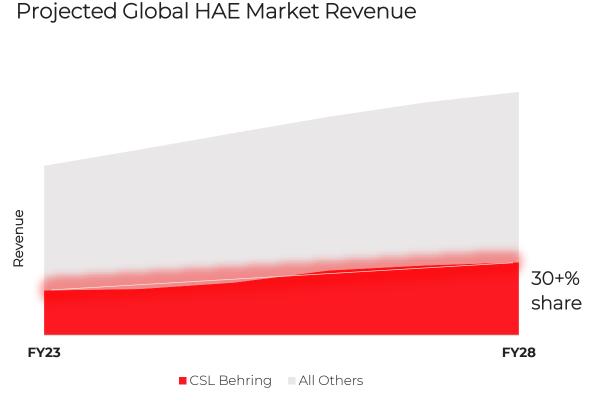
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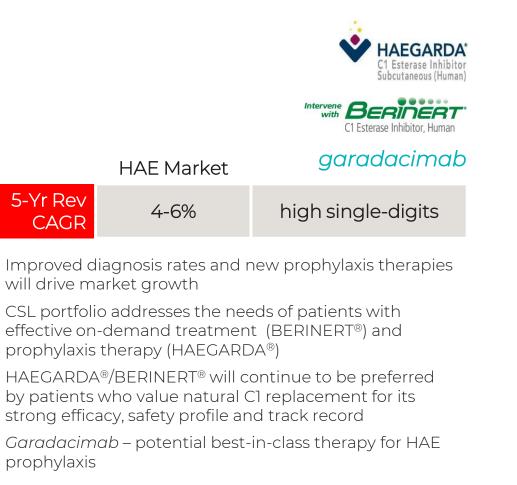
<sup>\*</sup>pivotal Phase 3 study results, + Longhurst H, Cicardi M, Craig T, Bork K, Grattan C, Baker J, COMPACT Investigators et al. Prevention of hereditary angioedema attacks with a subcutaneous C1 inhibitor. N Engl J Med. 2017;376:1131–1140. doi: 10.1056/NEJMoa1613627.

### **Behring HAE Portfolio to Outpace Market Growth**

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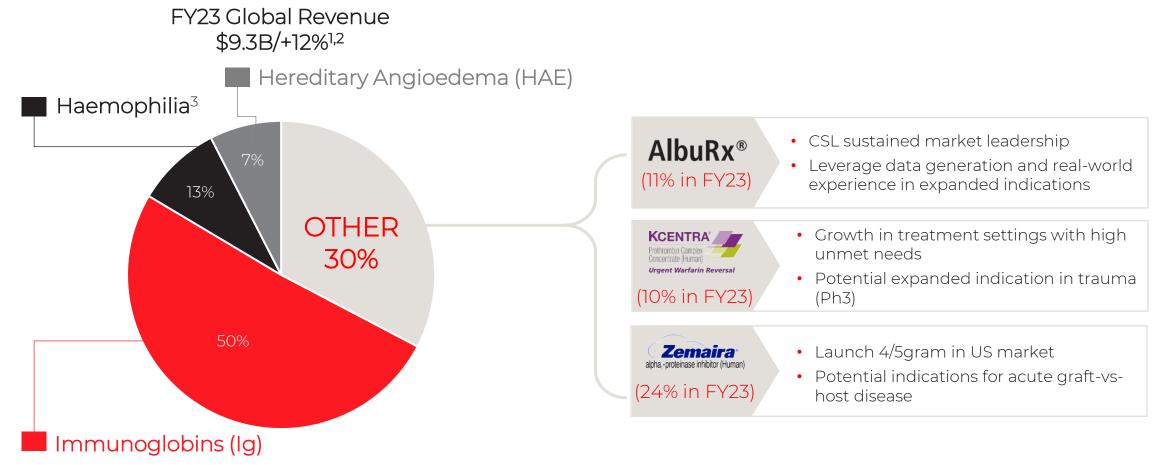
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### **Portfolio Enabled by Additional In-line Growth Drivers**

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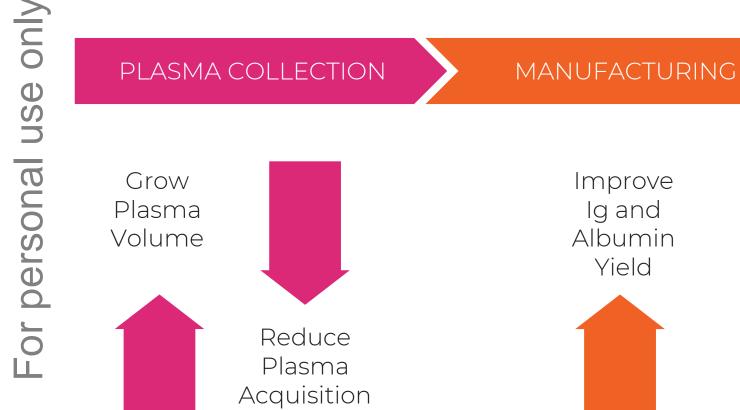


#### Source:

FY23 Growth percentages shown at constant currency <sup>2</sup> Includes HPV royalties & Ig Hyperimmunes
 Haemophilia includes Afstyla (Hem-A), Idelvion (Hem-B), Hemgenix (Hem-B), and other coagulation products.

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Working together from Donor to Patient



Cost





Grow Key Medicines and Deliver Successful Launches

COMMERCIALISATION



Working together from Donor to Patient

use only PLASMA COLLECTION For personal Improve lg and Albumin Deploy Rika, Yield Nomogram A/I, digital transformation and operational excellence

MANUFACTURING COMMERCIALISATION Grow Key Medicines and Deliver Successful Launches

Working together from Donor to Patient

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For perso	Deploy Rika, Nomogram A/I, digital transform and operational excellence

CTION COMMERCIALISATION MANUFACTURING 2 Grow Key Medicines and Deliver Successful Deliver Horizon 1 yield Launches improvements; advance Horizon 2 nation

Working together from Donor to Patient

PLASMA COLLECTION	MANUFACTURING	COMMERCIALISATION
Deploy Rika, Nomogram A/I, digital transformation and operational excellence	2 Deliver Horizon 1 yield improvements; advance Horizon 2	3 Outpace market growth in Ig, Haemophilia B and HAE



# Thank You / Questions

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# Information and Digital

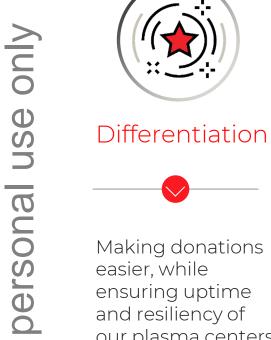
Mark Hill CDIO

We are  $\geq$ selective in o choosing digital opportunities Ja with the ogreatest potential to differentiate differentiate <u>u</u> our business

#### Our focus areas include:

- Interactions with donors
- The acceleration of science in pursuit of new therapies
- Scaling the enterprise
- Under these focus areas lies a massive injection of **information and automation**
- 3 Anchored in a mission to keep our company and its data safe and secure

### Value drivers for information and digital



easier, while ensuring uptime and resiliency of our plasma centers.

Merging biological and computer science for pipeline growth.

Integration



Automation



Information

i



Unified and standard business process workflows that drive continuous productivity and operational leverage.

Self-healing processes that reduce cycle time and improve the employee experience.

Making data the connective tissue of our enterprise ecosystem for real-time data flows.

Maintaining acceptable levels of risk by keeping technology current, employing cybersecurity measures, establishing business continuity, and meeting regulatory requirements.

Fusion of business and technology

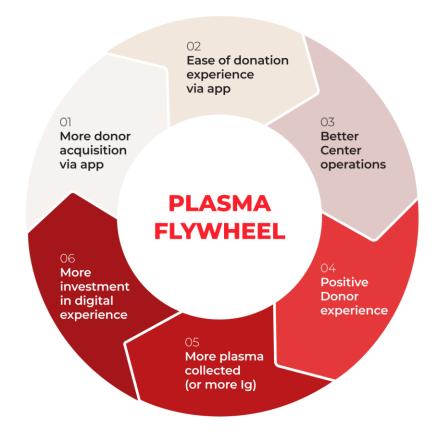
**PLASMA** 

Enterprise

R&D

#### **Plasma: Making donations easier, creating a more** positive donor experience, and bring in more donors

Digital Experience Data Artificial Intelligence (C Innovation



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Fusion of business and technology

Plasma

Enterprise

R&D

# R&D: Merging biological and computer science for pipeline growth

**Operational Excellence** Integrating our R&D systems and processes across businesses.





#### **Scientific Insights**

Accelerating the pace of discovery.



CSI

#### Data

The connective tissue across R&D, driving science at scale

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### **Enterprise: Capabilities for business performance and operational leverage**

Fusion of business and technology

Plasma

R&D

#### ENTERPRISE

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CSL Enterprise

Current State

#### Information

Real-time data flows that drive insights and seamless ecosystem connections.

#### Automation

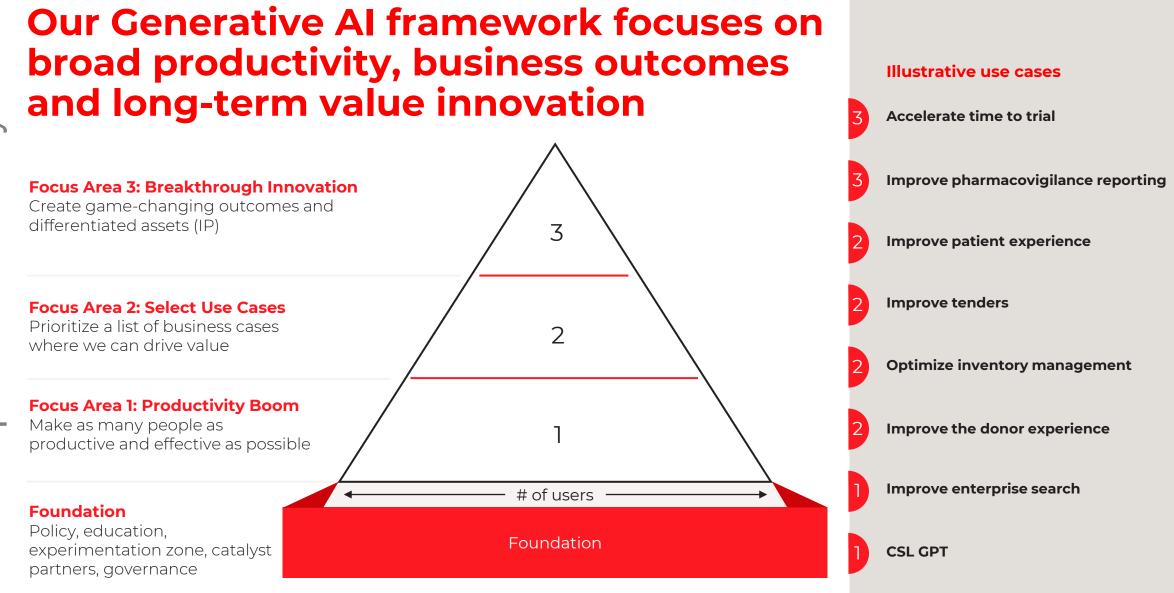
Self-healing processes that reduce cycle time and drive productivity at scale.

#### Integration

Unified and standard workflows to drive efficiencies and employee experience.



Target State



# Cybersecurity remains the biggest risk in digital transformation



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Shifting regulatory requirements and
 geopolitical threats



Generative Al



Cyber risk due to use of new technology/solutions and partners



#### Generative AI risks:

- Data leakage
- Hallucination (generating inaccurate responses)
- Making cyber criminals more efficient and effective
- Future capacity shortages (future phases of AI will require 100x more capacity than today)

Maintain an acceptable level of risk by keeping technology current, employing cybersecurity measures, establishing business continuity management and meeting regulatory requirements



We see digitalization as a mechanism of scale, accelerating our business growth at less physical cost.

Fusion of business and technology are potential differentiators of our business in the donor experience, the speed of science, and enterprise leverage (extending our moat).

A massive infusion of automation and information are the new table stakes for keeping pace with industry and our ecosystem of partners.

Generative AI is a potential leapfrog opportunity, but also difficult to harness because the speed of innovation is faster than anything we have seen.

Never forget our commitment to safety and security.

It is the most exciting time to be at the intersection of CSL and Digitalization.



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# Finance and Sustainability



**Joy Linton** CFO

# **Disciplined Management of Capital**

	Growing Cash I	Earnings	
<ul> <li>Maintain strong balance sheet</li> <li>Net debt / EBITDA target ratio of less than 2.0x</li> <li>Maintain investment grade credit rating</li> </ul>	<ul> <li>Returns to shareholders</li> <li>Dividend growth in line with NPATA growth <ul> <li>Circa 40-45% payout</li> </ul> </li> <li>Steady improvement in</li> </ul>	<ul> <li>Re-invest in the Business</li> <li>R&amp;D investment of 10 -11% of revenue</li> <li>BD – selective investment in R&amp;D assets</li> <li>Capex</li> </ul>	<ul><li>Capital structure</li><li>Annual Review</li><li>Excess capital returned to shareholders</li></ul>
	ROIC fuelled by double digit earnings growth	- Growth ~70% - Maintenance ~30%	<ul> <li>Partnering approach</li> <li>Long term valuation creation</li> <li>Capabilities, competencies, Adjacencies</li> </ul>

# **Capital Expenditure**<sup>1</sup>

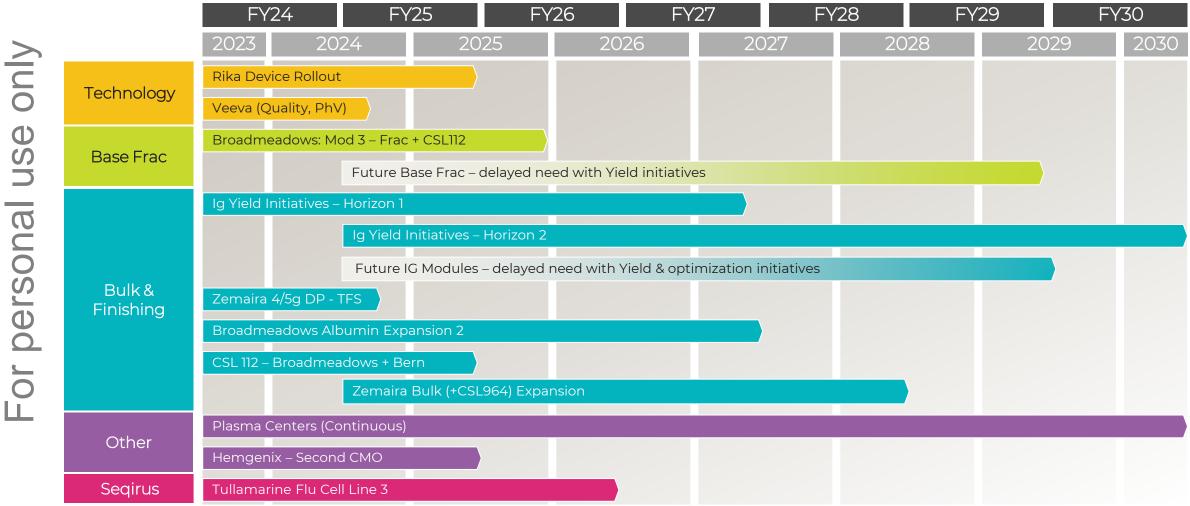


#### **Key Points**

- Significant investment continued during COVID years providing capacity to meet future demand
- Mid term capex needs reduced following natural run off of intensive program
- Capacity enhanced through yield initiatives and accessing CMO's for new capabilities - pushing out future capex needs

1. Capital Expenditure for Property, Plant & Equipment - net of disposals

# **Key Capital Projects - Completion Timeline**



**TSI** 

# **ROIC Outlook**

Earnings expansion fuelled by:

- Differentiated product portfolios
- Drive IG growth

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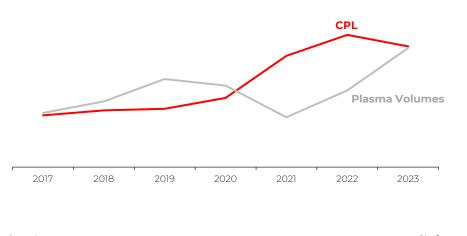
- New product launches
- CSL Behring gross margin recovery
- Continued growth in CSL Seqirus
- CSL Vifor strategy realisation

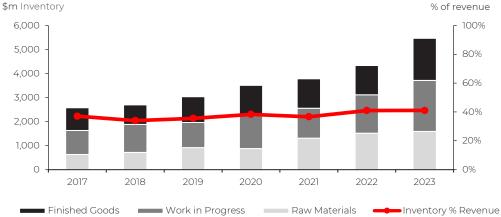
Continues to exclude potential CSL112 upside

<sup>1</sup>.ROIC is expected to modestly soften in FY24, driven by the timing mismatch between the raising of funds to acquire Vifor Pharma and the payment of consideration

Steady improvement<sup>1</sup> in ROIC fuelled by double digit earnings growth

# **Continued active management of inventory**





#### Increase in plasma volumes and CPL have accentuated the value of inventory

#### Key Challenges

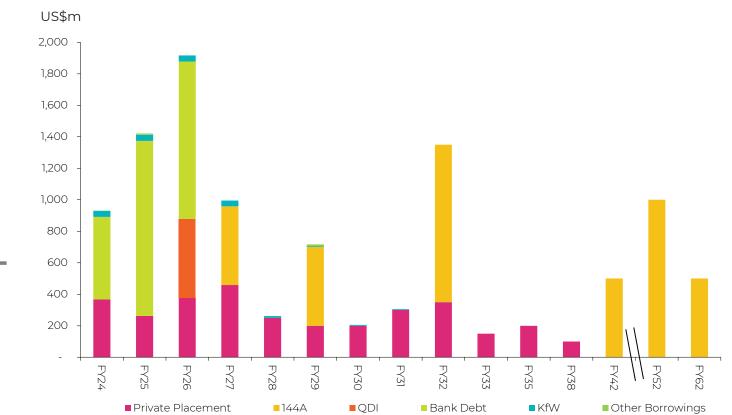
- Balancing inventory build versus fulfilling patient demand
- IG on EMA short supply list until June 2024
- Most ex-US markets require increased levels of safety stock
- Plasma collection costs remain high, although downward trending
- Inventory driven by higher CPL

#### Outlook

- Balancing inventory build versus fulfilling patient demand remains
- Pre pandemic, months of cover ~2.5x – 3.0x
  - FY25 target ~2.0x

### **Strong Balance Sheet**

Strong liquidity and competitive access to debt capital across multiple markets



As at 30 June 2023

# Debt is strongly weighted towards long tenors at fixed rates

- Net Debt / EBITDA 2.5x, expected to be ~2.0x by end FY24
- Business focus for further debt reduction to ensure credit ratings maintained
- 70% of debt fixed with average tenor of 8.9 years
- Weighted average cost of debt FY23 4.11% versus FY22 3.38%

#### Flexibility to continue access to deep and diverse capital pools

• Successful US 144 A program creates funding optionality in largest liquidity market (average tenor 18 years)

#### Stable investment grade credit rating

- S&P: A- (on negative watch)
- Moody's: A3

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# Sustainability

# **Sustainability Pillars**

Sustamar		Ongoing					÷.
		targeted efforts	Diagnostic / Baseline	Ambitions /Targets	Roadmap	Execution	Benefits realization
ENVIRONMENT (E) delivering on our promises to preserve a healthier plant	<ul> <li>Reduce Carbon Emissions</li> <li>Reduce Waste &amp; Emissions in the supply chain</li> <li>Environmental considerations embedded in strategy</li> </ul>	) In progress	<b>V</b> Completed	<b>√</b> Aligned	<b>√</b> Aligned	O In progress	In progress
SOCIAL (S) providing better care for brighter days ahead	<ul> <li>Donor Experience</li> <li>Patient &amp; Public Health Leader</li> <li>Access to Our Therapies</li> </ul>	O In progress	<b>√</b> Completed	O In progress	O In progress	O Next step	O Next steps
SUSTAINABLE WORKFORCE (W) it's the people behind our promise that makes us different	<ul> <li>Employee Engagement</li> <li>Diversity, Equity &amp; Inclusion</li> <li>Giving</li> </ul>	In progress	<b>C</b> ompleted	O In progress	O In progress	O Next step	Next Steps
				GOVERN	ANCE (G)		

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## **Key Sustainability Indicators and Highlights**

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Enviro	nment	Social		Workforce	
100%	SBTi 1.5°C	94% 📮	475 🟥	59%	
Renewable Electricity (RE) across all our major European manufacturing sites, with Australia to follow in Jan 2025.	Committed to be aligned with SBTi 1.5 °C Submitted to SBTi for validation in 2023	of plasma donors are willing to donate again and 91% are willing to refer a friend to donate plasma at their CSL plasma center	regulatory inspections of our manufacturing facilities and plasma collection centers with no impact to licenses	Female Employees	
Evaluating promising RE options for our US based manufacturing sites.		Approved Reflect RAP	>US \$1B 🛓	<b>44%</b> Female representation at board level	
5-star Green Star	190+	CSL's Reflect Reconciliation Action Plan launched in September 2023	investment into research and development		
by Design rating given to new Melbourne, AUS Headquarter from the Green Building Council of Australia; representing excellence in sustainable	Suppliers engaged setting their own SBTi aligned targets (Scope 3)	US \$13.7M supporting product access across the world		<b>45%</b> of people managers are women	
building practices.		Data as at 30 June 2023		Data as at 30 June 2023	

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# Research & Development

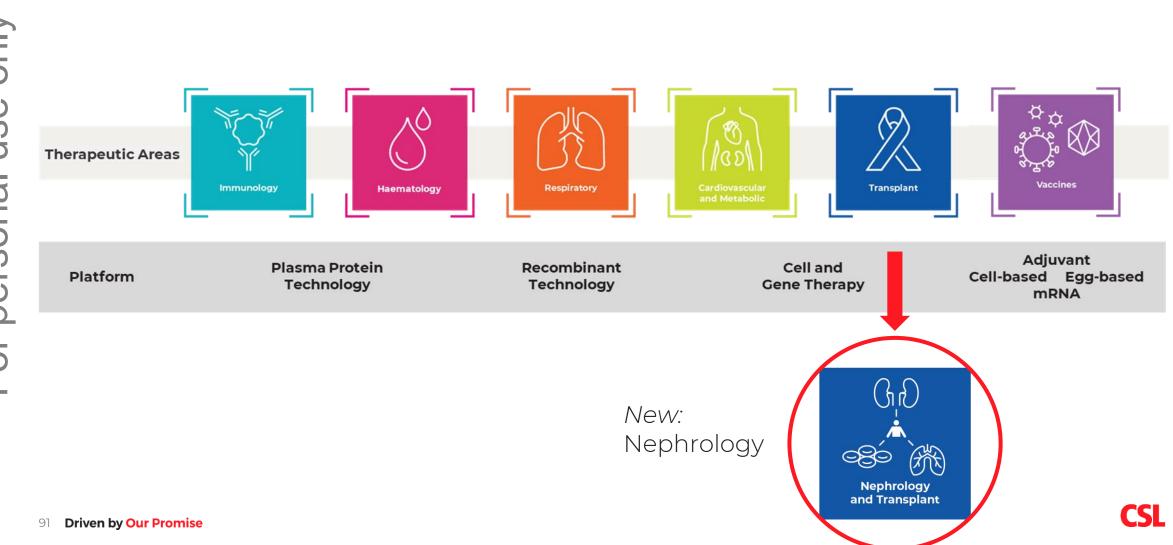
Bill Mezzanotte Executive Vice President, Head of R&D

# For bersonal use only Point personal use only **CSL Seqirus CSL Vifor CSL** Plasma

# **ONE** CSL R&D



#### **Focus Through Our Therapeutic Areas and Platforms**



# **Enhancing R&D's Global Capabilities**



#### Melbourne, Australia

- New Global Headquarters and Centre for R&D in Melbourne Biomedical Precinct
- ~40,000 m2 including:
  - 18 stories for >850 employees
  - 9 levels of world-class laboratories & facilities
- Australia's first-of-its-kind biotech incubator





#### Marburg, Germany

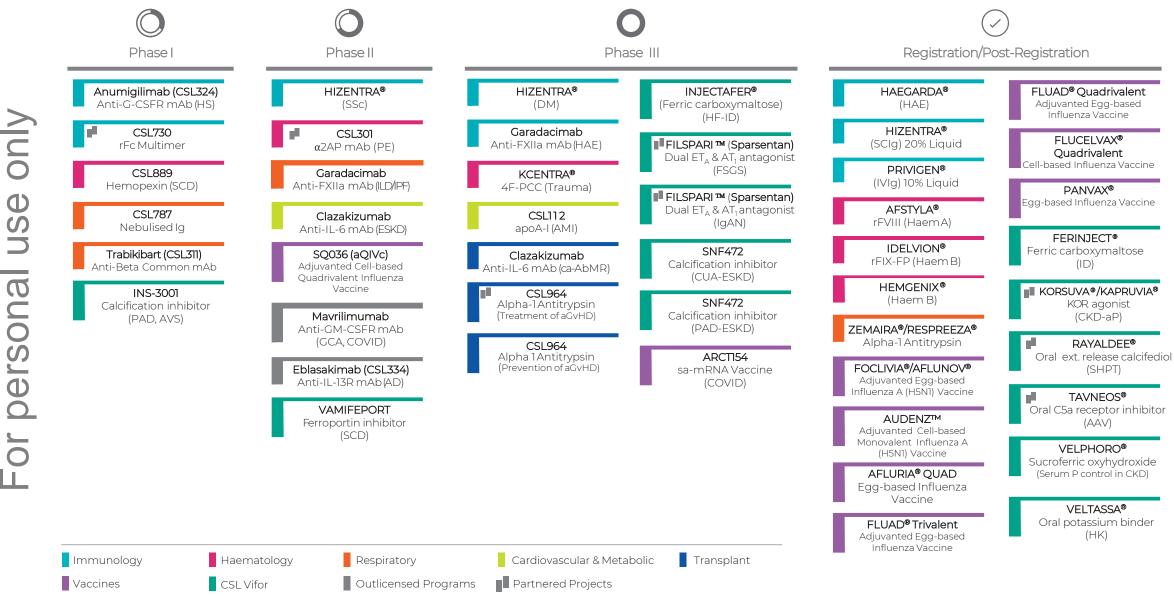
- New R&D Campus
- ~40,000 m2 for >500 R&D employees including:
  - 7,400m2 laboratory space
  - 10,300m2 working space
  - state-of-the-art vivarium
  - Collaborative laboratory space



#### Waltham, USA

- R&D centre supporting sa-mRNA technology for seasonal & pandemic influenza vaccines
- ~13,000 m2 including:
  - 5,000m2 laboratory space
  - Biosafety level 3 laboratory (BSL-3)
  - Collaborative laboratory space

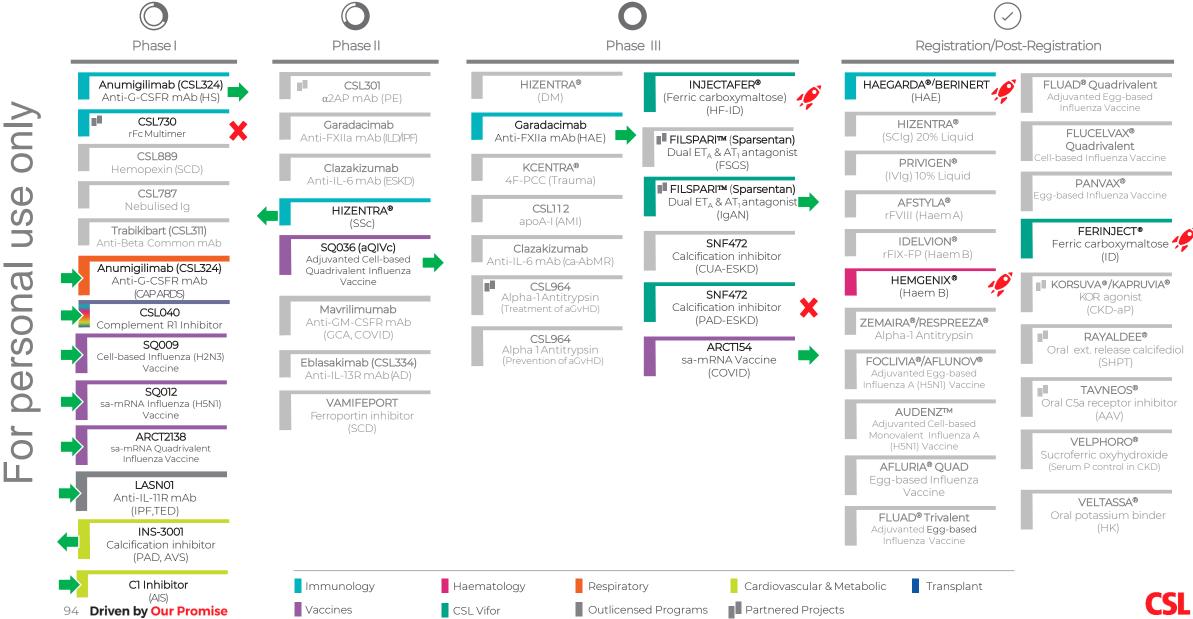
# CSL R&D Portfolio – FY23



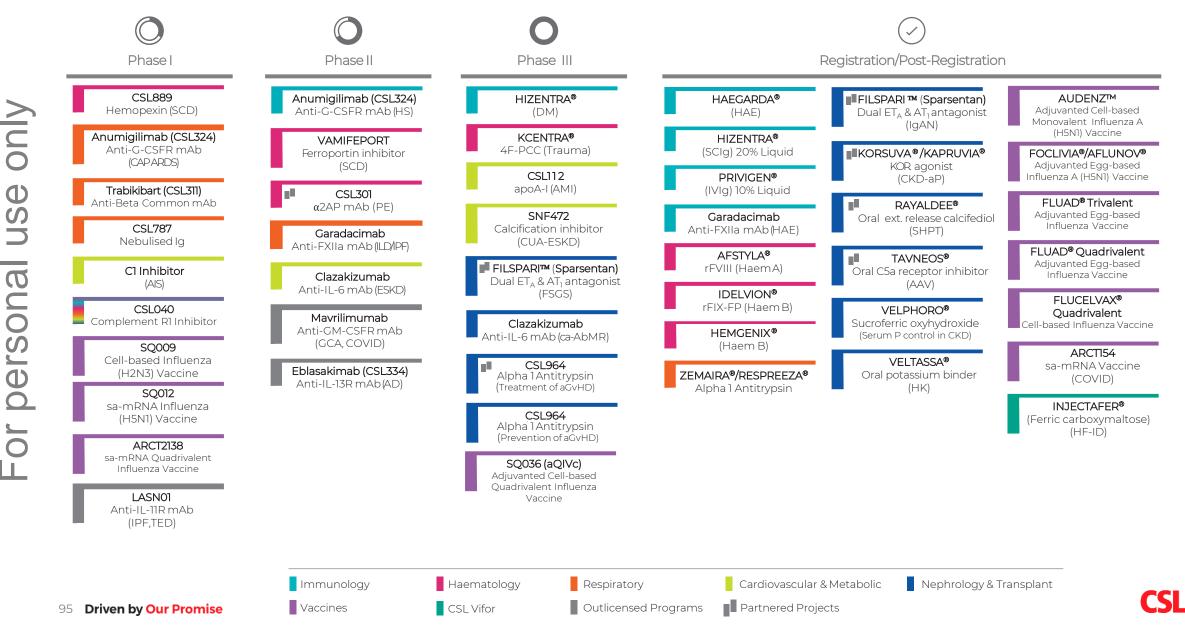
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CSL R&D Portfolio – FY23 Transitions



# CSL R&D Portfolio – FY24



#### **R&D Focus**

Investments Coming to Fruition



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#### Deliver a Promising Portfolio

- CSL112
- Garadacimab HAE
- Clazakizumab ca-AbMR
- KCENTRA® Trauma
- CSL964 aGvHD
- Sparsentan

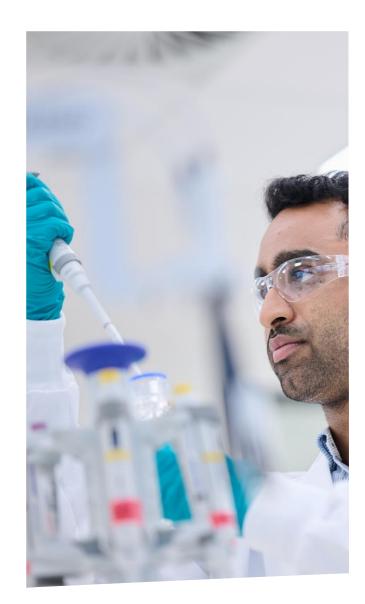
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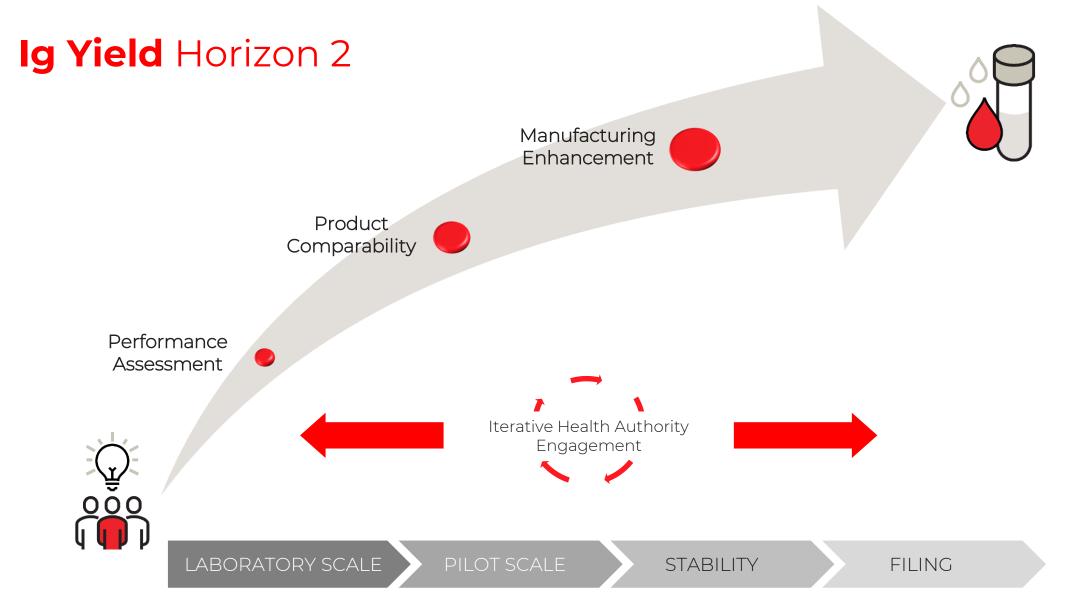
- sa-mRNA for COVID (near term) & Influenza (medium term)
- aQIVc



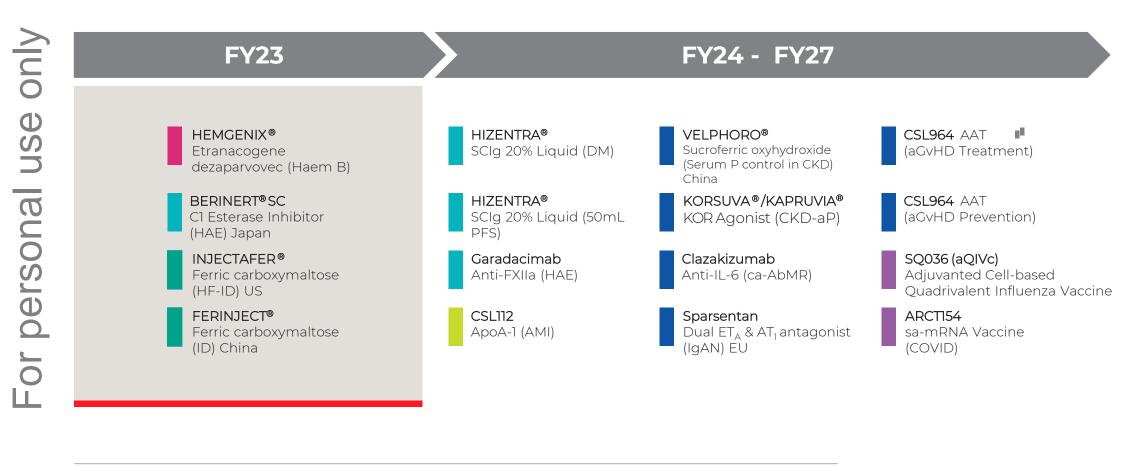
#### Strengthen our Core Platforms

- Flu Cell Culture yield
- Iron evidence & optimisation
- Patient Blood Management
- Ig yield





# **Significant Target Launch Dates**



 Immunology
 Haematology

 Vaccines
 CSL Vifor

- 35

Cardiovascular & Metabolic
Outlicensed Programs

Partnered Project

Nephrology & Transplant

# **Forward-Looking Portfolio Highlights – FY24**

#### Cardiovascular & Metabolic

- CSL112 (ApoA-1) AMI Phase III top line results
- Clazakizumab (ESKD)
  - Phase IIb complete
  - Phase III first patient in

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Immunology

- Garadacimab (Anti-FXIIa) HAE
- EU, US & JP submissions
- HIZENTRA® DM Phase III enrolment complete
- HIZENTRA<sup>®</sup> PFS 50mL
  - US Launch
  - EU submission
- Anumigilimab (Anti-G-CSFR) HS Phase II study first patient in

#### **CSL Behring** Horizon 2

- Ongoing pre-clinical studies with pilot plant materials
- Ongoing HA engagement



- IDELVION <sup>®</sup> China Phase III first patient in
- Vamifeport (SCD) last patient out
- CSL889 (Hemopexin) SCD Phase I top line results



#### Nephrology & Transplant

- Clazakizumab (Anti-IL-6) ca-AbMR Phase III study 200 patients enrolled
- CSL964 (Treatment of aGvHD) Phase III top line
  results
- FILSPARI™ (sparsentan) (IgAN) EU approval
- VELPHORO® China launch
- VELTASSA®
  - AU Launch
  - US & EU paediatric approval



- Trabikibart (Anti-Beta Common) ASTH Phase I
   study complete
- Garadacimab (Anti-FXIIa) IPF/ILD Phase IIa study complete
- CSL787 (Neb Ig) Phase I study complete



- aQIVc (Adjuvanted Cell-based Quadrivalent Influenza Vaccine) Phase III study 50yr+ first patient in
- ARCTI54 sa-mRNA (COVID)
  - JP approval
  - US & EU submissions
- SQ012 sa-mRNA (H5N1) Flu Phase I first patient in
- ARCT2138 sa-mRNA Quad Flu Phase I first patient in

Abbreviations: ca-AbMR - Chronic Active Antibody-Mediated Rejection; ESKD – End Stage Kidney Disease; EU – Europe; HA – Health Authority; HAE – Hereditary Angioedema; IgAN - IgA Nephropathy; ILD – Interstitial Lung Disease; IPF - Idiopathic Pulmonary Fibrosis; JP – Japan; Neb Ig - Nebulised Ig; PFS – Pre-Filled Syringe; samRNA – Self-Amplifying messenger RNA; RNA – Ribonucleic Acid; SCD – Sickle Cell Disease; US – United States

CSL



# Thank You / Questions



# **Concluding Remarks**

Paul McKenzie CEO & Managing Director

# **Financial Outlook**

#### FY24 Guidance

Revenue	Growth of 9-11% @CC	RE-AFFIRMED	
NPATA	Growth of 13-17% @CC		
	\$2.9 - \$3.0 billion @CC	RE-AFFIRMED	
Сарех	Down 30%		
Operating efficiency	G&A ~5% of revenue		
Balance sheet	Circa 2x net debt / EBITDA	Α	
Outlook			
CSL Behring gross margin	Recovering to pre-covid margin in 3-5 years		
ROIC	Steady improvement <sup>1</sup> in ROIC fuelled by double digit earnings growth		

# **Strategic Positioning**

- Growing global markets with significant unmet patient need
- Best in class, durable products driven by continued innovation
- Scaled manufacturing platforms underpinned by embedded know how

	Near Term / Recent Activity	Market Opportunities	
	Outpacing industry growth	Industry volume growth 6-8% p.a.	
Immunoglobulins	Ig yield initiatives underway (Horizon 1 & 2)	US/Canada/Aust Ig consumption 2-3x that of	
	Hizentra for dermatomyositis	EU	
	-	Disease prevalence consistent globally	
	New technologies aQIVc and sa-mRNA	Recovery in vaccination rates	
Vaccines	COVID vaccine – preparation for global licensure	Ongoing portfolio differentiation	
	Flu cell culture yield improvement		
Iron	Heart Failure label expansion for Injectafer in US	30% of population has iron deficiency; of which	
	Approval of Ferinject in China	50% have iron deficiency anaemia	
	Patient Blood Management strategy		

### **R&D Programs – Near Term Milestones**

	Opportunity	FY24
Garadacimab (HAE)	Potentially best in class treatment option for HAE patients	EU, US & JP submissions
Clazakizumab (ca-AbMR)	AbMR is leading cause of transplant failure	Phase III study - 200 pts enrolled
KCENTRA® (Trauma)	Trauma is leading cause of morbidity & mortality in US	Phase III study tracking towards 2000 patients enrolled for interim analysis
CSL112 ApoA-1 (AMI)	Potentially transform treatment of AMI patients at high-risk of recurrent cardiovascular events	Phase III top line results
Sparsentan (IgAN)	IgAN is major cause of kidney failure	EU approval
aQIVc	Potential to set standard of care for patients 50yr+	Phase III study 50yr+ first patient in
sa-mRNA Efficacy, tolerability, durability & flex for flu and beyond	Efficacy, tolerability, durability & flexibility	Japan approval (COVID)
	for flu and beyond	Phase I study first patient in (Flu)
Ig Yield initiatives	Horizon 1	Implementation of first improvements
	Horizon 2	Ongoing pilot plant activities

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# **Positioned for Annual Double-Digit Earnings Growth**



- Significant unmet need
- Durable products driven by continued innovation and embedded know how



#### **Robust R&D Portfolio**

- Near-to-mid-term launches
- Longer-term opportunities across platforms and therapeutic areas



#### Yield & capacity expansion

- Yield enhancement across plasma and manufacturing platforms
- Investing in Ig and cell capacity



# Disciplined capital allocation for growth

- R&D, CapEx and value-creating BD
- Partnerships across the value chain with leading companies



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#### CSL Contacts

Mark Dehring VP Investor Relations © +61 3 9389 3407 mark.dehring@csl.com.au

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Bernard Ronchi Investor Relations ① +61 3 9389 3470 bernard.ronchi@csl.com.au

Stephen McKeon Investor Relations Investor Relations +61 3 9389 6798 stephen.mckeon@csl.com.au