



# 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, appearing to read 'Fiona Mead'.

Fiona Mead  
Company Secretary

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# CSL Limited

## 2022 Half Year Results

16 February, 2022



**Paul Perreault**  
CEO and Managing Director

**Joy Linton**  
CFO

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## **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® +17%
- KCENTRA® +15%
- HAEGARDA® +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® Quadrivalent:
  - US and Argentina approval 6M+ indication
- Commenced construction on new cell culture influenza vaccine manufacturing facility

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.

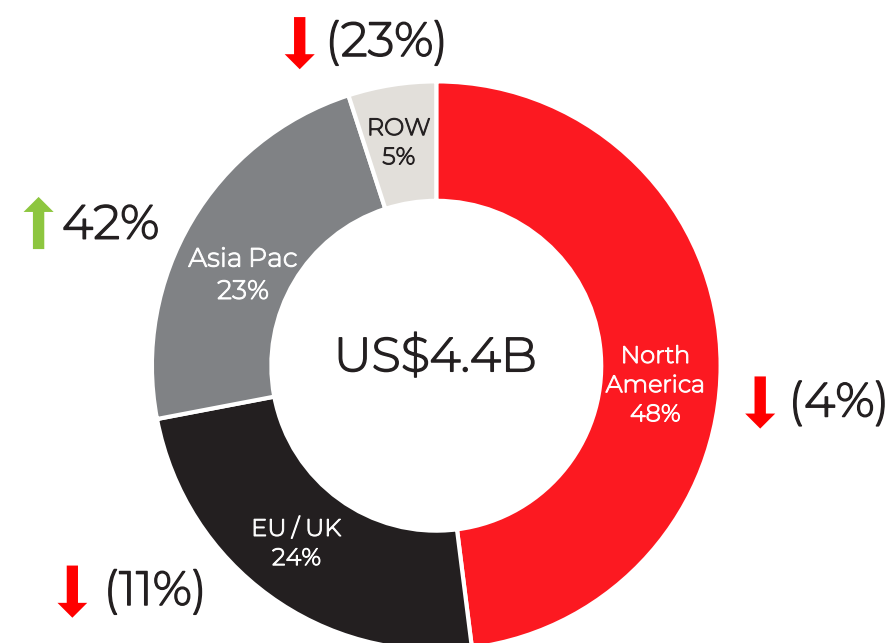
# CSL Behring

## 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%
Total	4,356	0%

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®
  - 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® and PRIVIGEN® 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

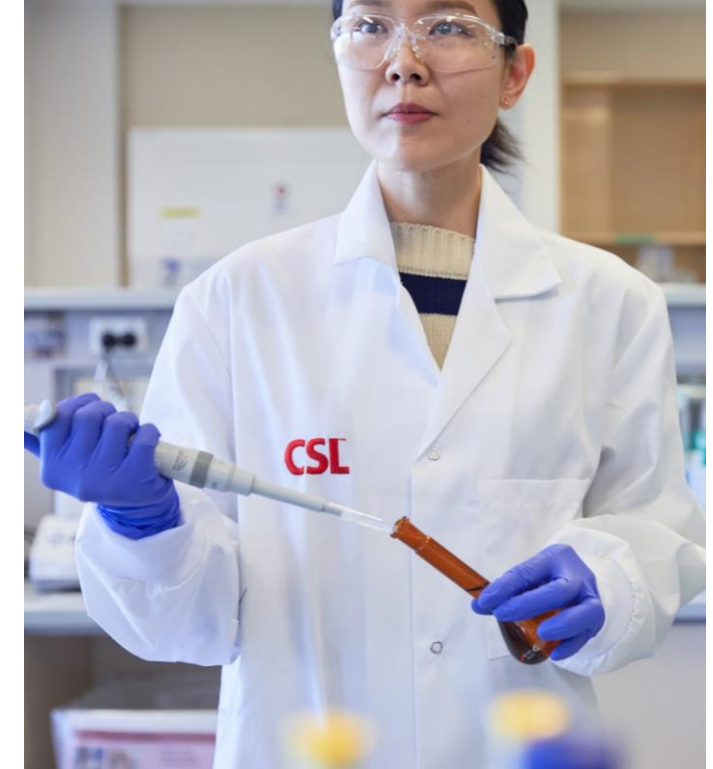
Sales up 1%<sup>1</sup>

## 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.

# Haemophilia

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

## Recombinant Coags

- IDELVION® +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® -13%:
  - Continued competitive market

## PD Coags

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

## Market

- Ongoing market movement towards new generation products

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®

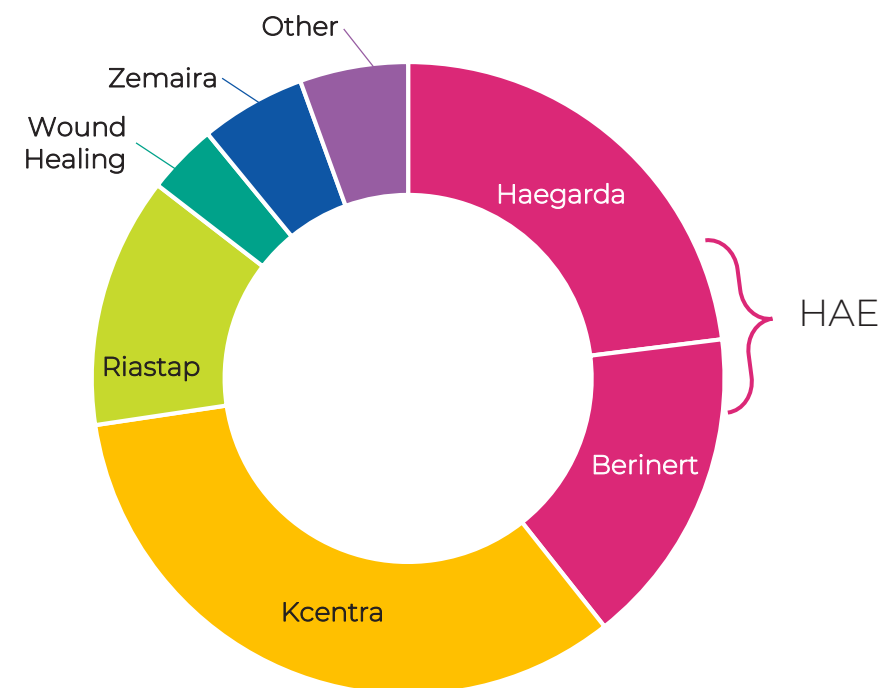
## Hospital Products

- 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

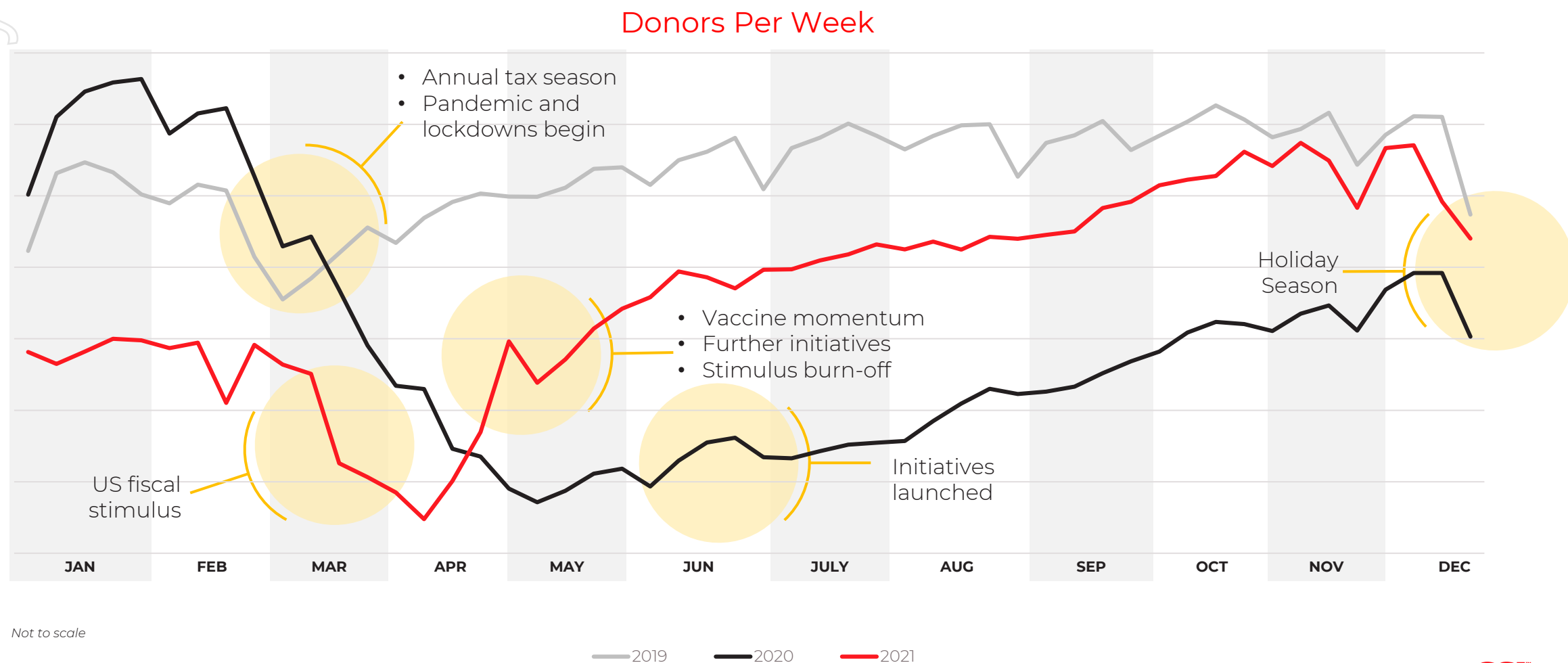
- Competitive donor fees
- Improved social mobility within COVID environment
- Enhanced operating and marketing initiatives bringing back lapsed and attracting new donors
- Enhanced donor experience through increased use of technology
- Collaborating with industry bodies to promote plasma donation

### 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



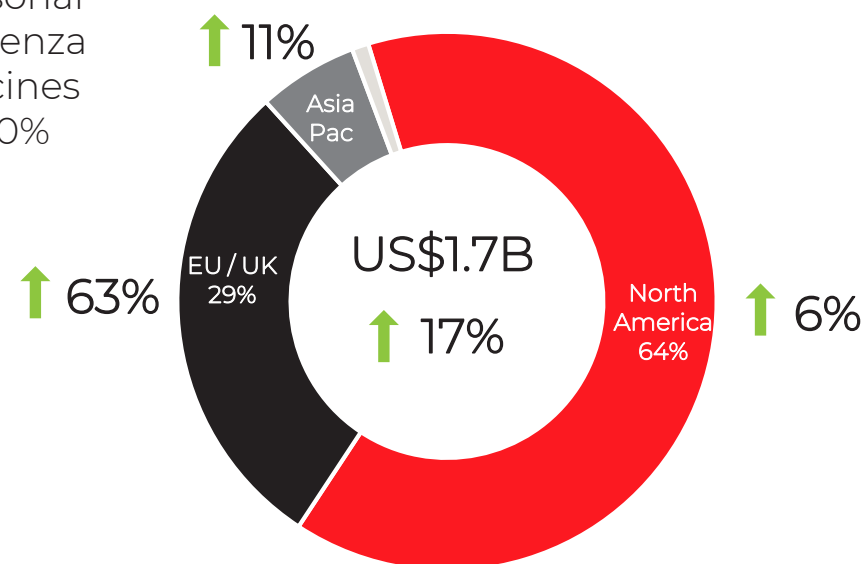
# Seqirus

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>



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.

# Seqirus

## Operating Highlights

- Record volume of ~110 million doses distributed NH 21/22
- EU:
  - Strong growth in differentiated products
  - FLUAD® 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® 6m+ age indication launch in US NH 22/23
- FLUCELVAX® 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-I) 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

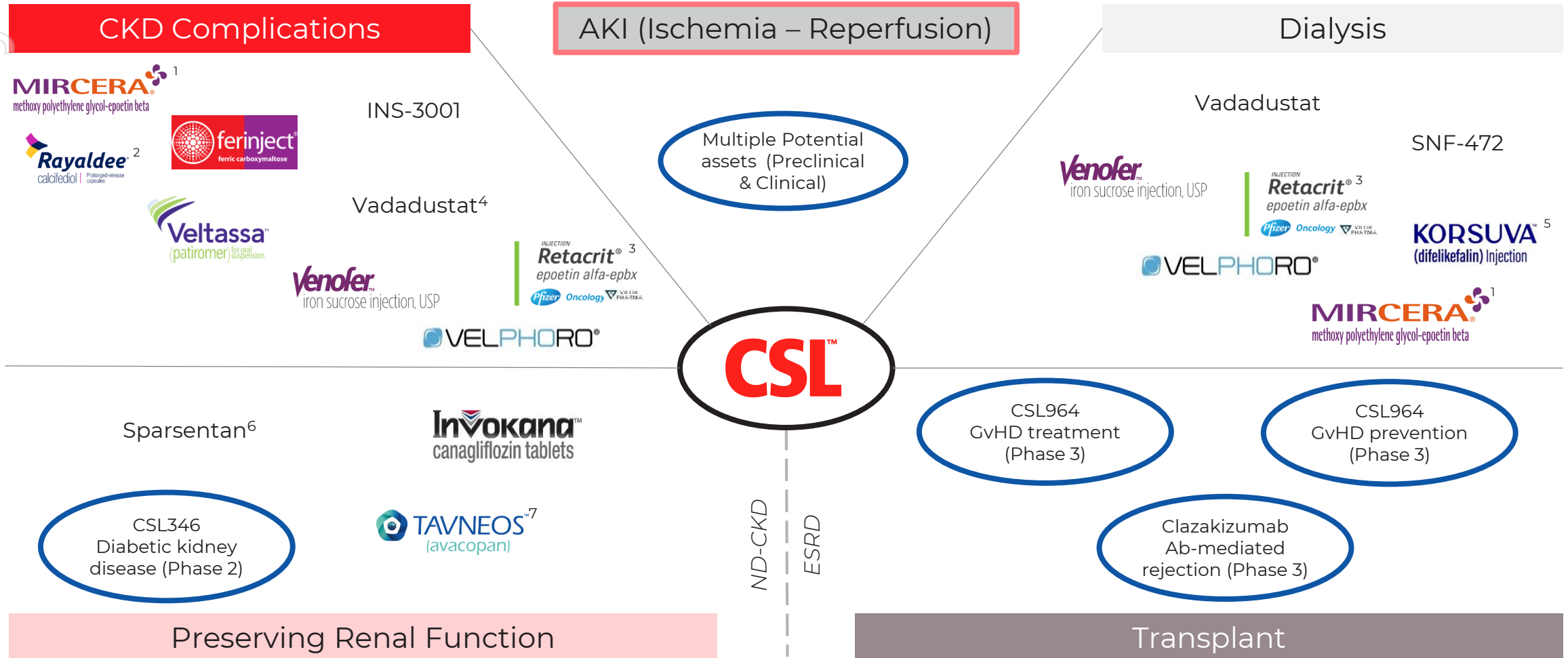


Compelling  
Financial Profile



Extends the Reach of  
CSL's High Value  
Pipeline

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



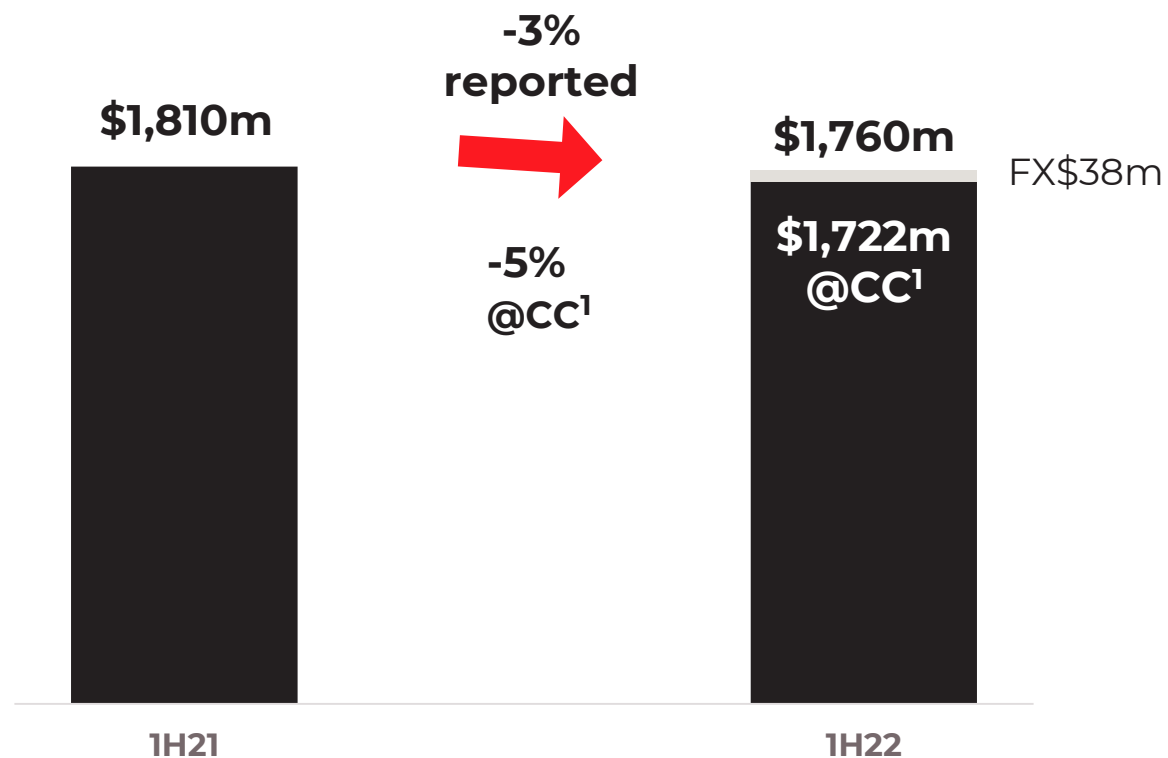
# Financials

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%)
GP margin	58.8%	54.0%	
EBIT	1,665	1,331	(22%)
EBIT margin	38.6%	30.6%	

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.

### 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%
GP margin	65.5%	65.0%	
EBIT	693	884	24%
EBIT margin	48.7%	52.5%	

# 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%)
ETR	17.9%		

1. 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%





# Our Sustainability Strategy

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.

- 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



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# 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.

