

#### For immediate release

16 August 2017

# Full Year Result 2017<sup>1</sup> CSL Delivers Exceptional Performance

CSL Limited (ASX:CSL; USOTC:CSLLY) today announced a net profit after tax (NPAT) of \$1,337 million for the 12 months ended 30 June 2017. Underlying<sup>2</sup> NPAT was up 24% and underlying earnings per share (EPS) grew 26%, both on a constant currency (CC)<sup>3</sup> basis.

#### PERFORMANCE HIGHLIGHTS

#### **Financial**

- Revenue \$6,923 million
  - Up 15% at CC<sup>3</sup>
- Earnings before interest and tax (EBIT) \$1,769 million
  - Underlying EBIT up 23% at CC
- NPAT \$1,337 million
  - Underlying NPAT up 24% at CC
- EPS \$2.94
  - o Underlying EPS up 26% at CC
- Total FY17 dividend<sup>4</sup> increased to \$1.36 per share, up 8%

# Operational CSL Behring

- Immunoglobulin (Ig) sales, excluding hyperimmunes, grew 16% at CC
- Specialty products sales increased 20% at CC
- Strong demand for Idelvion® (rFIX-FP) continued in its first full year of availability

<sup>&</sup>lt;sup>1</sup> All figures are expressed in US dollars unless otherwise stated.

<sup>&</sup>lt;sup>2</sup> Underlying excludes from FY16 financials the one off items relating to the Novartis influenza vaccines business, which was acquired on 31 July 2015.

<sup>&</sup>lt;sup>3</sup> Constant currency removes the impact of exchange rate movements, facilitating comparability of operational performance. For further detail please refer to CSL's Financial Statements 2016-2017 (Directors' Report).

<sup>4</sup> For shareholders with an Australian registered address, the final dividend of US\$0.72 will be unfranked for Australian tax purposes and paid on 13 October 2017 in A\$ at an amount of A\$0.915264 per share (at an exchange rate of A\$1.2712/US\$1.00). For shareholders with a New Zealand registered address, dividends will be paid in NZD at an amount of NZ\$0.986328 per share (at an exchange rate of NZ\$1.3699/US\$1.00). The exchange rates used are fixed at the date of dividend determination. All other shareholders will be paid in US\$. CSL also offers shareholders the opportunity to receive dividend payments in US\$ by direct credit to a US bank account.



Page 2 16 August 2017

- CSL 830 (Haegarda®) approved by the US Food and Drug Administration (FDA)
- Hizentra<sup>®</sup> Largest ever neurological clinical trial completed
- Opened 28 plasma centres during the year
- Three new monoclonal antibodies entered phase I clinical trials
- · License agreement reached with Momenta Pharmaceuticals.

#### Influenza (Segirus)

- Solid revenue growth of 23%, reflecting planned transition to quadrivalent products, FLUAD<sup>®</sup> and increase in pandemic reservation fees
- Four-fold increase in seasonal output at Holly Springs site

#### Corporate

- Acquisition of majority stake in Chinese plasma fractionator Ruide
- 'A' grade credit ratings issued by Moody's and Standard & Poor's
- A\$500 million share buyback<sup>5</sup>, ~91% complete<sup>6</sup>

"CSL's 2017 results were exceptional. Our strong year reflects the successful execution of our strategy," said CSL Chief Executive Officer and Managing Director Paul Perreault. "We delivered on our promise to provide innovative medicines to patients with rare and serious diseases in more than 60 countries. As a result, our business performance again created significant value for shareholders and other stakeholders."

"CSL Behring's strong performance included achieving two milestones which were particularly significant: the FDA approval of Haegarda® and the continued expansion of our next generation recombinant coagulations therapies, especially Idelvion®," Mr. Perreault noted. "Haegarda®, which treats Hereditary Angioedema (HAE), is a transformational therapy for patients. Haegarda® provides 95% reduction in oedema attacks, reduces the need for rescue medication and is the first and only subcutaneous formulation. Another area of strong growth is Idelvion® (rFIX-FP). In its first full year, Idelvion® has become the new standard of care for patients with Haemophilia B, given its unsurpassed profile and significant patient benefits. Feedback and product adoption from both patients and physicians have been extremely positive."

"We also continued to expand our plasma collection network. With nearly 180 centres in the US and Europe, CSL is uniquely positioned to leverage our network to drive future

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<sup>&</sup>lt;sup>5</sup> CSL reserves the right to terminate buy-backs at any time.

<sup>&</sup>lt;sup>6</sup> As at 16 August 2017



Page 3 16 August 2017

growth. We intend to open 25-30 centres over the next year, a level of expansion which is unmatched in the industry."

"Seqirus continued to make steady progress, including securing multiple new product licences and executing a number of initiatives designed to position the business for profitability and growth," Mr. Perreault added.

"To continue delivering on our promise to patients, we further strengthened our future growth opportunities in 2017, including three key initiatives," Mr. Perreault noted.

"We laid the groundwork in support of Hizentra by completing the largest ever neurological clinical study. This data is the basis for our licensure applications submitted to the FDA for use of both Hizentra® and Privigen®."

"Additionally, we reached an agreement with Momenta Pharmaceuticals in January to develop Fc multimer proteins."

"Later in the year, we acquired a majority stake in Chinese fractionator Ruide. This is a modest entry point into a one of the largest and fastest growing immunoglobulin markets in the world. We now have the capabilities to expand our efforts in delivering life-saving therapies to Chinese patients with rare and serious diseases," Mr. Perreault concluded.

#### OUTLOOK (at FY17 exchange rates)

Commenting on CSL's outlook, Mr. Perreault said, "We expect solid ongoing demand for CSL Behring biotherapies and strong market acceptance of our newly approved specialty product Haegarda<sup>®</sup>."

"The haemophilia market continues to evolve. Our new generation products, Idelvion® (rFIX-FP) and Afstyla® (rFVIII-SC) are well placed and expected to more than offset the anticipated decline in earnings contribution from Helixate®, as our supply contract ends this calendar year."

"Seqirus is expected to continue its path toward profitability," Mr. Perreault added.



Page 4 16 August 2017

"CSL Group's net profit after tax for FY18 is expected to be in the range of approximately \$1,480 million to \$1,550 million at constant currency. This compares to FY17 reported profit of \$1,337 million," Mr. Perreault concluded.

In compiling the company's financial forecasts for FY18, a number of key variables which may have a significant impact on guidance have been identified and these have been included the footnote<sup>7</sup> below.

#### **CAPITAL MANAGEMENT**

#### Share Buyback

In October 2016, CSL announced its intention to conduct an on-market share buyback of up to A\$500 million. To date, CSL has purchased approximately 3.6 million shares for approximately A\$454 million, representing approximately 91% of the intended buyback program. No share buyback is foreshadowed in FY18.

#### Debt Ratings

CSL's balance sheet and debt serviceability remain strong. Net debt to EBITDA stands at 1.5x. During the second half of FY17, CSL sought debt ratings to facilitate debt diversification and enable access to wider debt markets. Ratings issued are strong investment grades as follows:

- Moody's A3, stable outlook
- S&P A-, stable outlook

#### Capital management

During the first half of FY18, CSL intends to approach the US private placement market to raise approximately US\$600 million for general corporate purposes, as part of the company's overall capital management program.

pricing, reimbursement, access or tax; acquisitions and divestitures; research collaborations; litigation or

<sup>7</sup> Key variables that could cause actual results to differ materially include: the success of research and

government investigations; and CSL's ability to protect its patents and other intellectual property.

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,



Page 5 16 August 2017

#### **FURTHER INFORMATION**

Additional details about CSL's results are included in the company's 4E statement, investor presentation slides and webcast, all of which can be found on CSL's website <a href="https://www.csl.com.au">www.csl.com.au</a> A glossary of medical terms can also be found on the website. For further information, please contact:

#### Investors:

Mark Dehring VP Investor Relations CSL Limited

Telephone: +613 9389 3407 Email: mark.dehring@csl.com.au

#### Media:

Jemimah Pentland Head of Communications, Asia Pacific CSL Limited Mobile +61 412 635 483

Email: jemimah.pentland@csl.com.au

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Page 6 16 August 2017

### **Group Results**

Full year ended June US\$ Millions	Jun 2016 Reported	Jun 2016 Underlying <sup>8</sup>	Jun 2017 Reported	<b>Jun 2017</b> at CC <sup>9</sup>	Change %
Sales	5,909	5,909	6,616	6,688	13%
Other Revenue / Income	206	206	307	314	1070
Total Revenue / Income	6,115	6,115	6,923	7,002	15%
Earnings before Interest, Tax, Depreciation & Amortisation	1,658	1,749	2,048	2,163	24%
Depreciation/Amortisation	(220)	(220)	(279)	(285)	
Earnings before Interest and Tax	1,438	1,529	1,769	1,878	23%
Gain on Acquisition Net Interest Expense Tax Expense	176 (58) (314)	(58) (318)	- (79) (353)	(80) (371)	
Net Profit after Tax	1,242	1,153	1,337	1,427	24%
Total Dividend EPS	1.26 2.689	2.495	1.36 2.937	3.134	8% 25.6%

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<sup>&</sup>lt;sup>8</sup> Excludes one-off items relating to the acquisition of Novartis' influenza vaccines business, acquired on 31 July 2015.

<sup>&</sup>lt;sup>9</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability of operational performance. For further details please refer to CSL's Financial Statements 2016-2017 (Directors' Report).





### **Legal Notice**

#### **Forward looking statements**

The materials in this presentation speak only as of the date of these materials, and include forward looking statements about CSL Limited and its related bodies corporate (CSL) financial results and estimates, business prospects and products in research, all of which involve substantial risks and uncertainties, many of which are outside the control of, and are unknown to, CSL. You can identify these forward looking statements by the fact that they use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," "may," "assume," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. 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 and divestments; research collaborations; litigation or government investigations, and CSL's ability to protect its patents and other intellectual property. The statements being made in this presentation do not constitute an offer to sell, or solicitation of an offer to buy, any securities of CSL.

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### **Strategic Objectives**



Growth

Maximize portfolio value & deliver new product launches



**Efficiency** 

Be the most efficient, highest quality plasma player



Influenza

Deliver on influenza strategy



**Innovation** 

Pursue new opportunities to diversify portfolio and enhance growth



**People & Culture** 

Create a culture that attracts, retains and develops the best talent



### **Delivering on Strategy**



- Global Ig market leader
  - Focused commercial execution
- Innovation in haemophilia
  - IDELVION® new standard of care
  - AFSTYLA® new generation rFVIII
- Exceptional growth in specialty products
  - HAEGARDA® approved
- Ruide providing access to high growth China market



### **Delivering on Strategy**



### **Innovation**

- 3 global launches in 15 months
- Largest ever CIDP clinical study completed
- 3 new mAbs into phase 1 trials
- Collaboration to develop Fc mimetic
- Commercial scale cell based influenza vaccine



### **Efficiency**

- 5 years of margin expansion
- Most efficient plasma collection network
  - Industry leading expansion
- Track record of reliable supply
- Major progress on capital expansion projects



### **Delivering on Strategy**



### Influenza

- On-track to profitability
- Broad product portfolio driving strong sales growth
- Shipping commenced of >50m doses to US
- Four-fold increase in seasonal output at Holly Springs
- Multi-market pandemic vaccine agreements



### **People & Culture**

- Workforce ~20,000
- Maintaining and growing a values based culture
  - Patient focus
  - Geographic expansion
  - Talent development
  - Employee engagement
  - R&D capabilities



## **Revenue Highlights**



#### IMMUNOGLOBULINS \$2,774m +14%<sup>1</sup>





- Privigen® up 21%1
- Hizentra® up 10%1
- Total Ig<sup>2</sup> up 16%<sup>1</sup>

**HAEMOPHILIA** \$1,023m +4%<sup>1</sup>



### **OAFSTYLA**°

- Strong demand for IDELVION®
- Transition from Helixate<sup>®</sup> to AFSTYLA<sup>®</sup>

**SPECIALTY** \$1,174m +20%<sup>1</sup>

### **Kcentra®**



- Kcentra® up 35%1
- Berinert® up 31%1

**ALBUMIN** \$840m +7%<sup>1</sup>



- Expansion into additional cities
- China sales growth 13%

SEQIRUS \$900m +23%<sup>1</sup>



- Fluad®, QIVs and TIV all contributing
- Sustainable increase in pandemic reservation fees



<sup>1.</sup> Growth 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> Total Ig excludes hyperimmunes.

## **Strong Demand for Ig Products**





- SCIG in CIDP largely untapped
  - Hizentra<sup>®</sup> CIDP approval mid CY18
  - CIDP is largest Ig indication



- Developing new indications
  - Myositis
  - Scleroderma
- Fc mimetic technology in development
  - Momenta deal
  - Internal capabilities



## **New Products in Haemophilia**



#### **US IDELVION® PATIENT GROWTH**



27 weeks for 1st 100 patients 19 weeks for 2nd 100 patients 17 weeks 3<sup>rd</sup> 100 patients

- IDELVION® demand exceptionally strong
  - Capturing >2/3 of patient switches
- AFSTYLA® switches largely being driven from Helixate®
- IDELVION® & AFSTYLA® delivers sales growth and margin expansion in the recombinant coagulation portfolio



### **Specialty Products – HAEGARDA®**



- Product launched July 2017
- 7 year orphan exclusivity
- First and only subcutaneous formulation
- 95% reduction in HAE attacks
- >99% reduction in the need for rescue medication
- Strong patient, physician and provider engagement

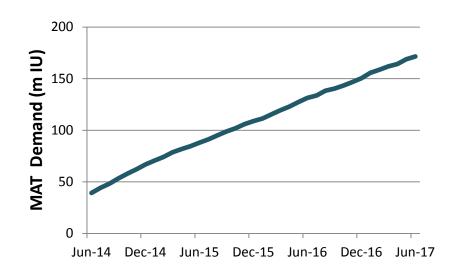




# **Specialty Products – Kcentra®/Beriplex®**



### **US Kcentra® demand since launch (volume)**

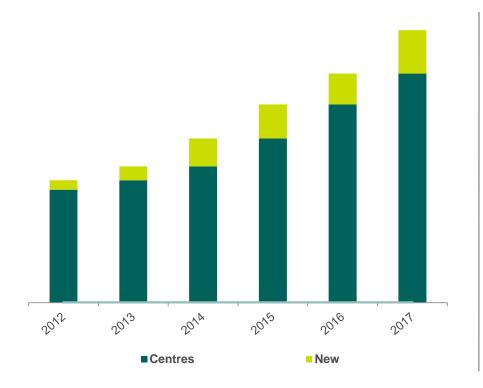


- US account expansion and penetration
- Broader awareness and understanding within hospital departments
- Demand for urgent Warfarin reversal remains robust in many markets
- Japan launch 2H17



# **Growing the most efficient Plasma Collections Network**





#### As at June 2017

- Collection centres 176
- Unmatched rate of centre openings
  - 2-3 per month

#### Outlook

- ~25 to 30 centre openings in FY18
- CPL improves as more centres at peak efficiency
  - ~3 years from opening
- Replicating efficiencies in China over time



### **Seqirus**



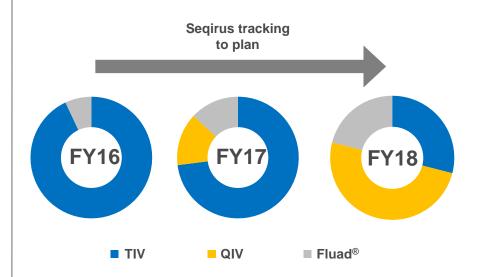
#### Strong Revenue Growth

- Fluad<sup>®</sup> and QIVs continue to build share in the US
- TIV demand robust in many markets
- Increase in pandemic reservation fees
- US 2017/18 season tracking to plan

### Operational Highlights

- Four fold increase in Holly Springs output
- Exiting GSK fill & finish following 2018 southern hemisphere season
- Liverpool formulation suite nearing completion
- First wave of Seqirus ERP live on 3 July

#### **Seasonal Influenza Sales Mix**

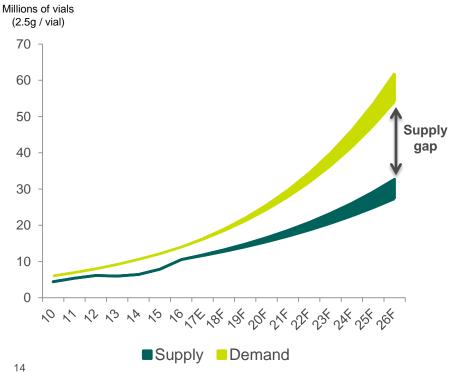




## Ruide Provides Presence in High Growth Market



#### China IVIG domestic supply & demand

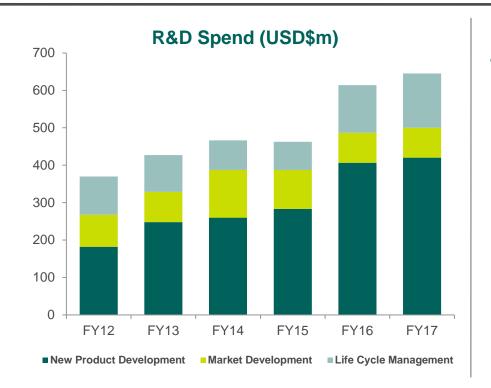


- Acquisition of a majority stake in Chinese plasma fractionator Ruide
  - Modest entry point to key market
  - Deal closed 2 August 2017
  - CSL Behring has operational control
- Plasma products market in China
  - ~US\$3.3b in 2016
  - 5 year growth rate ~15%
- China is the fastest Ig growth market
  - Second in volume to the US
  - Demand forecasted to outstrip supply
- Planning for plasma centre expansion



## **Innovation a Key Driver of Out-Performance**





- Growing proportion of spend directed to new product development
  - Hizentra<sup>®</sup> & Privigen<sup>®</sup> CIDP indications
  - Fc Mimetics
  - Monoclonal antibody expertise
  - Influenza vaccine
    - Cell-derived seed innovation
    - QIV development & expanding age indications
  - CSL112 planning for phase III
  - Transplant improving organ function & reducing rejection



## **Financials**

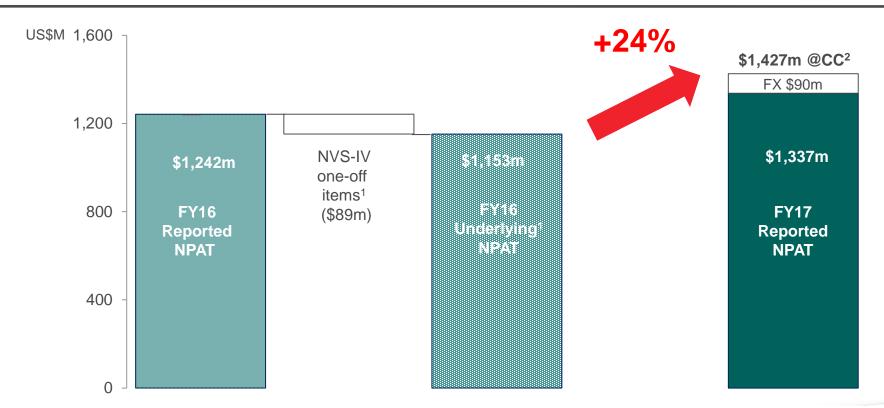
CFO – David Lamont





### **Financial Highlights**





<sup>&</sup>lt;sup>1</sup> Excludes one-off items relating to the acquisition of the Novartis influenza vaccines business (NVS-IV), acquired on 31 July 2015.



<sup>&</sup>lt;sup>2</sup> Constant Currency (CC) removes the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.

# **Financial Highlights**



Full year ended June US\$ Millions	FY 2016 Underlying <sup>1</sup>	FY 2017 Reported	<b>FY 2017</b> at CC <sup>2</sup>	Change <sup>3</sup>
Total Revenue	6,115	6,923	7,002	15%
EBIT margin	1,529 25.0%	1,769 25.6%	1,878 26.8%	23%
NPAT	1,153	1,337	1,427	24%
Cashflow from Ops	1,1784	1,247	-	6% <sup>3</sup>
ROIC	26.8%5	24.5%	-	-



<sup>&</sup>lt;sup>1</sup> Excludes one-off items relating to the acquisition of the Novartis influenza vaccines (NVS-IV) business acquired on 31 July 2015

<sup>&</sup>lt;sup>2</sup> Constant Currency (CC) removes the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.

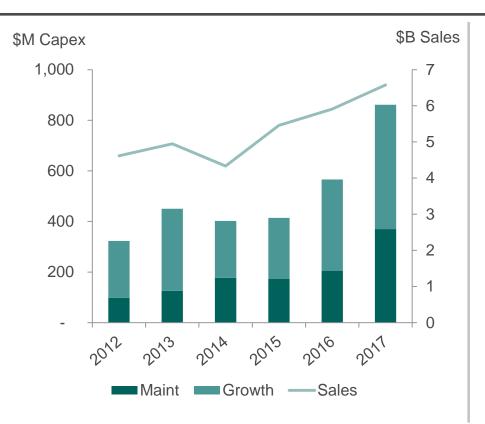
<sup>&</sup>lt;sup>3</sup> Percentage change is based off FY16 underlying financials which excluded the one-off items relating to the Novartis influenza vaccines business (NVS-IV), which was acquired on 31 July 2015

<sup>&</sup>lt;sup>4</sup> Based on reported numbers

<sup>&</sup>lt;sup>5</sup> Based on reported numbers including the gain acquisition of NVS-IV of \$176m

## **Investing to Support Sales Growth**





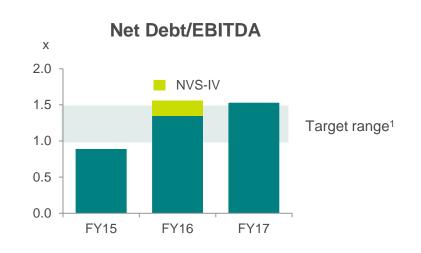
#### Key projects

- Lengnau
- Kankakee & Marburg: New base fractionation capacity
- Marburg: Additional Haegarda<sup>®</sup> / Berinert<sup>®</sup> capacity
- Broadmeadows: New albumin & Ig capacity
- Bern: New Ig capacity
- New collection centers
- Upgrade to ERP systems
- FY18 ~\$900m to \$1bn
  - Two thirds being growth projects



### **Prudent Capital Structure**

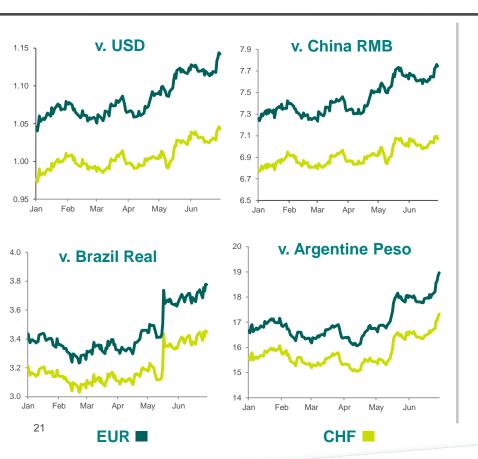




- Net Debt to EBITDA target<sup>1</sup> 1.0 1.5x
  - Currently ~1.5x; targeting lower end in 2yrs
- Strong investment grade ratings
  - Moody's A3, stable outlook
  - S&P A-, stable outlook
  - Facilitate debt diversification
  - Access wider debt markets
- Capital management
  - A\$45m remaining on existing buyback
  - Foreshadowing
    - ~US\$600m private placement in 1H18
    - No buyback in FY18



## Foreign Exchange



#### **Environment**

- CSL sells into ~60 countries
- Size of exposure in South America, Eastern Europe, China is increasing
- Manufacturing sites (Switzerland & Germany) carry weight of FX exposure

#### **FX drivers in FY17**

- Significant & rapid strengthening of CHF & EUR in last 6 weeks of financial year
- Lengthy period between US plasma collections
   & product sales



### Outlook for FY18<sup>1</sup>



# NPAT ~ \$1,480 - 1,550m @ CC<sup>2</sup> Revenue growth ~8% @ CC<sup>2</sup>

- Continued strong demand for plasma and recombinant products
- Ig & albumin growth dependent on access to plasma
  - ~25 to 30 new collection centre openings in FY18
- Haegarda<sup>®</sup> launch
- Seqirus tracking to plan
- Planning for CSL 112 (apoA-I) Phase III continuing
- Investing to support sales growth: FY18 ~\$900m to \$1bn



<sup>&</sup>lt;sup>1</sup> For forward looking statements, refer to Legal Notice on page 2

**Financial Appendix** 





# **Group Results**

Full year ended June US\$ Millions	FY 2016 Reported	FY 2016 Underlying <sup>1</sup>	FY 2017 Reported	<b>FY 2017</b> At CC <sup>2</sup>	Change %
Sales Other Revenue / Income Total Revenue / Income	<b>5,909</b> 206 <b>6,115</b>	<b>5,909</b> 206 <b>6,115</b>	<b>6,616</b> 307 <b>6,923</b>	<b>6,688</b> 314 <b>7,002</b>	13% 15%
Earnings before Interest, Tax, Depreciation & Amortisation	1,658	1,749	2,048	2,163	24%
Depreciation/Amortisation  Earnings before Interest and Tax	(220) <b>1,438</b>	(220) <b>1,529</b>	(279) <b>1,769</b>	(285) <b>1,878</b>	23%
Gain on Acquisition Net Interest Expense Tax Expense	176 (58) (314)	(58) (318)	(79) (353)	(80) (371)	
Net Profit after Tax	1,242	1,153	1,337	1,427	24%
Total Dividend EPS	\$1.26 \$2.689	\$2.495	\$1.36 \$2.937	\$3.134	8% 25.6%



Excludes one-off items relating to the acquisition of the Novartis influenza vaccines business, acquired on 31 July 2015
 Constant Currency (CC) removes the impact of exchange rate movements, facilitating comparability of operational performance. See end note for further detail.

# **CSL Behring Sales**

Full year ended June US\$ Millions	FY 2016	FY 2017	FY17 CC <sup>1</sup>	Change %
Immunoglobulins	2,457	2,774	2,811	14%
Albumin	811	840	868	7%
Haemophilia				
- Recombinants	415	461	466	12%
- Plasma	585	562	570	(3)%
Specialty	977	1,174	1,175	20%
Total Product Sales	5,245	5,811	5,891	12%
Other sales (mainly plasma)	12	24		
Total Sales	5,257	5,835		



### **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 (foreign currency effect). The sum of translation currency effect, transaction currency effect and foreign currency effect is the amount by which reported net profit is adjusted to calculate the result at constant currency.

#### Summary NPAT adjusted for currency effects

Reported net profit after tax	\$1,	337.4m
Translation currency effect (a)	\$	(0.5m)
Transaction currency effect (b)	\$	36.0m
Foreign Currency gains & losses (c)	\$	54.3m
Constant currency net profit after tax *	\$1,	427.2m

#### a) Translation Currency Effect \$(0.5m)

Average Exchange rates used for calculation in major currencies (twelve months to June 17/June 16) were as follows: USD/EUR (0.92/0.90); USD/CHF (0.99/0.98).

#### b) Transaction Currency Effect \$36.0m

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 Effect \$54.3m

Foreign currency losses during the period as recorded in the financial statements.

#### Summary Sales

Reported sales \$6,615.8m Currency effect \$72.7m Constant currency sales\* \$6,688.5m



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

### **CSL Limited**

Contact – Mark Dehring VP Investor Relations

Telephone: +613 9389 3407

Email: mark.dehring@csl.com.au



