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### ASX Announcement

For immediate release

12 August 2015

### **Strong Full Year Result**

Double digit growth in albumin and specialty products CSL becomes No.2 global influenza vaccines manufacturer New Privigen<sup>®</sup> facility completed Board to consider further share buyback

CSL Limited (ASX:CSL; USOTC:CSLLY) today announced a net profit after tax (NPAT) of US\$1,379 million for the full year ended 30 June 2015, up 6% on a reported basis when compared to the prior comparable period (PCP). NPAT grew 10% on a constant currency<sup>1</sup> basis, after adjusting for the one-off costs<sup>2</sup> associated with the acquisition of the Novartis influenza vaccine business.

### HIGHLIGHTS

### Financial

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- Sales US\$5,459 million, up 2% on PCP
  - Up 7% at constant currency<sup>1</sup>
- EBIT US\$1,758 million, up 7% on PCP
  - Up 12% at constant currency & after adjusting for acquisition costs<sup>2</sup>
  - NPAT US\$1,379 million, up 6% on PCP
    - o Up 10% at constant currency & after adjusting for acquisition costs
- Earnings per share US\$2.92, up 8% on PCP
  - o Up 13% at constant currency & after adjusting for acquisition costs
- Research and development investment was US\$463 million
- Final dividend<sup>3</sup> increased 10% to US\$0.66 per share, unfranked for Australian tax purposes, payable on 2 October 2015
  - Converted to Australian currency, the final dividend increased to approximately A\$0.90 per share, up 39% on PCP.

<sup>&</sup>lt;sup>1</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability. See end note for further detail.

<sup>&</sup>lt;sup>2</sup> One-off costs totalling \$22 million connected with the acquisition of the Novartis influenza vaccine business

<sup>&</sup>lt;sup>3</sup> For shareholders with an Australian registered address, dividends will be paid in A\$ at an amount of A\$0.899910 per share (at an exchange rate of A\$1.3635/US\$1.00), and for shareholders with a New Zealand registered address, dividends will be paid in NZD at an amount of NZ\$1.006104 per share (at an exchange rate of NZ\$1.5244/US\$1.00). The exchange rates used are fixed at the date of dividend determination. All other shareholders will be paid in US\$.



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### Operational

- Acquisition of Novartis' global influenza vaccine business
- bioCSL business turnaround
- Hizentra<sup>®</sup> (subcutaneous immunoglobulin) European Medical Agency & U.S. Food and Drug Administration (FDA) approved flexible dosing
- CSL 654 (rIX-FP) license application submitted to U.S. and European regulators
- CSL 627 (rFVIII-SingleChain) license application submitted to U.S. FDA
- CSL 112 (rHDL) global phase IIb clinical trial recruiting rapidly
- Major capital projects completed

### **Capital Management**

- A\$950 million share buyback completed
- New buyback<sup>4</sup> foreshadowed
- New private placement foreshadowed

"CSL's solid 2015 results demonstrate our track record of delivering strong shareholder returns," said CSL Chief Executive Officer and Managing Director, Paul Perreault. "Robust demand for our differentiated biotherapies continued, with albumin and specialty products growing at double digit rates. bioCSL is growing again with influenza vaccine sales increasing particularly well."

"We fast tracked the acquisition of the Novartis influenza vaccines business, which lets us get on with integration much earlier," Mr. Perreault said. "CSL is now the second largest influenza vaccine manufacturer in the world - a sector we understand deeply. The combined business has an extensive product portfolio, broad global sales reach, specialized R&D and scaled manufacturing, positioning the business very well to compete globally."

"We also invested to support our future growth, completing a number of key projects and advancing our major multi-site facilities expansion program," said Mr Perreault. "We recently 'broke ground' on our new recombinant coagulation manufacturing plant in Lengnau, Switzerland. We've completed validation runs in our new Privigen<sup>®</sup> facility in Broadmeadows, Australia and obtained U.S. FDA approval to commence operations in our recently completed base fractionation and albumin facility at Kankakee, in the U.S.," Mr. Perreault added.

<sup>&</sup>lt;sup>4</sup> CSL reserves the right to suspend or terminate buy-backs at any time.



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### OUTLOOK (at FY15 exchange rates)

CSL expects strong underlying demand for its products to continue in FY16, with sales growth similar to gains achieved FY15. The Company said the market place will remain competitive, particularly as new manufacturers and products emerge.

"FY16 will be a critical year in investing in our sustainable growth," Mr Perreault said. "We continue to invest substantially in our research and development pipeline. A major investment in our commercial capabilities will be made ahead of our anticipated launch of new recombinant coagulation products in 2017. Our significant capacity expansion coming on line in FY16 will trigger a lift in fixed asset depreciation. Notwithstanding these additional costs, we anticipate net profit after tax to grow by around 5%, with earnings per share growth to exceed profit growth.

"Given the accelerated close of the Novartis deal, we are not yet in a position to provide guidance on this business beyond what was announced<sup>5</sup> in October 2014. Consequently the gain on acquisition, integration costs and operational contribution are excluded from our guidance. We expect to provide an update on the outlook for this business in the coming months," Mr. Perreault said.

In compiling CSL's financial forecasts for the year ending 30 June 2016 a number of key variables which may have a significant impact on guidance have been identified and these have been included in the footnote<sup>6</sup> below.

<sup>&</sup>lt;sup>5</sup> On 27 October 2014, CSL announced the agreement to acquire Novartis' influenza vaccines business. Estimates of the financial impacts of the deal were provided and can be found on the company website at www.csl.com.au/investors

<sup>&</sup>lt;sup>6</sup> Key variables that could cause CSL's 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; fluctuations in interest and currency exchange rates; legislation or regulations that affect product production, distribution, pricing, reimbursement, access or tax; litigation or government investigations; and our ability to protect our patents and other intellectual property.



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### **OPERATING REVIEW**

**CSL Behring** sales of US\$5,029 million increased 7% in constant currency terms when compared to the prior comparable period.

*Immunoglobulin* product sales of US\$2,326 million grew 5% in constant currency terms, with 'normal' immunoglobulin volumes growing 8%.

Demand for intravenous immunoglobulin (IVIG) was led by Privigen<sup>®</sup>, with growth in Europe being particularly strong. Privigen's expanded indication in Europe to include its use in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) has underpinned this growth. This dynamic has contributed to the average IVIG sales price being adversely affected as a greater proportion of sales were made into lower priced markets. The U.S. market remains competitive.

Demand for subcutaneous immunoglobulin (SCIG) was strong in both North American and European markets. CSL's SCIG product, Hizentra<sup>®</sup>, offers patients the convenience of self-administration at home. In the U.S. the approval of flexible dosing has driven an increased penetration of the product into the Primary Immune Deficiency (PID) patient market.

*Albumin* sales of US\$754 million rose 12% in constant currency terms, driven by ongoing global demand. China continued to drive albumin performance boosted by improved penetration into Tier 2 and Tier 3 cities. CSL's uniquely broad suite of albumin presentations provides an attractive portfolio of choice to customers.

Haemophilia product sales of US\$1,026 million grew 3% in constant currency terms. Plasma derived haemophilia sales increased 4%, notwithstanding an ongoing transition towards recombinant therapies. Growth was largely driven by demand for Beriate<sup>®</sup> in Brazil, Poland and Germany. Haemate<sup>®</sup> and Humate<sup>®</sup> sales grew in Eastern Europe, the Middle East, Africa and North America. Helixate<sup>®</sup>, CSL's recombinant factor VIII, delivered modest growth following the successful introduction of a patient retention program. New entrants continue to make this market competitive.

*Specialty products sales* of US\$923 million grew 15% in constant currency terms, tempered by a sales decline of wound healing products in Japan. The remaining group of specialty products grew 18%, driven largely by strong sales of Kcentra<sup>®</sup>, Berinert<sup>®</sup> and Zemaira<sup>®</sup>.



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Kcentra<sup>®</sup> (4 factor pro-thrombin complex concentrate) continued to grow strongly following the launch of the surgical indication approved by the U.S. FDA. In December the U.S. Centres for Medicare and Medicaid Services approved an extension to the new technology add-on payment for Kcentra<sup>®</sup> through to September 2015, recognising its significant clinical advancement in reversing the effects of warfarin in patients who experience acute major bleeding.

Strong demand for Berinert<sup>®</sup> continued. Berinert<sup>®</sup> (C1-esterase inhibitor concentrate) is used for the treatment of acute attacks in patients with hereditary angioedema. In 2012, the U.S. FDA approved a label expansion to include self-administration and now in excess of 75% of patients are self-administering Berinert<sup>®</sup>.

Zemaira<sup>®</sup>, which is used to treat Alpha-1 associated emphysema, grew strongly. CSL's new DNA test kits have been invaluable for patient identification. More than 9,000 kits were processed during the year.

**bioCSL** sales of A\$480 million grew 11% in constant currency terms. Influenza vaccine sales increased 18% to A\$145 million. Contributing to this growth was the re-establishment of our in-house commercial capability. bioCSL's influenza vaccines were first to market in the U.S., U.K., and Germany – an important competitive advantage.

**CSL Intellectual Property** revenue of US\$137 million declined 5% in constant currency terms. This was driven by a reduction in royalties received on intellectual property associated with human papillomavirus vaccines, which contributed US\$106 million to revenue.

### **CAPITAL MANAGEMENT**

#### Share Buyback

During October 2014, CSL announced its intention to conduct an on-market share buyback of up to A\$950 million. This program is now complete, with the repurchase of approximately 10.6 million shares representing approximately 2.2% of CSL's shares on issue.

CSL's balance sheet remains sound and modestly geared and the Company continues to deliver strong free cashflow. Cash and cash equivalents were US\$557 million as at 30



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June 2015, with interest bearing liabilities of US\$2,281 million and undrawn debt facilities of \$141 million.

### Capital management foreshadowed during FY16

In the interests of improving shareholder returns, CSL aims to maintain an efficient balance sheet. CSL has been pursuing an objective of increasing its gearing to approximately one times net debt to EBITDA. At 30 June 2015, this gearing ratio stood at 0.9x. The Board of Directors is considering a further on market share buyback program of a similar amount to the most recent program.

During the first half of FY16, CSL intends to approach the U.S. private placement market to raise the equivalent of ~US\$500 million as part of CSL's overall debt management program.

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 <u>www.csl.com.au</u> A glossary of medical terms can also be found on the website. For further information, please contact:

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### Group Results US Dollars

Full year ended June US\$ Millions	Jun 2014 Reported	Jun 2015 Reported	<b>Jun</b> <b>2015</b> at CC <sup>#</sup>	Change %
Sales	5,335	5,459	5,733	7.5%
Other Revenue / Income	169	154	156	
Total Revenue / Income	5,504	5,613	5,889	7.0%
Earnings before Interest, Tax, Depreciation & Amortisation	1,832	1,939	1,994	8.8%
Depreciation/Amortisation	195	181	190	
Earnings before Interest and Tax	1,637	1,758	1,804	10.2%
Net Interest Expense / (Income) Tax Expense	33 297	44 335	44 348	
<b>Reported Net Profit after Tax</b>	1,307	1,379	1,412	8.0%
Acquisition costs <sup>7</sup>	-	22	22	
Adjusted Net Profit after Tax	1,307	1,401	1,434	9.7%
Total Ordinary Dividend (US\$) Final Dividend (US\$)	1.13 0.60	1.24 0.66	2.00	10% 10%
Basic EPS (US\$)	2.70	2.92	2.99	11%

<sup>&</sup>lt;sup>7</sup> One off costs associated with the acquisition of the Novartis influenza vaccine business



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(#) Constant currency removes the impact of exchange rate movements to facilitate comparability by restating the current period's results at the prior comparable period's rates. This is done in two parts: (a) by converting the current period 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"); and (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"). The sum of translation currency effect and transaction currency effect is the amount by which reported result is adjusted to calculate the result at constant currency.

Summary NPAT	
Reported Net Profit after Tax	\$1,379.0m
Translation Currency Effect (a)	\$ 91.4m
Transaction Currency Effect (b)	\$ (58.6m)
Constant Currency Net Profit after Tax *	\$1,411.8m

#### (a) Translation Currency Effect \$91.4m

Average exchange rates used for calculation in major currencies (twelve months to June 15/June 14) were as follows: USD/EUR (0.82/0.74); USD/CHF(0.94/0.91)

#### (b) Transaction Currency Effect (\$58.6m)

Transaction currency effect is calculated by reference to the applicable prior comparable period 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.

Summary Sales	
Reported Sales	\$5,458.6m
Currency Effect (c)	\$274.3m
Constant Currency Sales *	\$5,732.9m

#### c) Constant Currency Effect \$274.3m

Constant currency effect is presented as a single amount due to the complex and interrelated nature of currency impacts on sales.

\* Constant Currency Net Profit after Tax and Sales have not been audited or reviewed in accordance with Australian Auditing Standards.

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