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# ASX Announcement

**For immediate release**

19 August 2020

## **RESULTS PRESENTATION FOR THE FULL YEAR ENDED 30 JUNE 2020**

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

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

The briefing will be webcast and can be accessed at  
<https://csl.webcastcloud.com/account/register>.

Authorised for lodgment by:

A handwritten signature in blue ink, appearing to read 'F Mead', is positioned above the name of the authorised person.

Fiona Mead  
Company Secretary

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# CSL Limited

2020 Full Year  
Results

19<sup>th</sup> August, 2020



Paul Perreault  
CEO and MD

David Lamont  
CFO

# Legal Notice

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## **Trademarks**

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**A strong year for CSL  
with revenue up 9%<sup>1</sup>  
and profit after tax up  
17%<sup>1</sup> reflecting:**

- Strong growth in immunoglobulin portfolio
- Successful evolution of Haemophilia portfolio, driven by IDELVION<sup>®</sup>
- Transitioned to own distribution model in China
- Seqirus delivers on product differentiation strategy with strong profit growth

# FY20 Revenue Performance<sup>1</sup>

A strong year for CSL

## CSL Behring

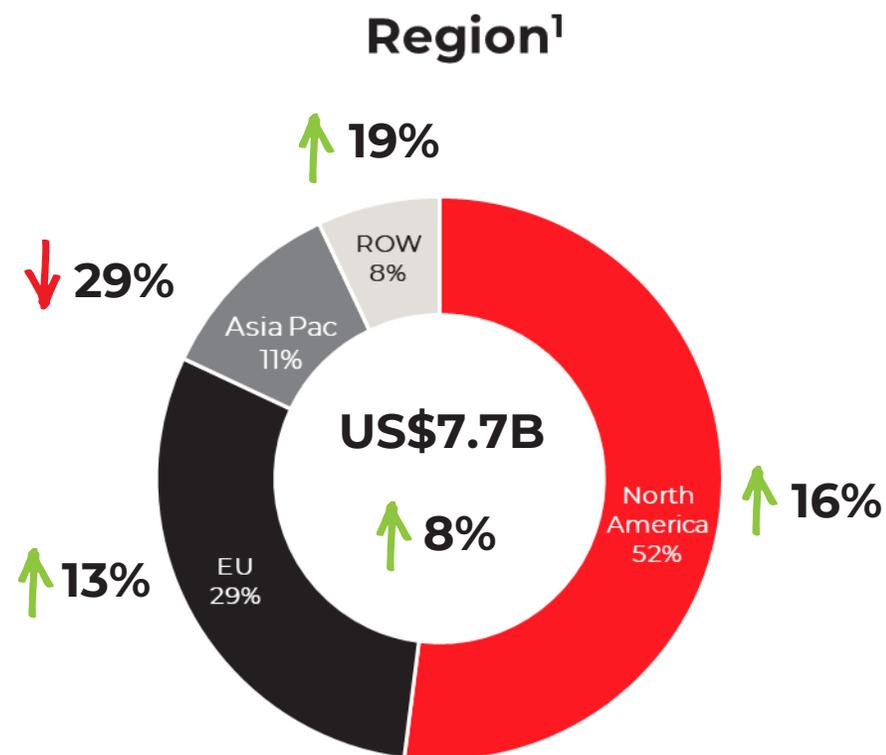
- PRIVIGEN<sup>®</sup> +20%
- HIZENTRA<sup>®</sup> +34%
- ALBUMIN<sup>®</sup> (36%) (GSP impact)
- IDELVION<sup>®</sup> +25%
- AFSTYLA<sup>®</sup> +21%
- HAEGARDA<sup>®</sup> +12%
- KCENTRA<sup>®</sup> +12%
- ZEMAIRA<sup>®</sup> +20%

## Seqirus

- Seasonal influenza sales +21%
- FLUAD<sup>®</sup>:
  - Preferred recommendations in UK and Australia
  - QIV launched in Australia and approved in USA & EU
- FLUCELVAX<sup>®</sup> launched EU

# CSL Behring Sales FY20

Therapy	Sales \$m	Change <sup>1</sup> %
<b>Immunoglobulins</b>	<b>4,014</b>	<b>22%</b>
- IVIG	2,699	16%
- SCIG	1,315	34%
<b>Albumin</b>	<b>640</b>	<b>(36%)</b>
<b>Haemophilia</b>	<b>1,122</b>	<b>8%</b>
- Recombinants	659	18%
- Plasma	463	(3%)
<b>Specialty</b>	<b>1,697</b>	<b>10%</b>
- Peri-Operative Bleeding	788	10%
- Other Specialty	909	9%
<b>Other<sup>2</sup></b>	<b>188</b>	<b>(1%)</b>
<b>Total</b>	<b>7,661</b>	<b>8%</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 Hyperimmunes

# Immunoglobulins

Sales up 22%<sup>1</sup>



20% growth<sup>1</sup>

- CIDP indication in the US and EU
- Expansion of SID usage
- Continued growth in PID



34% growth<sup>1</sup>

- Clear market leader
- New patient starts in PID
- Orphan exclusivity for CIDP in the US

## Market

- Global Ig demand remains strong

## Market Demand Drivers

- Increased disease awareness & improved diagnosis
- Increased usage for chronic therapies
- CIDP indication
- Expanding usage for SID

# Albumin

Sales down 36%<sup>1</sup>

- Volume up 16% globally, excluding China:
  - Europe up 24%
  - North America up 6%
  - Emerging markets, excluding China, up 28%
  - Pricing pressure in some markets
- China:
  - One-off financial impact from GSP in line with previous guidance
  - Market volume demand outlook mid to high single digits
  - Competitive environment



## Transitioned to Good Supply Practices (GSP) license in China

- Successful transition of business model
- Helps build brand and expand coverage to lower tier cities and hospitals
- No impact to patient supply

# Haemophilia

Sales up 8%<sup>1</sup>



- 25% growth<sup>1</sup>
- Differentiated product
- Strong growth in US, Japan and Switzerland
- Approval of 21-day dosing in EU, Switzerland and Japan



- 21% growth<sup>1</sup>
- Double digit growth in nearly all launched markets
- Patient retention strategies and ongoing switches in competitive environment

## Plasma Derived Coagulation Factors

- Modest growth in HUMATE<sup>®</sup>/HAEMATE<sup>®</sup> (vWF)
- pdVIII competitive pressures
- MONONINE<sup>®</sup> to IDELVION<sup>®</sup> switches

**Recombinant Coags +18%<sup>1</sup>**

**PD Coags (3%)<sup>1</sup>**

# Specialty Products

Sales increased by 10%<sup>1</sup>

- 12%<sup>1</sup> growth
- Deeper penetration into broad hospital segment
- Maintained global leadership position
- 5% growth



↑ 10%

Peri-Operative Bleeding

US\$1,697m

Other Specialty

9% ↑



- 12%<sup>1</sup> growth
- Capacity expansion
- New launches in EU and Canada



- 10%<sup>1</sup> growth



- 20%<sup>1</sup> growth
- Supply normalised

Wound healing

- 9% decline
- Return of competitor

<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.

# Plasma Collections

Continue to grow plasma collection network



**40** new centres opened in the United States



**ALL CENTERS REMAIN OPEN**



**277** centres:

- ✓ 261 United States
- ✓ 8 Germany
- ✓ 3 Hungary
- ✓ 5 China



Plan to open **20 - 30** new centres in FY21



# Plasma Collections

## COVID-19 Impact



### Challenge

- Plasma collections adversely impacted
- FY20 plasma collection volume down ~5% v FY19
- Additional collection costs incurred



### Mitigation

- Collection centres designated 'essential critical infrastructure'
- FDA approved inventory hold reduction from 60 to 45 days
- Utilisation of available finished goods inventory
- Potential to accelerate plasma collections
  - Enhanced marketing initiatives to increase collections
  - Investing in new centres



### Protecting Staff and Donors

#### Actions

- Pre-assessment of potential donors
- Re-direction of donors to sister centers if needed
- Plasma designed social distancing
- Enhanced cleaning & disinfectant procedures
- 'Safe passage' letters provided to staff, donors and key vendors

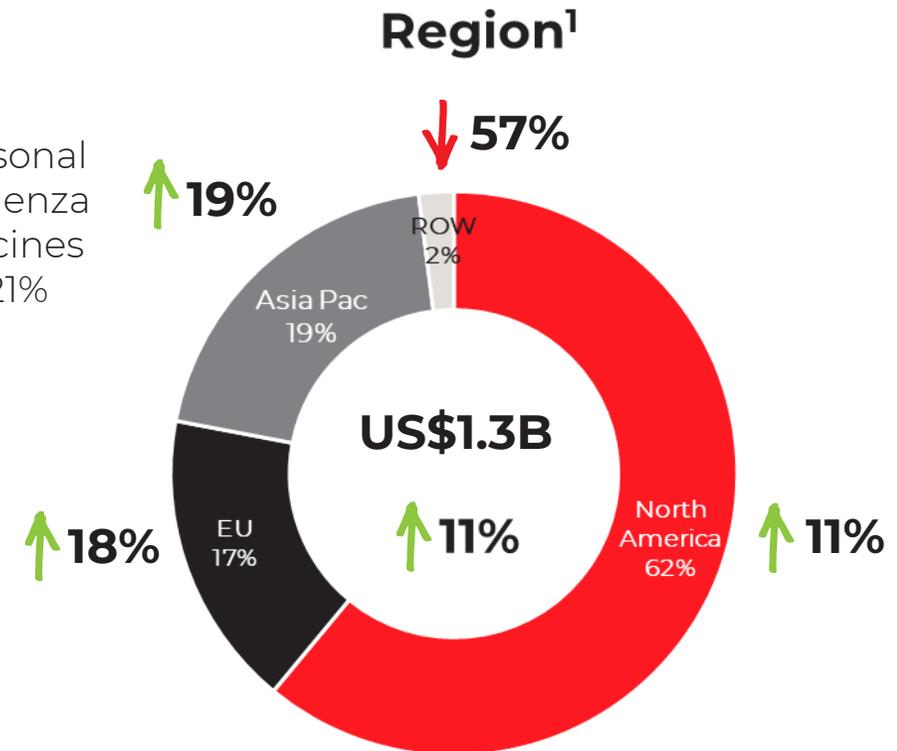
# Seqirus Revenue FY20

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

Therapy	Sales \$m	Change <sup>1</sup> %
QIV	542	27%
TIV	31	(53%)
Adjuvanted	379	30%
Other / In-licence	184	(11%)
<b>Total Product Sales</b>	<b>1,136</b>	<b>14%</b>
Pandemic	145	11%
Other Income	16	(64%)
<b>Total Revenue</b>	<b>1,297</b>	<b>11%</b>



Seasonal  
Influenza  
vaccines  
+21%



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

- Strong result driven by ongoing product differentiation
- Critical operations maintained during COVID pandemic
- Real world evidence continues to demonstrate the potential for improved effectiveness of FLUCELVAX® & FLUAD®
- Progression on fill and finish expansion projects

## Looking Forward

- COVID-19 driving demand:
  - Increased supply into the US of up to ~60m doses for NH20/21
- Fill & finish expansion:
  - Liverpool operational from NH 21/22
  - Holly Springs operational from NH 22/23



# Seqirus



## Operating Highlights

### FLUCELVAX®

- All strains manufactured using cell-specific seed for NH 2019/20 season
- Launched in EU (9 years+)

### FLUAD®

- Ongoing preferred recommendations in UK and Australia
- 65+ QIV launched in Australia; approved in US, EU and UK

### AFLURIA®

- QIV approved in Argentina and Germany

## Looking Forward

### FLUCELVAX®:

- Expanded paediatric in US and EU 2021
- aQIVc to commence clinical trials NH20/21

### FLUAD QIV®:

- US NH20/21 and EU NH21/22 launches



# R&D Highlights



## Immunology

- HIZENTRA® Phase III DM study initiated
- PRIVIGEN® Phase II SSc study initiated
- HAEGARDA® Phase III HAE study in Japan initiated
- PRIVIGEN® approved for PID & SID in Japan
- **Garadacimab** Phase II HAE study results presented at EAACI Congress
- FDA granted HIZENTRA® orphan drug exclusivity for CIDP; PRIVIGEN® ODD and fast track designation for SSc
- Alliance with Seattle Children's Research Institute to develop stem cell gene therapies for PID – WAS and XLA



## Respiratory

- CSL311 (Anti-Beta Common) Phase I study in mild asthmatic patients initiated



## Hematology

- CSL200 in SCD Phase I study initiated
- CSL889 Hemopexin Phase I SCD study initiated
- FDA granted CSL200 fast track designation
- CSL889 Hemopexin ODD approved in EU for SCD
- CSL agreed to acquire exclusive global license rights to adeno-associated virus gene therapy program, AMT-061 **EtranaDez** for hemophilia B\*

\*The transaction with uniQure is subject to customary regulatory clearances before closing



## Cardiovascular & Metabolic

- CSL112 (ApoA-1) Phase III study (AEGIS-II) >9500 patients recruited
- **CSL112** AEGIS-II first futility analysis conducted; trial to continue as planned



## Transplant

- AAT for prevention of GvHD Phase III study enrolment into Cohort 2 completed
- CSL acquired **Vitaeris** Inc. and Clazakizumab
- Clazakizumab AMR study initiated
- FDA granted Clazakizumab ODD and fast track designation



## Influenza Vaccines

- First cell-based quadrivalent seasonal influenza vaccine, FLUCELVAX® TETRA, approval in Europe
- US FDA approval of AUDENZTM - adjuvanted, cell-based influenza A (H5N1) pandemic vaccine
- **aQIVc** (cell antigen + MF59) new product development commenced

# COVID-19 Response

## PREVENTION

## TREATMENT

### Therapeutic Options

#### Vaccines



#### Hyperimmunes Polyclonal Antibodies

#### Monoclonal Antibodies



### Collaborators

- University of Queensland
- Coalition for Epidemic Preparedness Innovations (CEPI)

- Hyperimmunes
  - Alliance with Takeda and others
  - Australian program
- Polyclonal: SAB Therapeutics

- Academic clinical researchers



### Update

- Partnership formed to accelerate the development, manufacture and distribution of vaccine
- Vaccine to be available in 2021 if successful

- Clinical manufacture underway
- Clinical trial start targeted for this quarter

- FPI achieved for first mAb offering (CSL312)
- CSL324 IND submitted June 20; FPI expected in 3Q20

# COVID-19 Summary



COVID-19 presents some challenges however we remained focussed on strategy execution and continue to invest for growth.



## PEOPLE

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- Employees encouraged and supported to work remotely
- Flexible and robust IT systems facilitate ongoing productivity
- Development of strict protocols to ensure the safety of our employees and donors

## INNOVATION

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- Focussed response leveraging the Company capabilities:
- Prevention – vaccine collaboration
- Treatment:
  - Hyperimmune – Global, Australia and SAB
  - Pivoting Mabs and plasma products into ARDS patients
- Paused clinical trials to recommence in FY21

## DEMAND

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- Products are used to treat serious rare diseases and often used chronically
- Demand remains strong across the portfolio
  - Especially strong for IG & influenza vaccines
- Increased preference for home treatment driving HIZENTRA® demand

## SUPPLY

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- Recognised as an 'essential' business
- All plasma centres remain open
- CSL Behring & Seqirus manufacturing facilities operational
- Plasma collections adversely impacted by COVID-19 pandemic
- Multiple initiatives underway to ensure patient supply of therapies

## BALANCE SHEET

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- Ongoing conservative approach to liquidity and leverage
- Raised US\$750 million via private placement, bolstering existing strong capital position
- Net debt to EBITDA 1.5x. Available liquidity \$3.1 billion
- Credit ratings S&P A-, Moody's A3

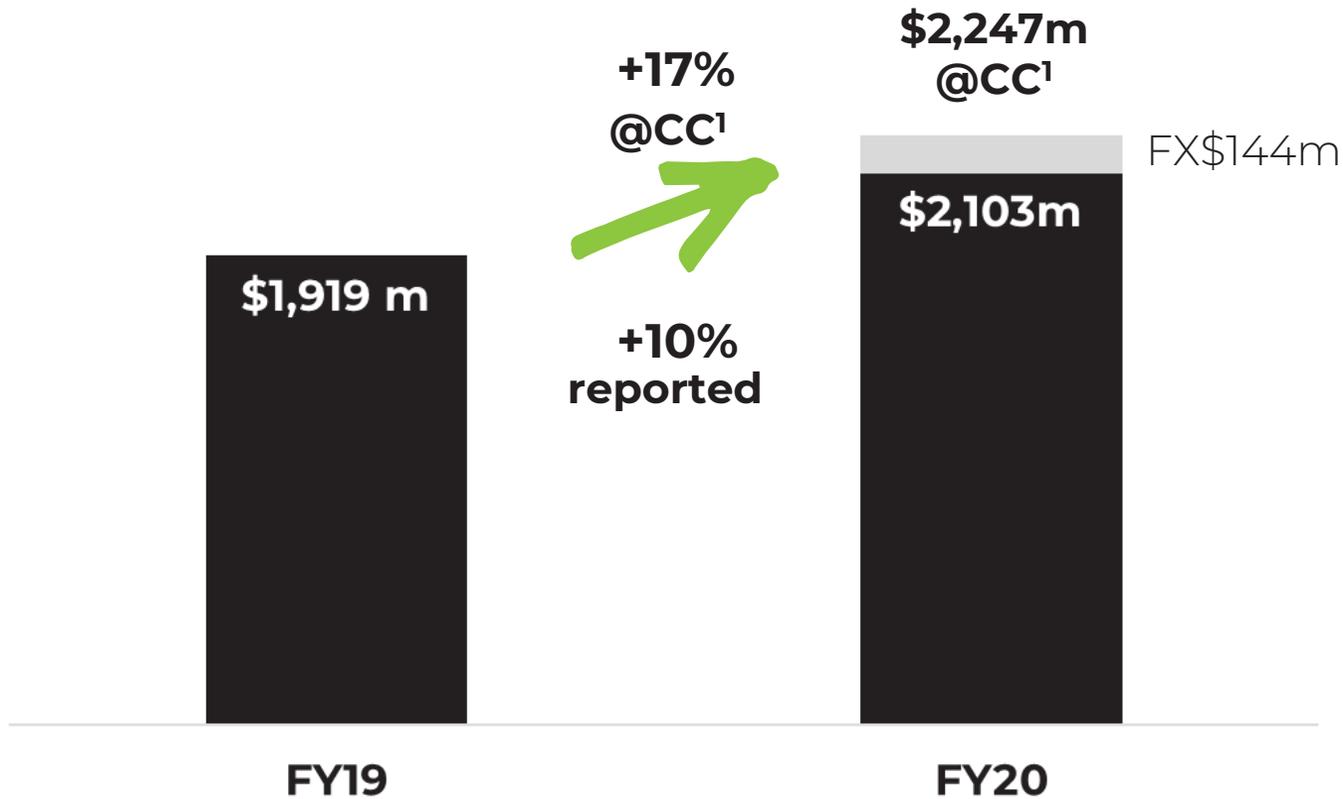
A woman with long dark hair, wearing clear safety glasses and a white lab coat, is looking intently at something out of frame in a laboratory setting. In the background, another person in a white lab coat and teal gloves is working. The scene is brightly lit with overhead fluorescent lights.

# Financials

David Lamont  
CFO

# Financial Highlights

Net Profit After Tax



## GSP China Transition

- Albumin sales reduction in line with guidance
- Profit effect in line with historical CSL Behring margin

## Other Income

- One-off \$30m benefit

## New lease standard

- Balance sheet gross up
- P&L impact immaterial

# Financial Highlights

CSL Group

Full year ended June US\$ Millions	FY19 Reported	FY20 Reported	FY20 at CC <sup>1</sup>	Change %
Total Revenue	8,539	9,151	9,295	9% <sup>1</sup>
Gross Profit	4,777	5,226	5,338	12% <sup>1</sup>
<i>GP margin</i>	56.0%	57.1%	57.4%	
EBIT	2,504	2,717	2,877	15% <sup>1</sup>
<i>EBIT margin</i>	29.3%	29.7%	31.0%	
NPAT	1,919	2,103	2,247	17% <sup>1</sup>
Cashflow from Operations	1,644	2,488		51%
ROIC	24.3%	21.6%		
EPS (\$)	4.24	4.63	4.95	17% <sup>1</sup>
DPS (\$)	1.85	2.02		9%

# Financial Highlights

## Segments

### CSL Behring

US\$ Millions	FY19 Reported	FY20 Reported	Change % at CC <sup>1</sup>
Sales	7,187	7,661	8%
Other Revenue	156	193	24%
Total Revenue	7,343	7,854	9%
Gross Profit	4,195	4,540	11%
<i>GP margin</i>	<i>57.1%</i>	<i>57.8%</i>	
EBIT	2,351	2,451	11%
<i>EBIT margin</i>	<i>32.0%</i>	<i>31.2%</i>	

### Seqirus

US\$ Millions	FY19 Reported	FY20 Reported	Change % at CC <sup>1</sup>
Sales	1,018	1,136	14%
Other Revenue	178	161	(7%)
Total Revenue	1,196	1,297	11%
Gross Profit	582	686	17%
<i>GP margin</i>	<i>48.7%</i>	<i>52.9%</i>	
EBIT	153	265	74%
<i>EBIT margin</i>	<i>12.8%</i>	<i>20.4%</i>	

# Financial Highlights

## Reported Expenses

	FY20 \$m	Change @ CC <sup>1</sup>	
		\$m	%
Research & Development	922	101	12
Sales & Marketing	896	39	5
General & Admin	692	48	8
Finance (Net)	144	(28)	(17)
Tax	470	72	17
ETR %	18.3%		

### R&D

- CSL112 phase III trial
- CSL200 SCD gene therapy trial initiated
- COVID-19 response

### Finance (Net)

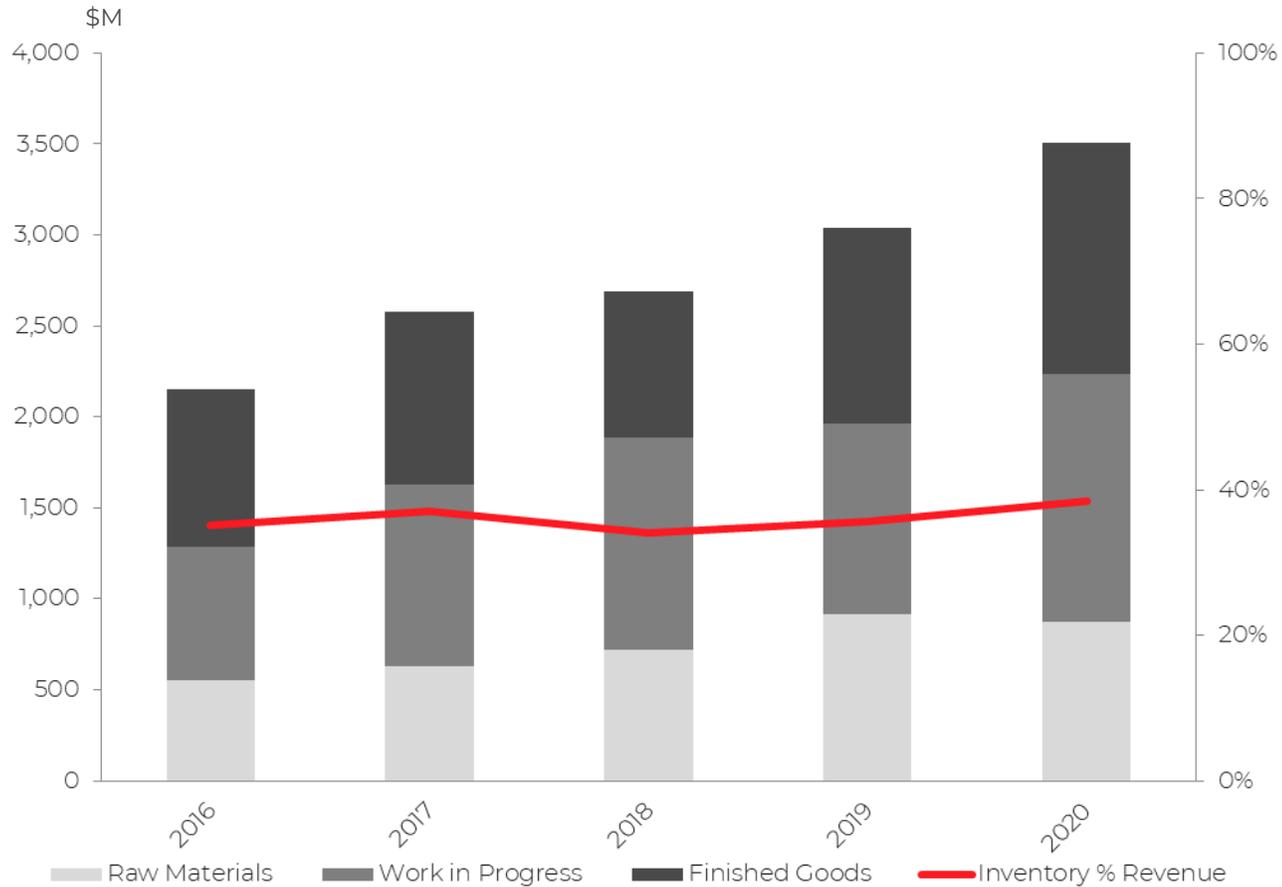
- AASB16 adoption - \$26m
- YoY variation in Swiss debt costs \$41m

### Tax

- Increase in-line with profit increase
- FY21 ETR rate ~20-22%

# Inventory Management<sup>1</sup>

Flexibility in the supply chain



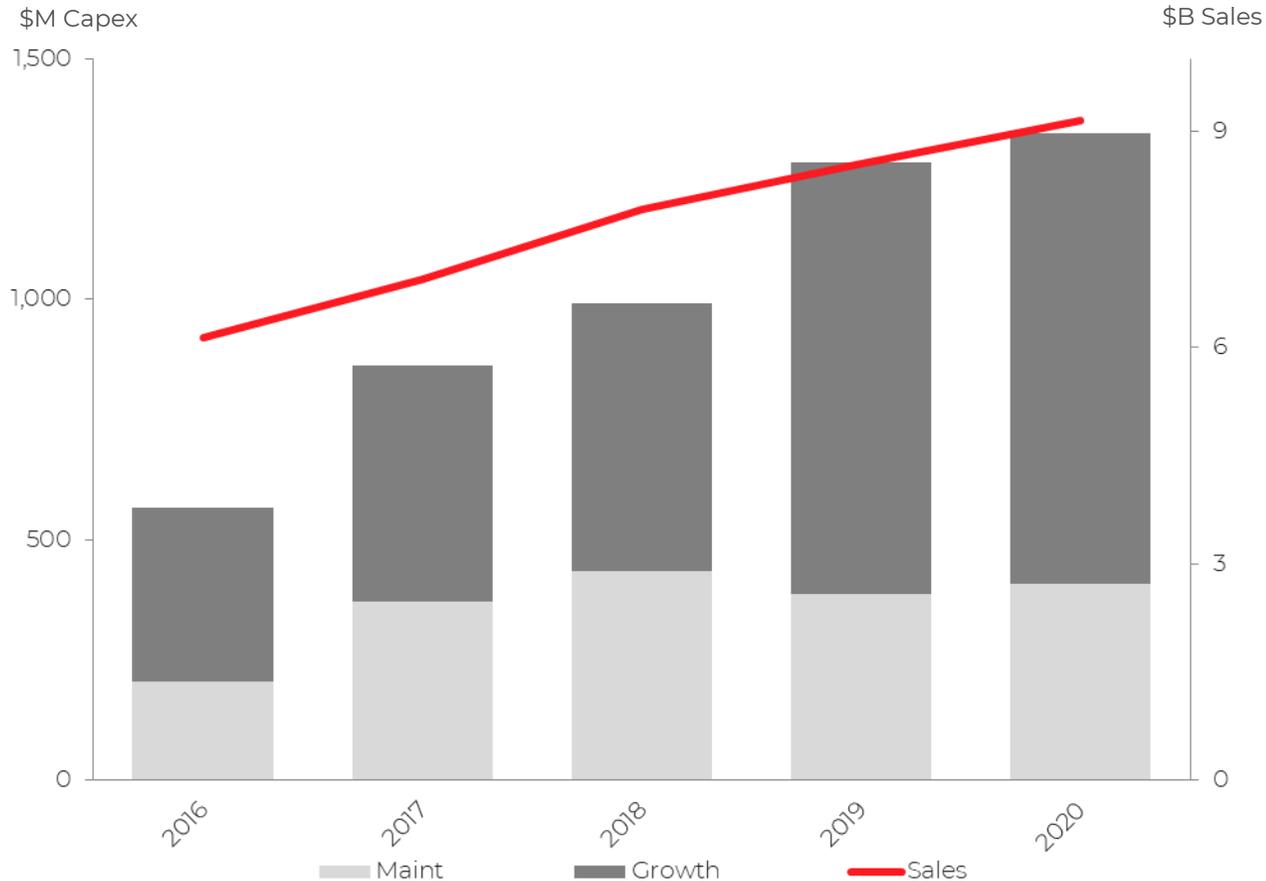
<sup>1</sup> Reported numbers

## Key Insights

- Continue to produce for demand
- Inventory as a percentage of revenue steady
- Seqirus inventory mix impacted by strain notification

# Capital Expenditure<sup>1</sup>

Investment to support demand



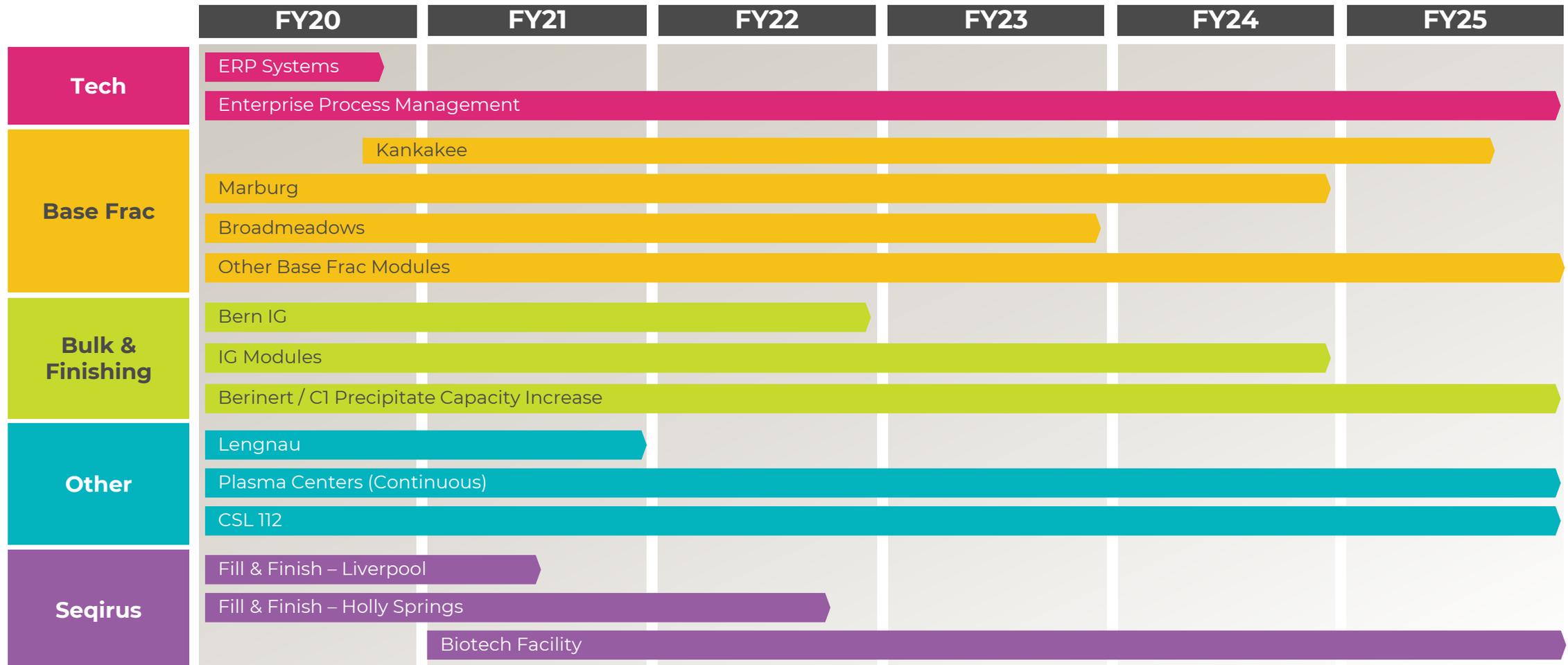
<sup>1</sup> Reported numbers

## Key Projects

- Significant new manufacturing capacity
- Additional plasma collection centers
- ERP systems completed
- Lengnau facility
  - Thermo Fisher lease
  - Accelerates optimisation of facility capability
- FY21 ~ \$1.6 billion

# Key Capital Projects

## Completion Timeline



# Outlook for FY21<sup>1</sup>

## Demand

- Continued strong demand for plasma and recombinant products
- Seqirus' product differentiation and COVID-19 expected to drive strong demand for influenza vaccines
- Albumin sales to normalize following GSP transition

## Plasma Collections

- COVID-19 restrictions expected to restrain plasma collections
- Additional plasma collection costs
- Multiple initiatives underway to mitigate impact

## R&D

- COVID-19 response and new growth initiatives to drive uplift in investment towards the top end of prior guidance range<sup>3</sup>



## FY21<sup>1</sup> Outlook

Revenue Growth  
~6 - 10% @CC<sup>2</sup>

NPAT  
~\$2,100 - \$2,265m @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 rates movements to facilitate comparability. See end note for further detail

<sup>3</sup> Previously provided R&D investment guidance of ~10-11% of revenue



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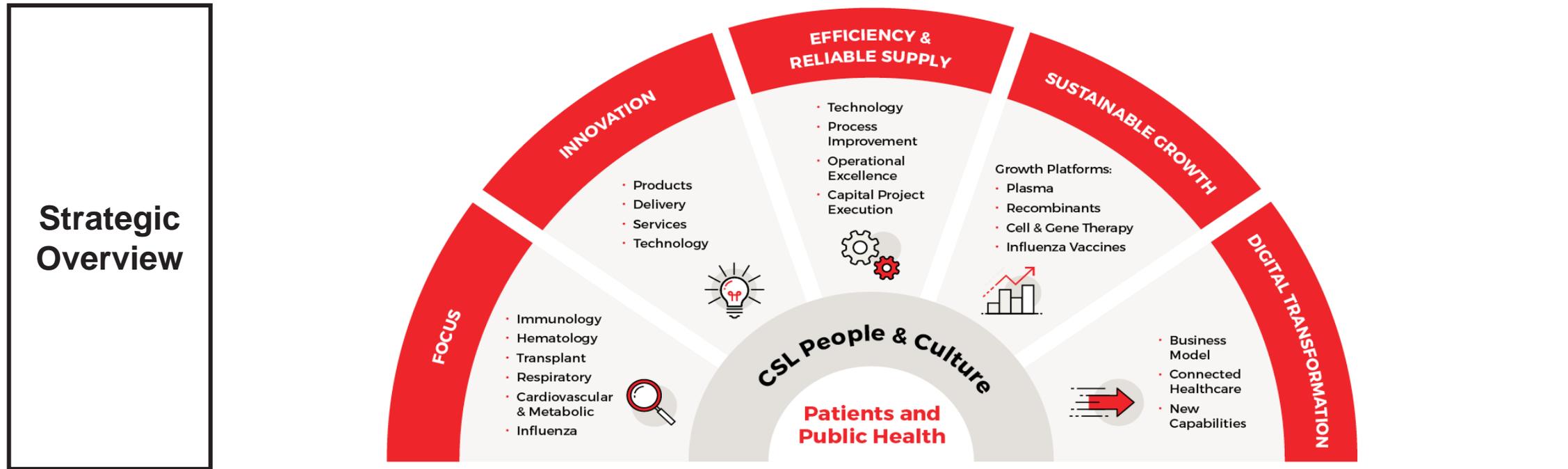
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# CSL Strategy and Values



# 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	\$2,102.5m
Translation currency effect (a)	\$ (1.0m)
Transaction currency effect (b)	\$ 60.1m
Foreign Currency (gains) & losses (c)	\$ 85.4m
Constant currency net profit after tax *	\$2,247.0m

## a) Translation Currency Effect \$(1.0m)

Average Exchange rates used for calculation in major currencies (Twelve months to June 20/June 19) were as follows: USD/EUR (0.90/0.87); USD/CHF (0.98/0.99).

## b) Transaction Currency Effect \$60.1m

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 Loss \$85.4m

Foreign currency gains recorded during the period.

## Summary Sales

Reported sales	\$8,796.6m
Currency effect	\$ 141.2m
Constant currency sales*	\$ 8,937.8m

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

