

CSL Limited  
45 Poplar Road Parkville  
Victoria 3052 Australia

T +613 9389 1911  
F +613 9389 1434  
www.csl.com.au



# ASX Announcement

**For immediate release**

16 February 2022

## **RESULTS PRESENTATION FOR THE HALF YEAR ENDED 31 DECEMBER 2021**

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](http://www.CSL.com)).

Authorised for lodgment by:

A handwritten signature in blue ink that reads 'F Mead'.

Fiona Mead  
Company Secretary

### **For further information, please contact:**

#### **Investors:**

**Bernard Ronchi**  
Investor Relations  
CSL Limited  
P: +61 3 9389 3470  
E: [bernard.ronchi@csl.com.au](mailto:bernard.ronchi@csl.com.au)

#### **Media:**

**Jimmy Baker**  
Communications  
CSL Limited  
P: +61 450 909 211  
E: [jimmy.baker@csl.com.au](mailto:jimmy.baker@csl.com.au)



# CSL Limited

## 2022 Half Year Results

16 February, 2022



**Paul Perreault**  
CEO and Managing Director

**Joy Linton**  
CFO

# Legal Notice

## IMPORTANT NOTICE AND DISCLAIMER

This presentation contains summary information about CSL Limited (ACN 004 089 936) and its related bodies corporate (together, **CSL**) and CSL's activities as at the date of this presentation. It is information given in summary form only and does not purport to be complete. It should be read in conjunction with CSL's other periodic corporate reports and continuous disclosure announcements filed with the Australian Securities Exchange (**ASX**), available at [www.asx.com.au](http://www.asx.com.au). This presentation is for information purposes only and is not a prospectus or product disclosure statement, financial product or investment advice or a recommendation to acquire CSL shares or other securities.

No representation or warranty, express or implied, is made as to the fairness, accuracy, completeness or correctness of the information, opinions and conclusions contained in this presentation. To the maximum extent permitted by law, none of CSL or its directors, employees or agents, nor any other person, accepts liability for any loss arising from the use of this presentation or its contents or otherwise arising in connection with it, including, without limitation, any liability from fault or negligence on the part of CSL or its directors, employees, contractors or agents.

This presentation contains forward-looking statements in relation to CSL, including statements regarding CSL's intent, belief, goals, objectives, initiatives, commitments or current expectations with respect to CSL's business and operations, market conditions, results of operations and financial conditions, products in research and risk management practices. Forward-looking statements can generally be identified by the use of words such as "forecast", "estimate", "plan", "will", "anticipate", "may", "believe", "should", "expect", "project", "intend", "outlook", "target", "assume" and "guidance" and other similar expressions.

The forward-looking statements are based on CSL's good faith assumptions as to the financial, market, risk, regulatory and other relevant environments that will exist and affect CSL's business and operations in the future. CSL does not give any assurance that the assumptions will prove to be correct. The forward-looking statements involve known and unknown risks, uncertainties and assumptions and other important factors, many of which are beyond the control of CSL, that could cause the actual results, performances or achievements of CSL to be materially different to future results, performances or achievements expressed or implied by the statements. Factors that could cause actual results to differ materially include: the success of research and development activities, decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; competitive developments affecting our products; the ability to successfully market new and existing products; difficulties or delays in manufacturing; trade buying patterns and fluctuations in interest and currency exchange rates; legislation or regulations that affect product production, distribution, pricing, reimbursement, access or tax; acquisitions or divestitures; research collaborations; litigation or government investigations, and CSL's ability to protect its patents and other intellectual property.

Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as at the date of the presentation. Except as required by applicable laws or regulations, CSL does not undertake any obligation to publicly update or revise any of the forward-looking statements or to advise of any change in assumptions on which any such statement is based.

## TRADEMARKS

Except where otherwise noted, brand names designated by a ™ or ® throughout this presentation are trademarks either owned by and/or licensed to CSL.



## **CEO Overview**

Paul Perreault

CEO & Managing Director





**CSL has performed  
in line with expectations**

As expected Ig & Albumin sales have been limited by COVID constrained plasma collections in FY21

Plasma collections have been returning and expected to underpin future sales growth

Strong performance by key specialty products and Idelvion

Agreement to acquire  
Vifor Pharma Ltd

# 1H22 Performance<sup>1</sup>

Revenue up 4% with net profit after tax down 5%

## CSL Behring

- IDELVION<sup>®</sup> +17%
- KCENTRA<sup>®</sup> +15%
- HAEGARDA<sup>®</sup> +7%
- HPV royalties +134%
- Immunoglobulin -9%
- 18 new collection centres opened
- Continued investment into digital transformational tools

## Seqirus

- Seasonal influenza vaccines +20%
- Record volume of ~110 million doses distributed NH 21/22
- Continued benefits of differentiated products
- FLUCELVAX<sup>®</sup> Quadrivalent:
  - US and Argentina approval 6M+ indication
- Commenced construction on new cell culture influenza vaccine manufacturing facility

# CSL Behring

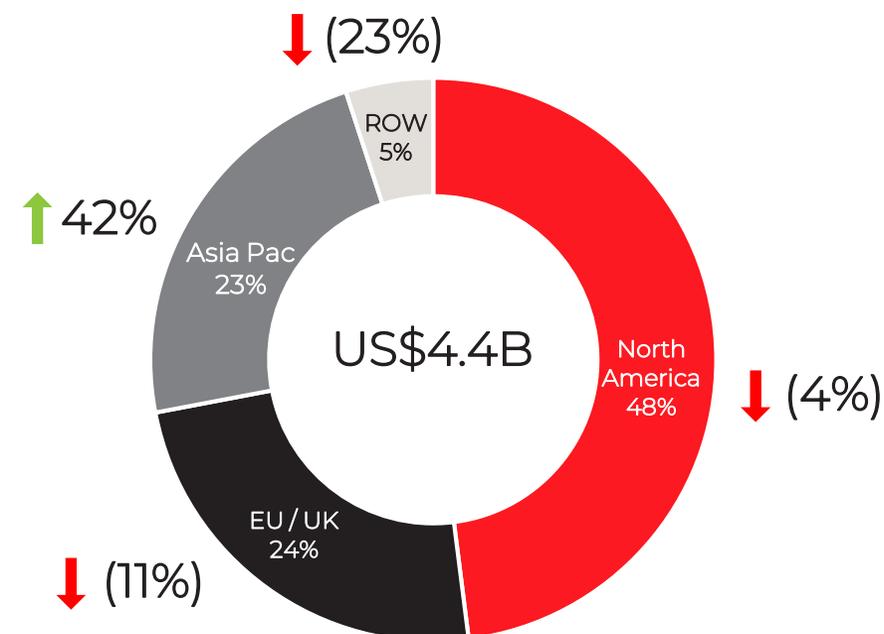
## Revenue steady

Therapy	Sales \$m	Change <sup>1</sup> %
Immunoglobulins	1,977	(9%)
- <i>IVIg</i>	1,255	(11%)
- <i>SCiG</i>	722	(4%)
Albumin	571	1%
Haemophilia	587	5%
- <i>Recombinants</i>	372	12%
- <i>Plasma</i>	215	(6%)
Specialty	914	2%
- <i>Peri-Operative Bleeding</i>	465	8%
- <i>Other Specialty</i>	449	(4%)
Other <sup>2</sup>	307	97%
<b>Total</b>	<b>4,356</b>	<b>0%</b>

1. 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 & Covid vaccines

## Revenue By Region<sup>1</sup>



# Immunoglobulins

Sales down 9%<sup>1</sup>

- Supply tightness has temporarily impacted growth
- HIZENTRA<sup>®</sup>
  - Clear market leader in SCIG with ~60% market share
  - Continued steady uptake for CIDP in US:
    - ~three-quarters of targeted physicians have now utilised Hizentra to treat CIDP
    - Neurologists confidence increasing driven by independent guideline support, increased Medicare access and enhanced label dosing with long term efficacy from PATH extension study<sup>2</sup>
- HIZENTRA<sup>®</sup> and PRIVIGEN<sup>®</sup> remain market leaders in the EU

1. 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. Combination of Medicare Part B reimbursement approval, updated Peripheral Nerve Society (PNS) treatment guidelines, PATH extension data



## Market

- Supply tightness continues in COVID environment
- 9-12 months plasma therapies manufacturing cycle

# Albumin

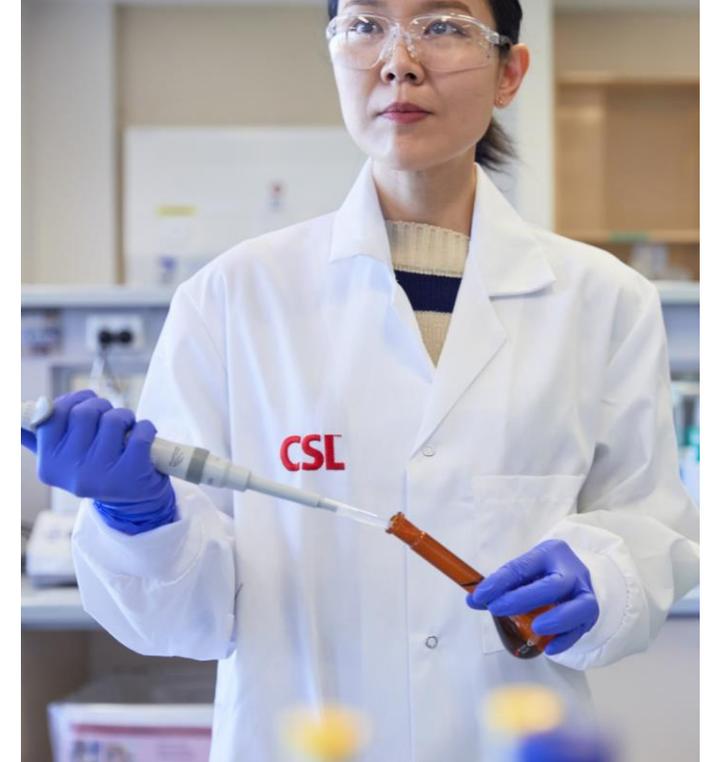
## Sales up 1%<sup>1</sup>

### China

- Maintaining market leadership with brand differentiation and effective HCP engagement
- Domestic and offshore players expand infrastructure and sales coverage to lower tier cities and hospitals
- Market demand outlook - volume growth mid to high single digits

### Other markets

- EU declined as local manufacturers increasingly compete for volume
- Decline in US as supply constraints stem from plasma collections



### Market

- Preference for albumin over artificial colloids
- Increased utilization in sepsis and liver disease patients
- Competitive pressure

1. 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.



## Market

- Ongoing market movement towards new generation products

# Haemophilia

Sales up 5%<sup>1</sup>

## Recombinant Coags

- IDELVION<sup>®</sup> +17%:
  - Market leader in Haem B
  - Compelling clinical profile drives patient demand & market share
  - Extension study enhances long term efficacy and safety profile
  - Approval of 21 day dosing in EU, Switzerland, Japan and Canada
- AFSTYLA<sup>®</sup> -13%:
  - Continued competitive market

## PD Coags

- HUMATE<sup>®</sup> / HAEMATE<sup>®</sup> +2%:
  - Russia tender win
- Decline in demand for BERIATE<sup>®</sup> due to competitive pressure and switches to recombinant

1. 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.

# Specialty Products

## Sales up 2%<sup>1</sup>

### HAE

HAEGARDA® +7%

- Successful launches in multiple EU countries, Canada & Australia
- 80% of US patients are long term users or returning patients from alternative therapies
- Demand driven by shift from on-demand to prophylaxis treatment

BERINERT® -8%

- Impacted by shift to HAEGARDA®

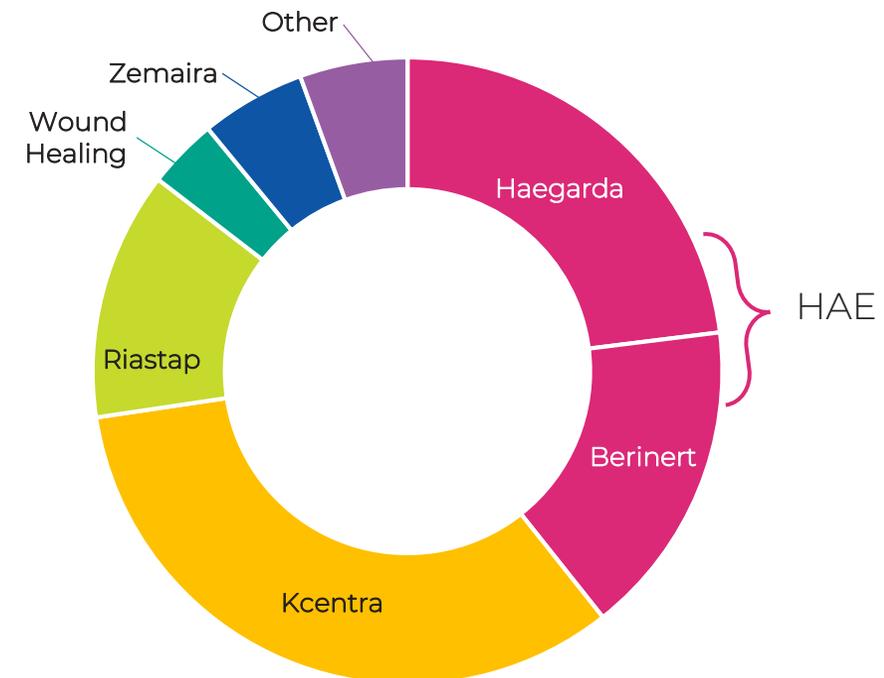
### Hospital Products

- KCENTRA® +15%
  - Return to pre-pandemic demand levels
- RIASTAP® / HAEMOCOMPLETTAN® -7%
  - Competitive pressures in EU
- Wound Healing +10%

ALPHA 1 -31%

- ZEMAIRA® / RESPREEZA®
  - Supply interruptions

1H22 Sales \$914m



1. 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.



**18** new centres  
opened in 1H22

up to  
**35** new centres  
planned to open  
in FY22

# Plasma Collections

## Volume Up 18%

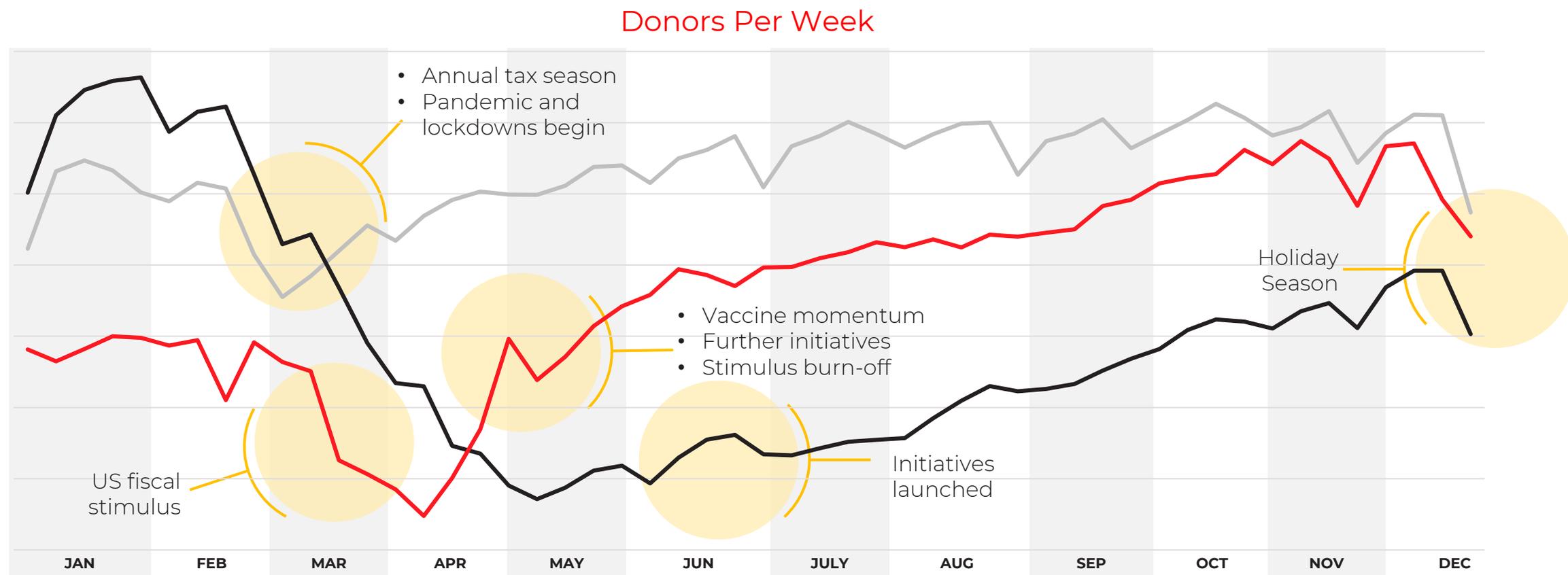
### Driving Growth

- Competitive donor fees
- Improved social mobility within COVID environment
- Enhanced operating and marketing initiatives bringing back lapsed and attracting new donors
- Enhanced donor experience through increased use of technology
- Collaborating with industry bodies to promote plasma donation

### Contemporary topics

- Omicron variant disruption to operations
- Competitive US employment environment
- Industrywide cost pressures
- Mexican border closure:
  - Litigation ongoing
  - Appealed standing decision
  - New complaint filed by border center employees and donors as well as patients
- 510(k) submitted by Terumo to US FDA for new plasmapheresis device

# Plasma Collections Improving



Not to scale

— 2019    — 2020    — 2021

# Seqirus

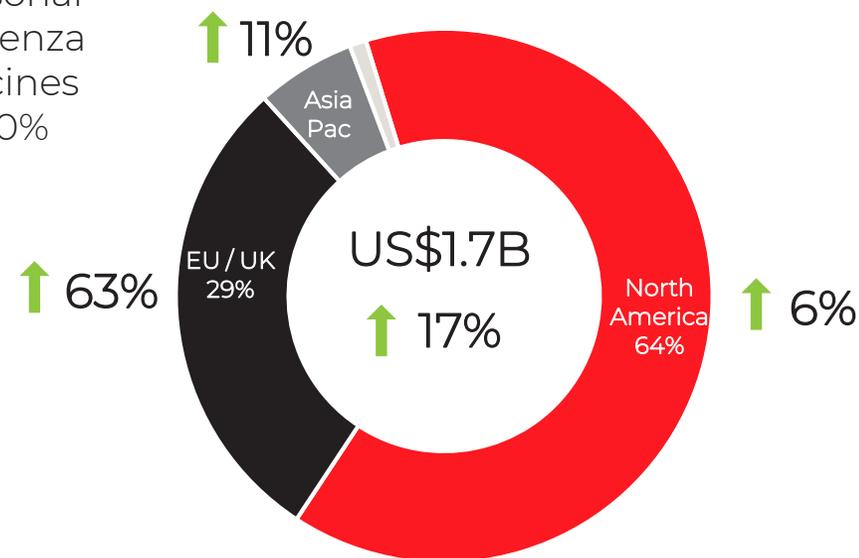
## Revenue up 17%<sup>1</sup>

Therapy	Sales \$m	Change <sup>1</sup> %
Egg Based	184	(28%)
Cell Culture	490	11%
Adjuvanted Egg	838	48%
Other / In-licence	80	(10%)
<b>Total Product Sales</b>	<b>1,592</b>	<b>18%</b>
Pandemic	82	2%
Other Income	11	38%
<b>Total Revenue</b>	<b>1,685</b>	<b>17%</b>



Seasonal  
Influenza  
vaccines  
+20%

### Revenue By Region<sup>1</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.

# Seqirus

## Operating Highlights

- Record volume of ~110 million doses distributed NH 21/22
- EU:
  - Strong growth in differentiated products
  - FLUAD<sup>®</sup> QIV<sup>1</sup> launched
  - Additional fill & finish capacity at Liverpool
- US:
  - US seasonal influenza vaccines >\$1 billion for the first time
  - Awarded new pandemic contract with US Govt for development of two influenza candidates

## Looking Forward

- Next generation self-amplifying mRNA:
  - Phase 1 expected to commence cal. 2022
  - Construction commenced on clinical GMP mRNA facility in Holly Springs
- FLUCELVAX<sup>®</sup> 6m+ age indication launch in US NH 22/23
- FLUCELVAX<sup>®</sup> 2y+ age indication launch in Australia (SH22) – private market
- Holly Springs Fill & Finish operational NH 22/23



Artist impression

Construction commenced on cell culture influenza vaccine manufacturing facility in Australia

# R&D Highlights



## Immunology

- **Garadacimab** (Anti-FXIIa) HAE
  - Phase III study enrolment completed (Last Patient In)
  - FDA confirmed Fast Track Eligibility
  - EMA Orphan Drug Designation granted



## Hematology

- **CSL888** (Haptoglobin) SAH US Orphan Drug Designation granted
- Primary Endpoint achieved in **EtranaDez** (Haem B gene therapy) HOPE-B study



## Cardiovascular & Metabolic

- **CSL112** (ApoA-1) 80% enrolment achieved



## Respiratory

- **Garadacimab** (Anti-FXIIa) IPF Phase II study initiated



## Influenza Vaccines

- **aQIVc** (cell antigen + MF59®) Phase II study complete
- **FLUCELVAX®** Quadrivalent
  - US & Argentina approval 6M+ indication
- **FLUCELVAX®** QUAD
  - Australia 2yr+ extension
  - New Zealand 9yr+ extension approval
- **FLUAD®** Quadrivalent
  - Adults 50-64yr Phase III study enrolment completed



## Partnerships & Alliances

- CSL, WEHI, & University of Melbourne secured State Government funding to create biotech start-up incubator in CSL's new global headquarters, under construction, in Melbourne



## R&D Expansion

- **Melbourne:** New HQ and R&D facilities under construction; on track for completion early 2023
- **Marburg:** New seven storey R&D Campus to house 500 researchers set to open 2022
- New Seqirus facility in **Waltham** to be operational in 2022; will host ~300 employees supporting CSL's R&D portfolio including sa-mRNA technology platform



On 14 December 2021, CSL announced a tender offer to acquire 100% of Vifor Pharma Ltd, a global specialty pharmaceutical company with leadership in renal disease and iron deficiency

## Agreement to Acquire Vifor Pharma Ltd

- Institutional placement for A\$6.3 billion completed
- Share Purchase Plan for A\$750 million completed
- Debt - \$6 billion bridge in place to be replaced by long term funding in 1H calendar 2022
- Tender offer for publicly held Vifor shares underway, closing 2 March 2022
- Integration planning underway
- Regulatory approvals and deal closure anticipated by the end of FY22

# Vifor Pharma

## Compelling Strategic Rationale



Strengthens CSL's  
Value Driven  
Strategy



Materially Enhances  
Scale and Free Cash  
Flow



Builds a Significant  
Renal Franchise

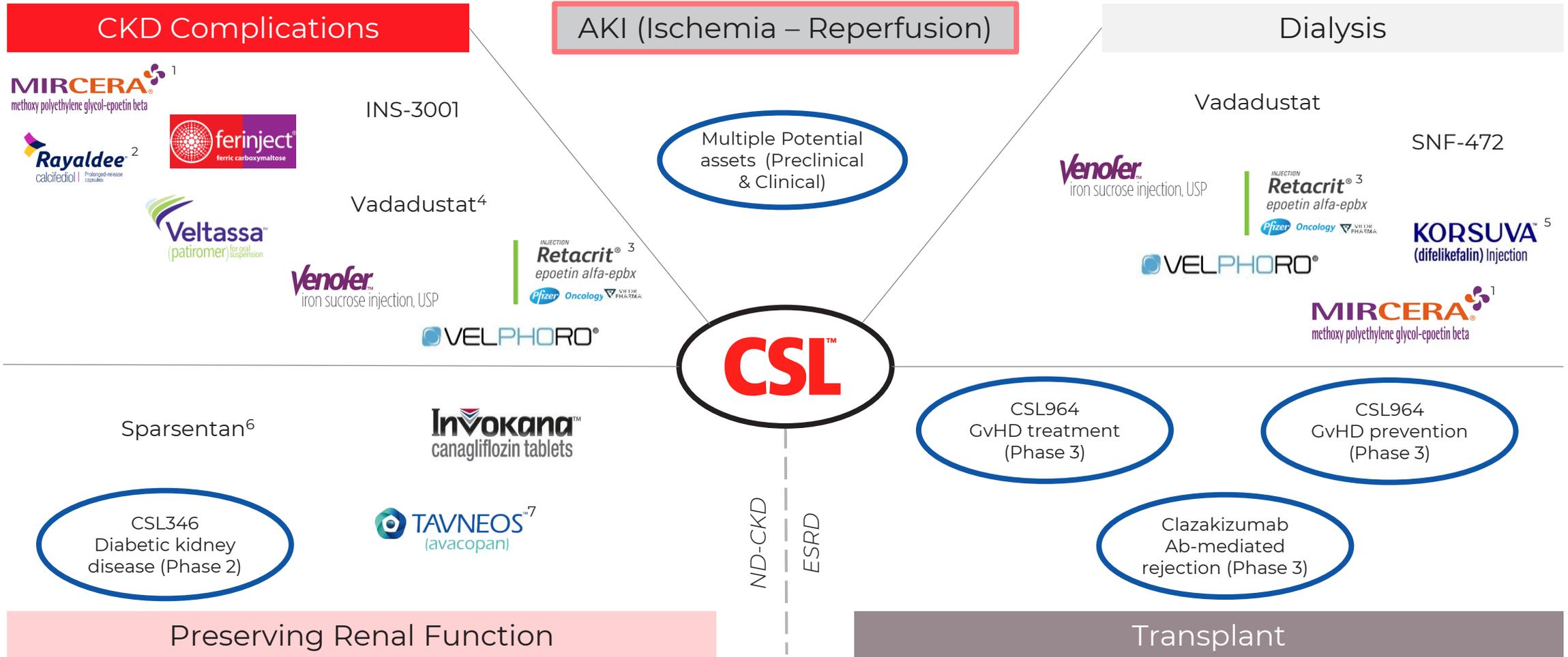


Compelling  
Financial Profile



Extends the Reach of  
CSL's High Value  
Pipeline

# CSL's Rich Pipeline Aligns With Vifor's Renal Framework



1. Licensed from F. Hoffman-La Roche AG.  
 2. Licensed from OPKO Health, Inc.  
 3. Licensed from Pfizer Inc.  
 4. Licensed from Akebia Therapeutics, Inc., subject to certain conditions and limited to selling Vadadustat to certain providers within the US dialysis market.

5. Licensed from Cara Therapeutics, Inc.  
 6. Licensed from Travele Therapeutics, Inc.  
 7. Licensed from ChemoCentryx.



## Financials

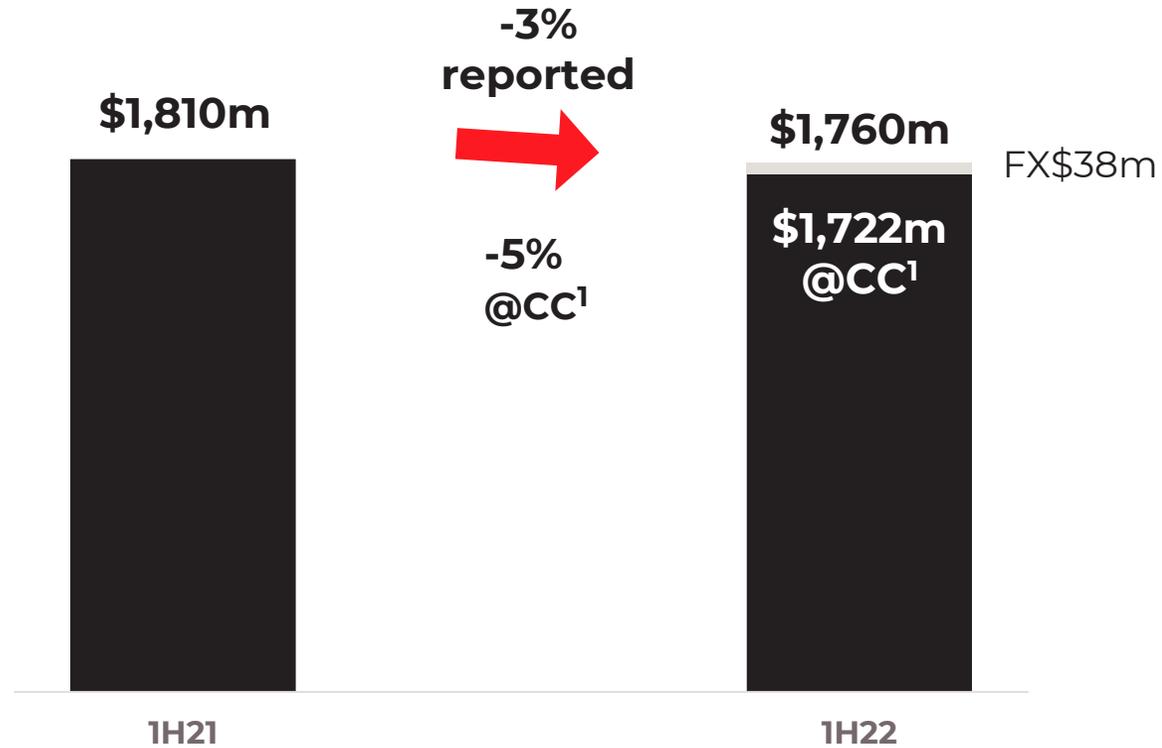
Joy Linton

CFO



# Financial Highlights

## Net profit after tax



*1. 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 has performed in line with expectations
- Increased collections costs
- Higher fixed cost absorption on lower plasma volumes
- Includes \$17m Vifor transaction costs

# Financial Highlights

## CSL Group

	1H21 Reported	1H22 Reported	1H22, at CC <sup>1</sup>	Change %
Total Revenue	5,739	6,041	5,993	4% <sup>1</sup>
Gross Profit	3,472	3,449	3,417	(2%) <sup>1</sup>
GP margin	60.5%	57.1%	57.0%	
EBIT	2,358	2,215	2,165	(8%) <sup>1</sup>
EBIT margin	41.1%	36.7%	36.1%	
NPAT	1,810	1,760	1,722	(5%) <sup>1</sup>
Cashflow from Operations	2,321	1,427		(39%)
EPS (\$)	3.98	3.85	3.77	(5%) <sup>1</sup>
DPS (\$)	1.04	1.04		0%

<sup>1</sup> Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability. See end note for further detail

# Financial Highlights

## Segments

### CSL Behring

US\$ Millions	1H21 Reported	1H22 Reported	Change % at CC <sup>1</sup>
Sales	4,256	4,216	(2%)
Other Revenue	59	140	139%
Total Revenue	4,315	4,356	0%
Gross Profit	2,539	2,353	(8%)
<i>GP margin</i>	<i>58.8%</i>	<i>54.0%</i>	
EBIT	1,665	1,331	(22%)
<i>EBIT margin</i>	<i>38.6%</i>	<i>30.6%</i>	

<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.

### Seqirus

US\$ Millions	1H21 Reported	1H22 Reported	Change % at CC <sup>1</sup>
Sales	1,340	1,592	18%
Other Revenue	85	93	6%
Total Revenue	1,425	1,685	17%
Gross Profit	933	1,096	17%
<i>GP margin</i>	<i>65.5%</i>	<i>65.0%</i>	
EBIT	693	884	24%
<i>EBIT margin</i>	<i>48.7%</i>	<i>52.5%</i>	

# Financial Highlights

## Reported Expenses

	1H22 \$m	Change @ CC <sup>1</sup>	
		\$m	%
Research & Development	486	57	13%
Sales & Marketing	432	16	4%
General & Admin	317	64	24%
Finance (Net)	70	(40)	(38%)
<i>ETR</i>	<i>17.9%</i>		

<sup>1</sup> Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability. See end note for further detail

### R&D

- Trials resuming post COVID pause
- FY22 est. 10-11% of revenue



### Sales and Marketing

- Modest uplift in advance of commercial launches



### General Admin

- Higher I&T/SaaS
- Vifor acquisition costs



### Finance

- Movement in unrealised FX on debt



### Tax

- Geographic profit mix
- FY22 ETR est. ~18 – 20%





CSL is committed to a healthier world. **Our vision** is a sustainable future for our employees, communities, patients and donors, inspired by innovative science and a values-driven culture.

# Our Sustainability Strategy

- Sustainability Strategy approved by the Board in 2021
- Executive Sustainability Committee representing all areas of the business
- Focused on 3 key strategic pillars – Environment, Social and Sustainable Workplace
- Good progress on defining meaningful and achievable targets
- Ensure long term sustainability and growth for all our stakeholders

# Outlook

FY22 result heavily skewed to 1H

## CSL Behring

- Improving plasma collections expected to underpin stronger Ig and albumin sales

## Seqirus

- >80% of sales in 1H, with expenses falling more evenly over the year giving rise to a loss in 2H, consistent with seasonality

## CSL Group

- Guidance includes ~\$90 - \$110m Vifor transaction costs

**FY22 progressing in line with expectations**  
**Positive mid-term outlook as COVID recedes**  
**Promising cluster of R&D programs nearing completion**



**FY22<sup>1</sup> Outlook  
Guidance  
Reaffirmed**

NPAT  
~\$2,150 - \$2,250m @CC<sup>2</sup>

<sup>1</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



## CSL Contacts

Mark Dehring

VP Investor Relations

☎ +61 3 9389 3407

[mark.dehring@csl.com.au](mailto:mark.dehring@csl.com.au)

Bernard Ronchi

Investor Relations

☎ +61 3 9389 3470

[bernard.ronchi@csl.com.au](mailto:bernard.ronchi@csl.com.au)

Stephen McKeon

Investor Relations

☎ +61 3 9389 6798

[stephen.mckeon@csl.com.au](mailto:stephen.mckeon@csl.com.au)



# 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.

## Summary NPAT

Reported net profit after tax	\$1,760.3m
Translation currency effect (a)	\$ (9.0m)
Transaction currency effect (b)	\$ (21.7m)
Foreign Currency (gains) & losses (c)	\$ (7.4m)
Constant currency net profit after tax *	\$1,722.2m

### a) Translation Currency Effect \$(9.0m)

Average Exchange rates used for calculation in major currencies (6 months to Dec 21/Dec 20) were as follows: USD/EUR (0.86/0.85); USD/AUD (1.36/1.40); USD/CHF (0.92/0.92); USD/CNY (6.44/6.83); USD/GBP (0.73/0.77).

### b) Transaction Currency Effect \$(21.7m)

Transaction currency effect is calculated by reference to the applicable prior year exchange rates. The calculation takes into account the timing of sales both internally within the CSL Group (ie from a manufacturer to a distributor) and externally (ie to the final customer) and the relevant exchange rates applicable to each transaction.

### c) Foreign Currency Gain (\$7.4m)

Foreign currency gains recorded during the period.

## Summary Revenue

Reported revenue	\$6,041.2m
Currency effect	\$ (47.9m)
Constant currency revenue*	\$5,993.3m

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

