# CSL

**CSL Limited** 

2023 Half Year Results

14 February 2023



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### 1H23 Performance

*Ig franchise growing strongly* CSL Vifor progressing well

#### **CSL Behring**

- Ig franchise growing strongly
- Record levels of plasma collections

#### **CSL Vifor**

- Successful acquisition closure
- ~5 months financial contribution

#### **CSL Segirus**

- Strong sales growth driven by differentiated products
- Licence agreement for latestage self amplifying mRNA vaccine technology

#### R&D

- Gene therapy HEMGENIX® approved
- Multiple late stage programs



\$1.62b<sup>2</sup>

 $0\%^{1}$ 

**NPAT** 

Incl. one-off costs associated with Vifor acquisition

\$1.82b<sup>2</sup> +10%1 **NPATA**<sup>3</sup>



<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. **Driven by Our Promise™** 2. Attributable to the shareholders of CSL Limited

## **CSL Behring**

Revenue up 11%<sup>1</sup>

Revenue	Change <sup>1</sup>
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	Revenue	Charige		
Therapy	\$m	%	Performance	Major Brands
IG	2,227	19%	<ul> <li>Product supply improving in post COVID environment</li> <li>Strong growth across all geographies especially EU and emerging markets</li> </ul>	Hizentra" Pivigen* Immune Globulin Subcutaneous (Human) 20% Liquid (Human), 10% Liquid
Albumin	585	11%	<ul> <li>Strong growth in US &amp; EU driven by improved supply</li> <li>Albumin growth in China constrained by COVID</li> </ul>	AlbuRx®
Haemophilia	611	12%	<ul> <li>Strong performance by IDELVION® due to:</li> <li>Higher patient demand with increased in-person doctor visits</li> <li>Increased utilisation in Japan</li> </ul>	Coopulator Factor (Recombinant), Horum Fiscon Protein  HUNATE-P° Antithemophilic Factor/Your Willebrand Factor Complex (Human)  Haemate* P 1000
Specialty	915	5%	<ul> <li>KCENTRA® continues to gain market share in the US as hospital demand returns to pre-pandemic levels</li> </ul>	Protrombia Complex Concentrate (Human)  Urgent Warfarin Reversal  HREMOCOMPLETTEN Fibranogen Concentrate
Other <sup>2</sup>	218	(31%)	COVID-19 vaccine supply contract substantially completed in FY22	
Total	4,556	11%		

<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 2. Includes HPV royalties & Hyperimmunes & COVID vaccines



## **CSL Behring**

### Operational Highlights



#### Plasma Collections

- Strong increase in plasma collected +36% with levels now 10% above pre-pandemic
- Mexico border re-opened with collections recovering strongly
- 7 new centers in US and 1 in Germany
- Continued adoption of technology
  - CSL Plasma donor app downloads >2.5m
  - Online health questionnaire
- RIKA program commenced



#### Manufacturing

- Broadmeadows and Marburg base fractionation facilities completed and opened
- Continued investment in yield initiatives





## **CSL Seqirus**

Revenue up 9%1

	Revenue \$m	Change <sup>1</sup> %	Performance	Major Brands
Egg Based	123	(33%)	9% revenue growth in seasonal influenza vaccines against a backdrop of reduced rates of immunisation	influenza vaccine afluria.  Quadrivalent
Cell Culture	599	28%	<ul> <li>110 million doses distributed in NH</li> <li>US seasonal influenza vaccines &gt;\$1 billion for the second year running</li> </ul>	Influenza Vaccine FLUCELVAX. QUADRIVALENT
Adjuvanted Egg	845	7%	Continue to benefit from differentiated product portfolio	FLUAD°
Other / In License	86	17%		
TOTAL Product Sales	1,653	9%		
Pandemic	76	1%		
Other Income	9	(13%)		
Total	1,738	9%		



## **CSL Seqirus**

### Operational Highlights



#### Seasonal influenza products

- 6 months+ age indication for FLUCELVAX® now approved in the US, Argentina, Canada & Taiwan with Australia and New Zealand under evaluation
- FLUAD included as a preferentially recommended seasonal vaccine option for adults aged 65+ years in the US



#### COVID-19

 Contract completed for the manufacture ~50 million doses of Astra Zeneca's COVID vaccine in Australia



#### Pandemic influenza

- Awarded BARDA task order for the manufacture of H5N8 clinical material and Phase 2 clinical study
- Supplied AFLUNOV® pre-pandemic stockpile (H5N1) to Singapore



#### Manufacturing

- Additional fill and finish capacity completed at Holly Springs and Liverpool
- Building works well advanced for the new A\$800m cell-culture facility in Melbourne



## **CSL Vifor**

#### ~5 months revenue contribution<sup>1</sup>

**Integration and cost** synergies on track

~15% revenue growth<sup>2</sup>

		Revenue \$m	Major Brands	Highlights
Iron		427	ferinject ventocymultose ventocymult	US Heart Failure label variation submitted – response expected in Feb 23
	Dialysis	377	I MIRCERAS DELPHORO Contractor de la Con	<ul> <li>Agreement with large US kidney care provider for ESA portfolio effective Dec 22</li> <li>Korsuva® / Kapruvia® approved in Australia, Canada, Singapore</li> </ul>
Nephrology	Didiy3i3	377	Retacrit* epoetin alfa-eptx  KORSUVA*	<ul> <li>and Switzerland.</li> <li>Long-term exclusive licensing agreement signed for Korsuva® in China</li> </ul>
N B B	Non Dialysis	55	Veltassa (avacopan)	Tavneos® approved in Great Britain, Switzerland, UAE
All Other		30		
	Total	889		



## R&D Highlights\* – 1H23



#### **Immunology**

- Garadacimab (Anti-FXIIa) HAE
  - Phase III study data announced
  - Global submissions started
- BERINERT® SC HAE JP PMDA launch
- Anumigilimab (CSL324; G-CSFR antagonist)
   Phase Ib study complete



#### Haematology

- CSL889 (Hemopexin) Phase I study last patient out
- HEMGENIX® (Etranacogene dezaparvovec)
  - US Launch
  - EU launch
  - HOPE-B extension study 24-month data showed durable protection & sustained FIX activity
- KCENTRA® Trauma Phase III study first patient in



#### Respiratory

- Garadacimab (Anti-FXIIa) IPF Phase II study enrolment complete
- CSL787 (Neb Ig) Phase I study enrolment complete



## Cardiovascular & Metabolic

- CSL112 (ApoA-1) Phase III study enrolment complete
- Clazakizumab (ESKD) Phase IIb/III study first patient in



#### **Vaccines**

- aQIVc (cell antigen + MF59®) Phase IIb study results available
- ARCT-154 COVID vaccine global submissions started



 CSL964 (AAT) treatment of GvHD – Phase III study last patient in

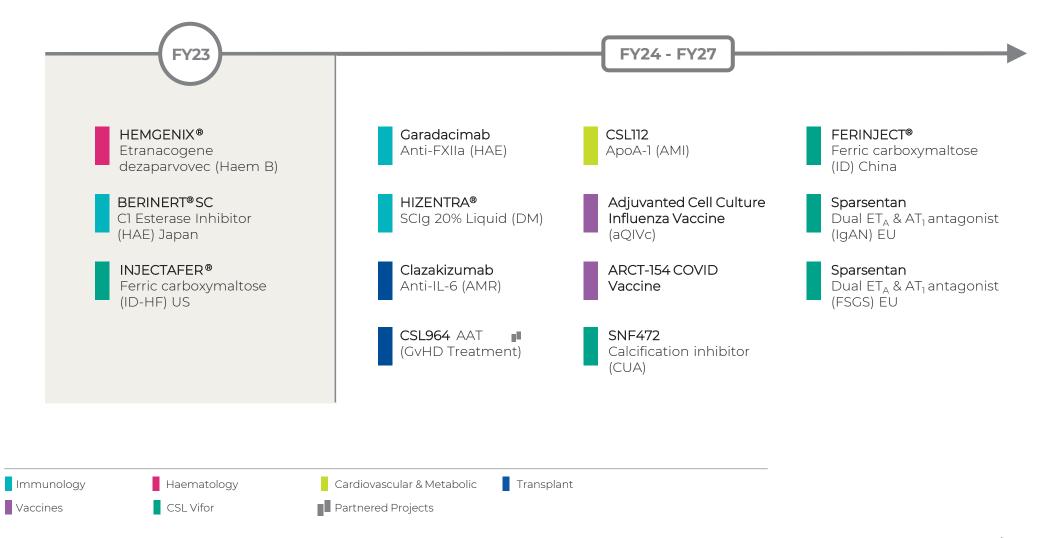
#### **CSL Vifor**

- INS-3001 (AVS) Phase I study first patient in
- FERINJECT® (ferric carboxymaltose) ID China approval
- INJECTAFER® (ferric carboxymaltose) ID-HF Phase III data available
- KORSUVA®/KAPRUVIA® (difelikefalin) multiple country approvals
- SNF472 CUA
  - Phase III study complete
  - Top Line Data
- Sparsentan (IgAN) CMA EU submitted
- VELPHORO® (sucroferric oxyhydroxide) China approval
- Vamifeport (SCD) Phase IIa study recruitment complete



<sup>\*</sup>FY23 Forward-looking Highlights as presented at the CSL R&D Investor Briefing in November 2022. Green text - highlights achieved as at 30 Dec 2022.

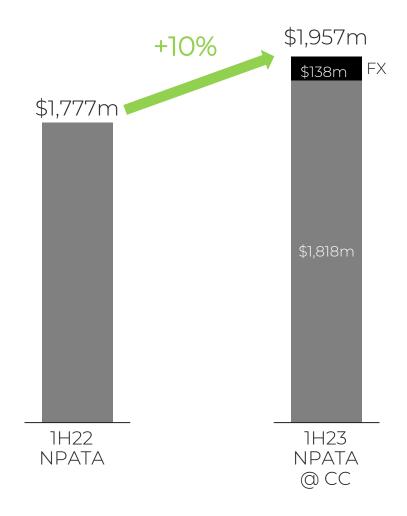
## Significant Target Launch Dates<sup>1</sup>



## **Financials** Joy Linton CFO



## NPATA<sup>3</sup>



1H23 NPATA @ CC <sup>1</sup>	\$1,957m
Acquired intangible assets amortisation	(\$96m)
Other acquisition adjustments	(\$190m)
Tax on adjustments	\$37m
NPATA Attributable to NCI <sup>2</sup>	\$58m
1H23 NPAT @ CC	\$1,766m
NPAT Attributable to NCI <sup>2</sup>	(\$13m)
1H23 NPAT @ CC <sup>1</sup>	\$1,753m

<sup>3.</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 acquisition accounting related adjustments.



<sup>1.</sup> Attributable to the shareholders of CSL Limited.

<sup>2.</sup> Non-Controlling Interest

## CSL Group

### Financial Highlights

US\$ Millions	1H22 Rep	1H23 Rep	1H23 at CC <sup>1</sup>	Change % <sup>1</sup>
Total Revenue	6,041	7,184	7,575	25%
Gross Profit <sup>3</sup>	3,448	4,052	4,275	24%
GP % <sup>3</sup>	57.1%	56.4%	56.4%	
Sales & Marketing	431	669	712	65%
Operating Result <sup>3</sup>	3,017	3,383	3,563	18%
R&D	486	577	606	25%
G&A <sup>3</sup>	300	400	378	26%
Finance (Net)	70	171	167	139%
NPATA <sup>2</sup>	1,777	1,818	1,957	10%
ETR %	17.8%	16.0%		
Cashflow From Ops <sup>4</sup>	1,427	981		(31%)
NPATA EPS <sup>2</sup> (\$)	3.89	3.77	4.06	4%
DPS (\$) <sup>4</sup>	1.04	1.07		3%

## Ig franchise growing strongly Includes ~5 months of Vifor financials

#### R&D

Projects within cardiovascular, haematology and immunology

#### S&M

HEMGENIX® commercial activities

#### G&A

5 months of CSI Vifor

#### **Finance**

Acquisition of Vifor and higher interest rates

#### Tax

Lower ETR due to geographic profit mix and **lower Vifor FTR** 

#### **Cashflow from Operations**

Strong growth in plasma collections



<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

Driven by Our Promise™ 3. Underlying results have been adjusted to exclude impairment and amortisation of acquired IP, business acquisition and transaction costs and other acquisition related adjustments 4. At reported currency

## CSL Group

## 1H23 by Segment

US\$ Millions	CSL Behring	CSL Seqirus	Total	Change % at CC <sup>1</sup>	CSL Vifor <sup>3</sup>	CSL Group	Change % at CC <sup>1</sup>
Sales	4,414	1,653	6,067	10%	876	6,943	26%
Other Revenue	142	85	227	1%	13	241	7%
Total Revenue	4,556	1,738	6,294	10%	889	7,184	25%
Gross Profit <sup>4</sup>	2,238	1,198	3,436	5%	615	4,052	24%
GP % <sup>2,4</sup>	50.3%	65.9%	54.6%		69.7%	56.4%	
Sales & Marketing	363	90	453	12%	215	669	65%
Operating Result	1,875	1,108	2,983	4%	400	3,383	18%
Segment % <sup>2,4</sup>	42.3%	60.7%	47.4%		44.6%	47.0%	
Operating Result adjusted for non recurring COVID vaccine				8%			

<sup>4.</sup> Underlying results have been adjusted to exclude impairment and amortisation of acquired IP, business acquisition and transaction costs and other acquisition related adjustments

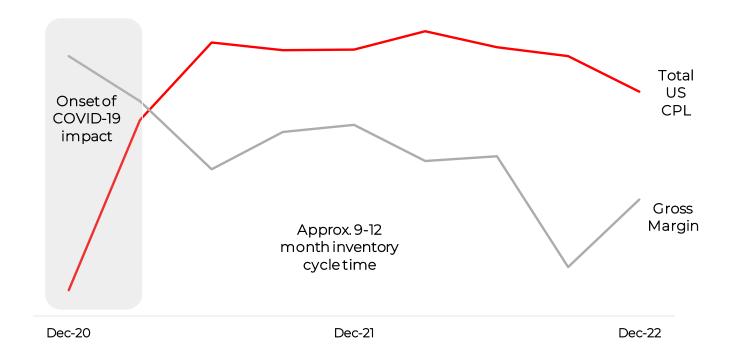


<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.

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

Percentages shown at constant currency to remove the impact of exchange rate movements, racintating comparability of operational performance, set
 Acquired 9<sup>th</sup> August 2022 ~approximately 5 months contribution

## CSL Behring Gross Margin



Gross margin expected to improve over the medium term



- Higher plasma collection costs in COVID environment
- Inflationary pressures
- Long inventory cycle
  - 9-12 month lag to gross margin impact
- Continuous focus on improving collection efficiency



## Foreign Currency Impact

Volatility in world currency markets

1H23 \$138m NPATA headwind - largely driven by strong USD

#### Realised losses:

- USD/CNY
- GBP/USD

#### Unrealised losses:

- USD/EUR
- Emerging market currencies against USD

Full year FX impact is estimated to be \$175m unfavourable, assuming FX rates remain steady for the balance of the financial year

#### **Currency Average Rates**

	1H22	1H23	% change
USD/EUR	0.86	0.99	15.1%
USD/CHF	0.92	0.97	5.4%
USD/GBP	0.73	0.85	16.4%
USD/CNY	6.44	6.97	8.2%
USD/AUD	1.36	1.49	9.6%



### FY23 Outlook

#### Guidance Re-affirmed

#### 2H23 Considerations

#### CSL Behring

- Strong plasma collections and Ig growth expected to continue
- Gene therapy HEMGENIX® US commercialisation

#### CSL Segirus

Seasonal business with less than 20% of total annual sales in 2H

#### **CSL Vifor**

• Continued integration and delivering on synergy objectives.

#### R&D portfolio progressing

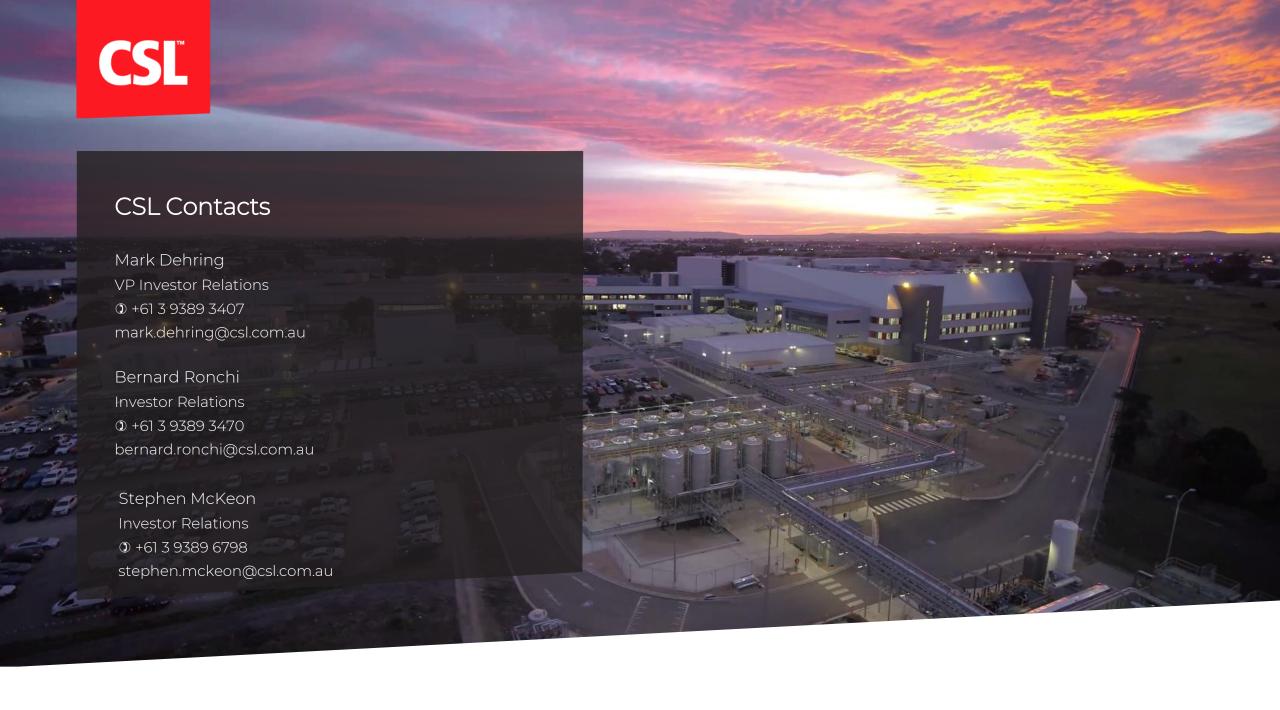


#### FY23<sup>1</sup> Result Skewed to 1H

Revenue
28 - 30% growth @ CC<sup>1</sup>

**NPATA**<sup>2,3</sup> ~\$2,700 - \$2,800m @CC<sup>1</sup> 13 - 18% growth





#### 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 \$1,623.2m \$ 130.2m Currency effect Constant currency net profit after tax\* \$1.753.4m

Average exchange rates for major currencies for half year ended 31 December 2022/31 December 2021 include: USD/EUR (0.99/0.86), USD/AUD (1.49/1.36), USD/CHF (0.97/0.92), USD/CNY (6.97/6.44) and USD/GBP (0.85/0.73).

Summary NPATA attributable to members of	
the parent entity	US\$m
Reported net profit after tax	1,623.2
Amortisation of acquired intellectual property	63.7
Acquisition accounting adjustments	76.1
Acquisition and integration costs	84.1
Income tax credit on above adjustments	(28.8)
NPATA <sup>1</sup> attributable to members of the	1,818.3

Summary NDATA1 attributable to members of

parent entity

Currency effect attributable to members of the 138.4 parent entity Constant Currency# NPATA1 attributable to 1,956.7 members of the parent entity



#### **Summary Revenue**

\$7.183.5m Reported revenue Currency effect \$ 391.6m Constant currency revenue\* \$7,575.1m

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



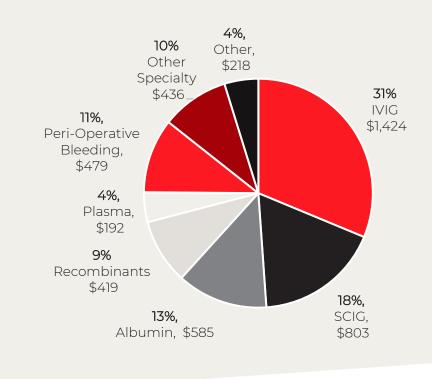
## Appendix



## Appendix A CSL Behring - Key Products

CSL BEHRING	Therapy Group	Sales \$m	Change <sup>1</sup> %
Privigen	IVIG	1,306	22%
Hizentra	SCIG	801	17%
Albumin	Albumin	585	11%
Idelvion	Haemophilia	363	22%
Kcentra	Specialty	325	8%
Haegarda	Specialty	224	1%
Berinert	Specialty	131	4%
Haemocomplettan	Specialty	112	9%
Humate	Haemophilia	90	10%
Haemate	Haemophilia	52	(3%)

## 1H23 Revenue By Therapy Group





## Appendix B CSL Vifor & CSL Seqirus – Key Products

CSL SEQIRUS	Therapy Group	Sales \$m	Change <sup>1</sup> %
Fluad	Adjuvanted	845	7%
Flucelvax	Cell culture	599	28%
Afluria	Egg-based	113	(34%)

CSLVIFOR	Therapy Group	Sales \$m
Ferinject / Injectafer	Iron	315
Mircera	Dialysis	258
Velphoro	Dialysis	77
Venofer	Iron	74
Veltassa	Non Dialysis	49
Maltofer	Iron	36

#### 1H23 Revenue By Therapy Group \$m

