

**CSL Limited** 

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# ASX Announcement

For immediate release

13 February 2024

# Results Presentation for the Half-year ended 31 December 2023

Melbourne, Australia - CSL (ASX:CSL; USOTC:CSLLY)

Please find attached the slides for the presentation on the half year results that will be given by the Chief Executive Officer and the Chief Financial Officer shortly.

The briefing will be webcast and can be accessed in the "Investor" section of CSL's website (www.CSL.com).

Authorised for lodgement by:

Fiona Mead

**Company Secretary** 

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# **CEO Overview**

Paul McKenzie CEO & Managing Director





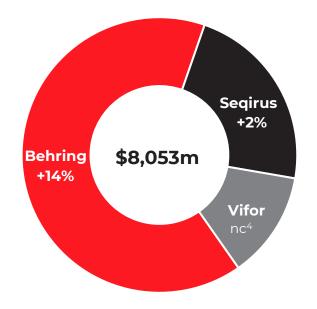
# Strong performance<sup>1</sup> Revenue +11%, NPATA<sup>2,3</sup> +13%, NPAT +20%

## **CSL Behring**

# Strong growth across the portfolio especially Ig

- Ig +23%, KCENTRA® +12%, HAFGARDA® +9%
- Gross margin recovery underway
- Good progress with plasma initiatives
- Garadacimab filed

# Revenue by Segment



## **CSL Seqirus**

# Solid performance in a challenging season

- FI UAD® +14%
- Regulatory approval for world first sa-mRNA COVID vaccine
- aQIVc phase 3 last patient enrolled Jan 2024

#### **CSL Vifor**

# Well prepared for transitioning Iron market

- Successful TAVNEOS® EU launch
- Strong patient conversion to MIRCERA®



<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail...

<sup>2.</sup> NPATA is defined as the statutory net profit after tax before impairment and amortisation of acquired intellectual property, business acquisition and integration costs and unwind of the inventory fair value uplift.

3. Attributable to the shareholders of CSL Limited.

<sup>4.</sup> Not comparable

# **CSL Behring**Revenue up 14%<sup>1</sup>

Therapy	Revenue \$m	Change <sup>1</sup> %	Performance	Major Brands
lg	2,757	23%	<ul> <li>Strong growth across all geographies         <ul> <li>PRIVIGEN® / INTRAGAM® +27%, HIZENTRA +18%</li> </ul> </li> <li>Significant patient demand in core indications</li> <li>HIZENTRA® 50ml pre-filled syringe launch in the US</li> </ul>	Hizentra* Immune Gidbulin Suboutareous (Human) 20% Uquid  Prividen* Immune Gidbulin Intravenous (Human), 10% Uquid
Albumin	613	8%	<ul> <li>Strong growth in emerging markets</li> <li>Solid growth in US and EU</li> <li>Competition remains strong in China</li> </ul>	AlbuRx®
Haemophilia	662	8%	<ul> <li>IDELVION® remains the standard of care, +7%</li> <li>Market leader in key markets</li> <li>Significant HCP and patient interest in HEMGENIX®</li> </ul>	Humate-P° Antihemophilic Rador/Yon Willebrand Factor Complex (Human)  Haemate* P 1000  Gualatin Rador/Quenthand, Abunin/Goon-Precin  etranacogene dezaparvovec drib
Specialty	976	6%	<ul> <li>KCENTRA® +12%</li> <li>Continues to be the gold standard for warfarin reversal</li> <li>HAEGARDA® +9%</li> <li>Strong EU performance</li> <li>Continue to add new patients</li> </ul>	Prothrombin Complex. Concentrate (Human)  HAEGARDA' C1 Esterase Inhibitor Subcutaneous (Human)  HIPEMOCOMPLETTIN' P Fibrinogen Concentrate  C1 Esterase Inhibitor, Human
Other <sup>2</sup>	230	(16%)	COVID-19 vaccine supply contract in prior period	
Total	5,238	14%		

<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail. 2. Includes HPV royalties & Hyperimmunes



# **CSL Behring**Plasma Highlights

- Underlying fundamentals of plasma collection remain strong
- 10% reduction in CPL<sup>1</sup>
- Expanding geographic footprint of plasma collection network
- RIKA
  - Currently >30 centres converted
  - Roll out plan over next 18 months
  - Individualised Nomogram filed with the FDA
- Gross margin recovery underway

# Benefits of RIKA Plasma Donation System

- Fewer donor deferrals; reduced donation time by ~30%
- Individualised Nomogram will improve average donation yield by ~10%
- Reduced biohazard disposable waste by 10-15%
- Improved productivity

<sup>1.</sup> US only and average over the periods.

# CSL Seqirus Revenue up 2%<sup>1</sup>

#### **Current Season Dynamics**

- Reduced rates of immunisation
- Competitive price pressures
- Overburdened healthcare system

	Revenue \$m	Change <sup>1</sup> %	Performance	Major Brands
Egg Based	123	0%	<ul> <li>Revenue growth in the northern hemisphere influenza market in a challenging season</li> </ul>	influenza vaccine afluria.
Cell Culture	529	(13%)	<ul> <li>Heightened recognition of benefits of differentiated product portfolio</li> <li>Continued FLUAD® preferential recommendation in the UK</li> </ul>	Influenza Vaccine  FLUCELVAX.  QUADRIVALENT
Adjuvanted Egg	988	14%	<ul> <li>First season following US ACIP preferred recommendation for FLUAD® in 65+</li> </ul>	FLUAD°
In License	65	(23%)	Transition to single dose Gardasil vaccine program	
Pandemic	85	9%		
Other Income	14	67%		
Total	1,804	2%		

<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.



# **CSL Seqirus**Operational Highlights



# Seasonal influenza products

- FLUCELVAX® 6-month+ age extension approved in UK, Australia and New Zealand
- FLUAD®
  - 50-year+ age extension approved in the EU.
  - Received preferential recommendation in Canada for the 65+ population



#### **Product Innovation**

- Phase III clinical study commenced for aQIVc
- Regulatory approval for world first sa-mRNA COVID vaccine
  - Japanese approval for ARCT-154
  - R&D development program beyond influenza
- Phase 1 trial for sa-mRNA for seasonal and pandemic influenza



#### Pandemic influenza

- UK Advance Purchase Agreement awarded solely to CSL Seqirus
- Selected by BARDA for delivery of H5N8 A/Astrakhan antigen to the U.S. government for preparedness against potential avian flu outbreak in humans



# **CSL Vifor**

		Revenue <sup>1</sup> \$m	Major Brands	Highlights
Iron		505	ferinject <sup>®</sup> rente curbosymaltose  Venose: iron sucrose injection, USP	<ul> <li>China FERINJECT® inclusion in the National Reimbursement Drug List</li> <li>Well prepared for a transitioning iron market</li> <li>US step edit pressure</li> </ul>
Nephrology	Dialysis	399	NIRCERÁ*  actual polythelex glad-specia leta  OVELPHORO*  Retacrit* apparente alifa-apptax  KAPRUVIA*	<ul> <li>MIRCERA®         <ul> <li>Strong ESA performance in the U.S., as patients convert</li> </ul> </li> <li>KAPRUVIA®         <ul> <li>Approved in multiple emerging markets</li> <li>Strong performance in Germany, France and Austria</li> </ul> </li> <li>VELPHORO®         <ul> <li>US inventory adjustment</li> <li>China approval and inclusion in the National Reimbursement Drug List</li> </ul> </li> </ul>
	Non-Dialysis	90	Veltassa*	<ul> <li>Strong TAVNEOS® performance in all EU launch markets, with regulatory approval obtained in South Korea</li> <li>Paediatric indication of VELTASSA® in US Oct-23, EU Jan-24</li> </ul>
All Other		17		
	Total	1,011		



<sup>1.</sup> The prior comparable period included only 5 months revenue following the acquisition of Vifor Pharma in August 2022.

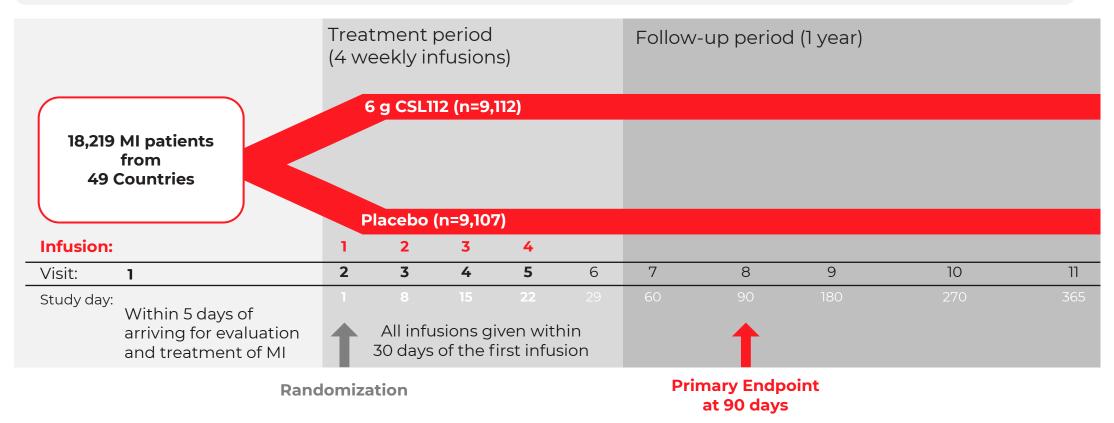
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# Pipeline Bill Mezzanotte EVP & Head of R&D



# CSL112 Apolipoprotein A-I (human) - AEGIS-II

**Objective:** to evaluate the efficacy and safety of CSL112 on reducing the risk of cardiovascular (CV) death, myocardial infarction (MI), or stroke



Time to first occurrence of any component of the composite endpoint of CV death, MI, or stroke from time of randomization through 90 days



# CSL112 Apolipoprotein A-I (human) - AEGIS-II

**Objective:** to evaluate the efficacy and safety of CSL112 on reducing the risk of cardiovascular (CV) death, myocardial infarction (MI), or stroke

- For the primary efficacy endpoint at 90 days, the trial did not meet the threshold for statistical significance
- There are no plans for a near-term regulatory filing
- Additional analyses are ongoing to understand the complete data and determine next steps
- Study results will be presented at the American College of Cardiology (ACC) Scientific Sessions, 6 April 2024, and published in a peer-reviewed journal



# **Recent Late-Phase R&D Highlights**

- Clazakizumab for reduction of cardiovascular events in patients with End-Stage Kidney Disease (ESKD)
  - Well-characterized link of inflammation and cardiovascular morbidity and mortality in patients with ESKD
  - Positive phase 2b data; Phase 3 prepared to start 2Q 2024
- Garadacimab for Hereditary Angioedema
  - High efficacy, Favorable safety and tolerability; patient-friendly presentation and regimen
  - Global submissions and regulatory review underway; First approval expected 4Q 2024
- HIZENTRA® for Dermatomyositis
  - 5-year mortality rate 10-30%, high comorbidity; Better treatments needed
  - Enrolment complete for phase 3; Data expected 3Q 2024
- Adjuvanted, cell-based Quadrivalent Influenza Vaccine (aQIVc)
  - aQIVc combines benefits of MF59® adjuvant, higher antigen dose and cell-derived antigen to increased influenza protection via heightened immune response
  - Phase III Immunogenicity study (50 years+) enrolment completed ahead of schedule; Data expected 4Q 2024

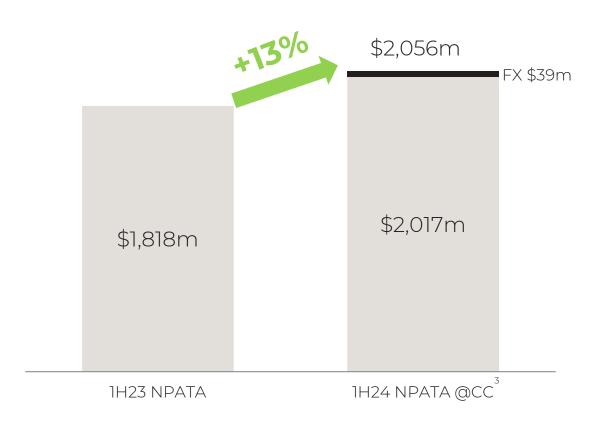


Financials Joy Linton CFO





# NPATA<sup>1</sup>



	1H23 Rep	1H24 @ CC <sup>3</sup>
NPATA	\$1,818m²	\$2,056m <sup>2</sup>
Acquired intangible assets amortisation	(\$88m)	(\$129m)
One-off acquisition adjustments	(\$184m)	(\$49m)
Tax	\$35m	\$31m <sup>4</sup>
NPATA Attributable to NCI <sup>5</sup>	\$59m	\$53m
NPAT	\$1,640m	\$1,962m
NPAT Attributable to NCI <sup>5</sup>	(\$17m)	(\$20m)
NPAT	\$1,623m <sup>2</sup>	\$1,942m <sup>2</sup>



<sup>1.</sup> NPATA is defined as the statutory net profit after tax before impairment and amortisation of acquired intellectual property, business acquisition and integration costs and unwind of the inventory fair value uplift 2. Attributable to the shareholders of CSL Limited.. 1H23 includes ~5 months of CSL Vifor contribution

<sup>3.</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability of operational performance for the Group 4. Tax attributable to amortisation of acquired intellectual property \$24m. Tax attributable to one-off acquisition adjustments (including unwind of the inventory fair value uplift) \$7m

<sup>5.</sup> Non-Controlling Interest

# CSL Group Financial Highlights

US\$ Millions	1H23 Rep	1H24 Rep	1H24 at CC <sup>1</sup>	Change % <sup>1</sup>
Total Revenue	7,184	8,053	7,954	11%
Gross Profit <sup>3</sup>	4,042	4,494	4,491	11%
GP % <sup>3</sup>	56.3%	55.8%	56.5%	
Sales & Marketing	683	707	696	2%
Operating Result <sup>3</sup>	3,359	3,787	3,796	13%
R&D <sup>3</sup>	593	669	661	11%
$G&A^3$	360	323	335	(7%)
Finance (Net)	171	234	226	32%
NPATA <sup>2</sup>	1,818	2,017	2,056	13%
ETR %	16.0%	19.2%	18.1%	
Cashflow From Ops	980	1,069		9% <sup>4</sup>
NPATA EPS <sup>2</sup> (\$)	3.77	4.18		11%4
DPS (\$)	1.07	1.19		11% <sup>4</sup>

Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail



#### R&D

Growth in line with sales Anticipate FY24 within 10-11% of revenue

#### G&A

Favourable FX differences Efficiencies driven by centralisation of Enabling Functions

#### **Finance**

Higher interest rates

#### **Tax**

Higher ETR due to geographic profit mix and increased UK tax rate

## **Cashflow from Operations**

Increase in cash earnings from growth in sales



<sup>2.</sup> Attributable to the shareholders of CSL Limited.

<sup>3.</sup> Underlying results have been adjusted to exclude impairment and amortisation of acquired IP, business acquisition and transaction costs and unwind of the inventory fair value uplift

<sup>4.</sup> At reported currency

# CSL Group 1H24 by Segment

US\$ millions reported	CSL Behring	CSL Seqirus	CSL Vifor	CSL Group	Change % at CC <sup>1</sup>
Sales	5,093	1,705	1,006	7,804	11%
Other Revenue	145	99	5	249	2%
Total Revenue	5,238	1,804	1,011	8,053	11%
Gross Profit <sup>2</sup>	2,617	1,207	670	4,494	11%
Reported GP % <sup>2</sup>	50.0%	66.9%	66.3%	55.8%	
Sales & Marketing	396	89	222	707	(2%)
Operating Result	2,221	1,118	448	3,787	13%
Operating Segment %2	42.4%	62.0%	44.3%	47.0%	



<sup>1.</sup> Percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail. 2. Underlying results have been adjusted to exclude impairment and amortisation of acquired IP, business acquisition and transaction costs and unwind of the inventory fair value uplift

# **CEO Overview**

Paul McKenzie CEO & Managing Director



# Outlook<sup>1</sup>

#### **CSL Behring**

- Underlying patient demand for Ig in core indications remain strong
- 2H growth expected for HFMGFNIX®
- Plasma and yield initiatives ongoing
- Gross margin recovery underway

#### **CSL Segirus**

- Progression of global registrations for nextgeneration mRNA COVID vaccine
- ~85% of sales in 1H, with expenses falling more evenly over the year giving rise to a loss in 2H, consistent with seasonality

#### CSI Vifor

- Well positioned for iron competition
- Nephrology launch momentum
- Unlock value across CSL commercial and operations e.g. patient blood management with CSL Behring



## FY24 Guidance Reaffirmed

#### **Revenue Growth**

~ 9 - 11% @CC<sup>2</sup>

## **NPATA Growth**

~ 13 – 17% @CC<sup>2,3</sup> to ~\$2.9 – \$3.0b @CC<sup>2,4</sup>



For forward looking statements, refer to Legal Notice on page 2

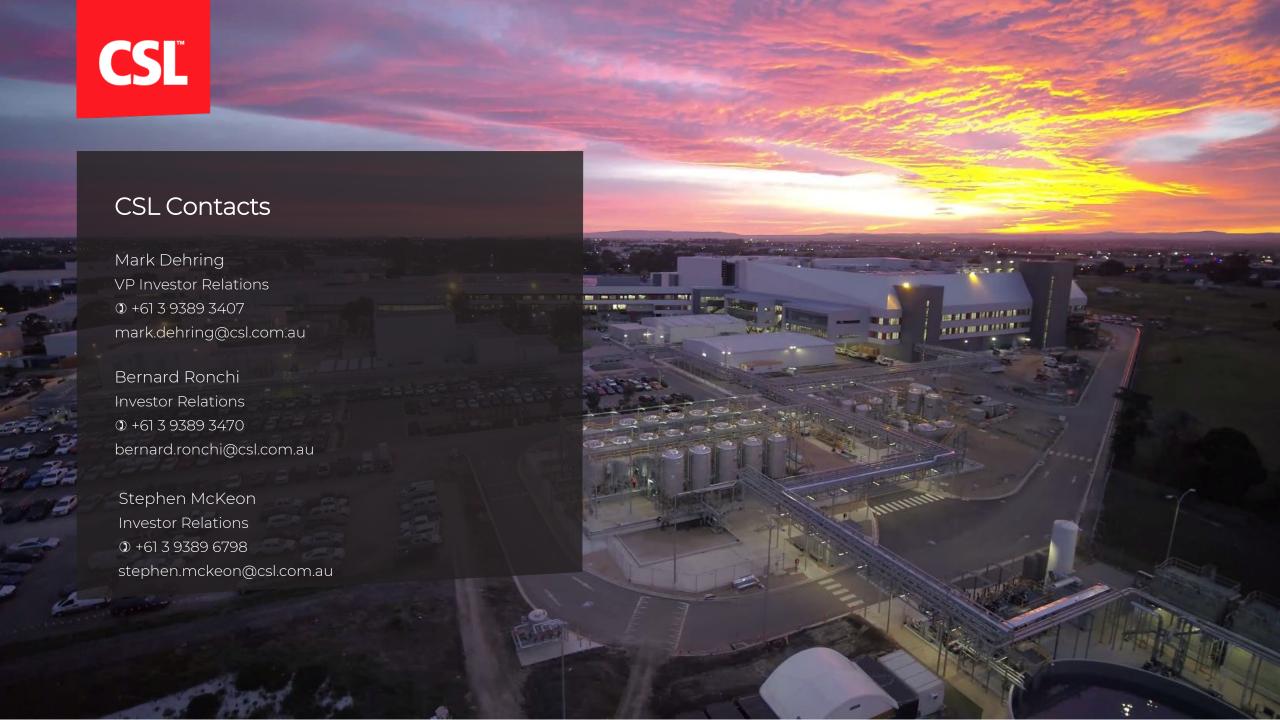
<sup>2</sup> Constant Currency (CC) removes the impact of exchange rate movements to facilitate comparability. See end note for further detail

 <sup>%</sup> growth rates exclude the one-off gain from the sale of property in FY23 (NPATA \$44m)
 NPATA to NPAT adjustments are estimated to be:

<sup>•</sup> Amortisation of acquired intellectual property. FY24 estimate \$320m (pre-tax), \$270m (post tax)

<sup>•</sup> CSL Vifor integration costs and the unwind of inventory fair value uplift. FY24 estimate \$85m (pre-tax), \$70m (post-tax)

<sup>\*</sup> FY24 FX impact expected to be a headwind of ~\$85M if current rates remain unchanged for the remainder of the financial year



## Notes

(#) Constant currency removes the impact of exchange rate movements to facilitate comparability of operational performance for the Group. This is done in three parts: a) by converting the current year net profit of entities in the group that have reporting currencies other than US Dollars, at the rates that were applicable to the prior comparable period (translation currency effect); b) by restating material transactions booked by the group that are impacted by exchange rate movements at the rate that would have applied to the transaction if it had occurred in the prior comparable period (transaction currency effect); and c) by adjusting for current year foreign currency gains and losses. The sum of translation currency effect, transaction currency effect and foreign currency gains and losses is the amount by which reported net profit is adjusted to calculate the operational result.

#### **General Disclaimer Non-IFRS**

There are references to IFRS (International Financial Reporting Standards) and non-IFRS financial information in this document. Non-IFRS financial measures are financial measures other than those defined or specified under any relevant accounting standard and may not be directly comparable with other companies' information. Non-IFRS financial measures are used to enhance the comparability of information between reporting periods, and enable further insight and a different perspective into the financial performance. Non-IFRS financial information should be considered in addition to, and is not intended to be a substitute for, IFRS financial information and measures. Non-IFRS financial measures are not subject to audit or review.

#### **Summary NPAT attributable to members** of parent entity

Reported net profit after tax \$1.901m \$41m Currency effect Constant currency net profit after tax\* \$1,942m

Average exchange rates for major currencies for half year ended 31 December 2023/31 December 2022 include: USD/EUR (0.92/0.99), USD/AUD (1.53/1.49), USD/CHF (0.89/0.97), USD/CNY (7.24/6.97) and USD/GBP (0.80/0.85).

Summary NPATA <sup>1</sup> attributable to members of the parent entity	US\$m
Reported net profit after tax	1,901
Amortisation of acquired intellectual property	102
Unwind of inventory fair value uplift	21
Acquisition and integration costs	19
Income tax credit on above adjustments	(26)
NPATA <sup>1</sup> attributable to members of the parent entity	2,017
Currency effect attributable to members of the parent entity	39
Constant Currency <sup>#</sup> NPATA <sup>1</sup> attributable to members of the parent entity	2,056



#### **Summary Revenue**

Reported revenue \$8.053m Currency effect (\$99m) Constant currency revenue\* \$7,954m

\*Constant currency net profit after tax and constant currency sales have not been audited or reviewed in accordance with Australian Auditing Standards.

1. NPATA is defined as the statutory net profit after tax before impairment and amortisation of acquired intellectual property, business acquisition and integration costs and unwind of the inventory fair value uplift



# Appendix

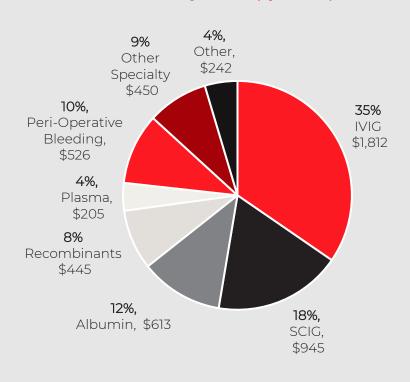


# Appendix A CSL Behring – Key Products

CSL BEHRING	Therapy Group	Sales \$m	Change <sup>1</sup> %
Privigen	IVIG	1,768	35%
Hizentra	SCIG	945	18%
Albumin	Albumin	613	8%
Idelvion	Haemophilia	390	7%
Kcentra	Specialty	366	12%
Haegarda	Specialty	245	9%
Berinert	Specialty	120	(7%)
Haemocomplettan	Specialty	115	0%
Humate	Haemophilia	97	8%
Haemate	Haemophilia	58	16%

<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail

#### HY24 Revenue By Therapy Group \$m





# Appendix B CSL Vifor & CSL Seqirus – Key Products

CSL SEQIRUS	Therapy Group	Sales \$m	Change <sup>1</sup> %
Fluad	Adjuvanted	988	14%
Flucelvax	Cell culture	529	(13%)
Afluria	Egg-based	123	9%

CSLVIFOR	Therapy Group	Sales \$m
Ferinject/Injectafer	Iron	376
Mircera	Dialysis	313
Venofer	Iron	82
Veltassa	Non Dialysis	66
Velphoro	Dialysis	46
Maltofer	Iron	46

<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.

## HY24 Revenue By Therapy Group \$m

