



# ASX Announcement

For immediate release

17 August 2016

## Full Year Result 2016

### CSL Delivers Another Strong Performance

- **Double-digit sales growth in all plasma therapy groups**
- **Novel recombinant coagulation products approved and launched**
- **Seqirus formed – business turnaround program on track**
- **CSL Board to consider further share buyback of ~A\$500 million**

CSL Limited (ASX:CSL; USOTC:CSLLY) today announced a net profit after tax (NPAT) of US\$1,242 million for the full year ended 30 June 2016. After excluding the financials relating to the Novartis influenza vaccines business acquired during the year, underlying<sup>1</sup> NPAT grew 5% and earnings per share (EPS) grew 7% on a constant currency (CC)<sup>2</sup> basis.

### HIGHLIGHTS

#### Financial

- Revenue US\$6,129 million
  - *Underlying revenue up 8% at CC*
- Earnings before interest and tax (EBIT) US\$1,438 million
  - *Underlying EBIT up 7% at CC*
- NPAT US\$1,242 million
  - *Underlying NPAT up 5% at CC*
- EPS US\$2.69
  - *Reported EPS down 8%*
  - *Underlying EPS up 7% at CC*
- Research and development investment US\$614 million
- Final dividend<sup>3</sup> of US\$0.68 per share, up 3% on PCP
  - Unfranked for Australian tax purposes, payable on 7 October 2016
  - Converted to Australian currency, the final dividend is approximately A\$0.89 per share

<sup>1</sup> Underlying excludes financials relating to the Novartis influenza vaccines business (NVS-IV). NVS-IV was acquired on 31 July 2015. See end note for further detail.

<sup>2</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability. See end note for further detail.

<sup>3</sup> For shareholders with an Australian registered address, dividends will be paid in A\$ at an amount of A\$0.886652 per share (at an exchange rate of A\$1.3039/US\$1.00), and for shareholders with a New Zealand registered address, dividends will be paid in NZD at an amount of NZ\$0.943364 per share (at an exchange rate of NZ\$1.3873/US\$1.00). The exchange rates used are fixed at the date of dividend determination. All other shareholders will be paid in US\$.

**Operational****CSL Behring**

- Product sales up 10% at CC
- Idelvion® (rFIX-FP) approved by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA) and Health Canada
- Afstyla® (rFVIII-SC) approved by US FDA
- Respreeza® (AATD) approved by the EMA
- New Privigen® (IVIG) manufacturing facility in Broadmeadows, Australia, approved by US FDA

**Influenza (Seqirus)**

- Novartis influenza vaccines acquisition closed 31 July 2015
- Seqirus business launched – No. 2 global influenza vaccine leader. Turnaround program on track
- Fluad™ (influenza vaccine) approved by US FDA
- Flucelvax Quadrivalent™ (influenza vaccine) approved by US FDA
- Afluria Quad™ (influenza vaccine) approved by Australian Therapeutics Goods Administration (TGA)

**Capital Management**

- A\$1 billion share buyback<sup>4</sup> ~92% completed<sup>5</sup>

“2016 has been a transformational year for CSL,” said CSL Chief Executive Officer and Managing Director Paul Perreault. “In our 100<sup>th</sup> anniversary year, it is clear CSL has evolved from an organization that largely brought international discoveries to Australians - to an established and growing global leader which translates its own early research into commercial medicines for patients in more than 60 countries. While CSL has changed over 100 years, one aspect has not: We continue to be driven by our promise to improve lives. Over the past 12 months we have secured approvals and launched five new products – including our two novel recombinant coagulation products Idelvion® and Afstyla® – an enormous achievement and the fruit of many years of work.”

“CSL Behring, our core business, continues to perform well, delivering double digit sales growth in all biotherapy groups. This includes another outstanding performance by our subcutaneous immunoglobulin product Hizentra®, growing sales by 31%. To support this

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<sup>4</sup> CSL reserves the right to terminate buy-backs at any time.

<sup>5</sup> As at 11 July 2016

growth sustainably into the future, we have a major facilities expansion program underway around the world.”

“Early in the financial year, CSL acquired the loss-making influenza vaccines business of Novartis at a steep discount to book value. Combined with our existing flu business, we created Seqirus, the second largest influenza vaccine provider in the world,” added Mr. Perreault. “The Seqirus business turnaround program is now well underway. The transition to quadrivalent influenza vaccines has commenced, we’ve increased production from our unique cell culture facility and we received approval and launched our differentiated adjuvanted influenza vaccine, Flud™. Notably, we were the first manufacturer to have an influenza vaccine released in the US market for its upcoming flu season,” Mr. Perreault added.

#### **OUTLOOK (at FY16 exchange rates)**

Commenting on CSL’s outlook, Mr. Perreault said, “At the core, CSL is a growing, broad-based, stable business which generates solid earnings growth. We are igniting this growth with innovative biotechnology advancements, including our newly approved and launched novel recombinant therapies Idelvion® and Afstyla®. In fact, we expect to benefit this year from a full 12 months’ contribution from Idelvion® and Afstyla®. Ongoing demand for our CSL Behring therapies is expected to continue, with ongoing strong performance in differentiated products such as Hizentra®. Our range of specialty plasma products is again expected to grow strongly.”

Mr Perreault added, “The turnaround of Seqirus is on track and is expected to breakeven in FY18. Consistent with previously announced plans, Seqirus is expected to report a loss in the current fiscal year.”

“CSL is well positioned for sustainable growth and delivering shareholder value. CSL Group’s net profit after tax (NPAT) is expected to grow approximately 11%, at constant currency, on the FY16 result after adjusting for the one-off gains and costs associated with the acquisition of the Novartis influenza vaccines business. On the same basis, earnings before interest, tax, depreciation and amortisation (EBITDA) is expected to grow approximately 14% this financial year. Earnings per share (EPS) are again expected to exceed profit growth,” Mr Perreault concluded.

In compiling the company's financial forecasts for the year ending 30 June 2017 a number of key variables which may have a significant impact on guidance have been identified and these have been included the footnote<sup>6</sup> below.

## OPERATING REVIEW

**CSL Behring** product sales of US\$5,245 million increased 10% at constant currency when compared to the prior comparable period.

*Immunoglobulin* product sales of US\$2,457 million grew 11% at constant currency.

The key growth driver has been Hizentra<sup>®</sup>, CSL Behring's subcutaneous immunoglobulin product where demand has been strong in both the US and Europe. Hizentra<sup>®</sup> grew sales 31% at constant currency. New patient starts, selective partnering in the Specialty Pharmacy segment and the increase in home treatment contributed to the strong performance.

Demand for intravenous immunoglobulin has also been solid led by Privigen<sup>®</sup>, which delivered sales growth of 7% at constant currency. In the US, market share was maintained in the highly competitive hospital setting. In Europe, Privigen<sup>®</sup> saw strong growth, especially in France and UK, driven by Privigen's<sup>®</sup> expanded indication to include its use in the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP). The introduction of IG IsoLo<sup>®</sup>, a manufacturing step to reduce isoagglutinin levels which contributes to further improving the product safety profile, has been well received. In Australia, Privigen<sup>®</sup> was introduced into the market following a successful tender with Australia's National Blood Authority.

*Haemophilia product* sales of US\$1,000 million grew 4% at constant currency. Plasma derived haemophilia sales grew 14% at constant currency. This increase was largely

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<sup>6</sup> Key variables 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; litigation or government investigations, and CSL's ability to protect its patents and other intellectual property.

driven by solid demand for Beriate<sup>®</sup>, led by Poland and Germany and successful tenders in Russia and Iran. Strong demand for Humate<sup>®</sup> in the US also contributed.

The strong growth in plasma derived therapies was offset to a large extent by the decline in sales of Helixate<sup>®</sup>, CSL's licensed recombinant factor VIII product. Competition in this market continues to increase with the launch of new generation recombinant FVIII products including CSL's recently approved Afstyla<sup>®</sup>.

*Specialty products sales* of US\$977 million grew 11% at constant currency. Sales of Kcentra<sup>®</sup> (4 factor pro-thrombin complex concentrate) in the US were strong driven by our fully established sales force and greater brand awareness.

Beriner<sup>®</sup> (C1-esterase inhibitor concentrate) was another solid contributor. Beriner is used for the treatment of acute attacks in patients with hereditary angioedema (HAE). Beriner<sup>®</sup> has seen strong growth in Europe due to the increased awareness and diagnosis of HAE.

Respreeza<sup>®</sup> (Alpha-1 Proteinase Inhibitor) was launched in a number of European countries following the granting of marketing authorisation. Respreeza<sup>®</sup> is a maintenance treatment for severe Alpha-1 Antitrypsin Deficiency patients and has been shown to slow the progression of emphysema. Following the initial launch, Respreeza will be rolled out more broadly in Europe this year.

*Albumin* sales of US\$811 million rose 12% at constant currency, driven by ongoing significant global demand particularly in China and the US. In China, demand for albumin is exceptionally strong and is expected to continue. CSL is well positioned with a broad portfolio of products and an extensive distribution network that is focused on the fast growing second and third tier cities in China.

**Seqirus** sales of US\$652 million reflects 11 months of sales since the acquisition of Novartis' influenza vaccines business on 31 July 2015. Sales of influenza vaccine were adversely impacted by a mild influenza season in the northern hemisphere. The Seqirus business turnaround program remains on track<sup>7</sup>.

**CSL Intellectual Property** revenue of US\$123 million declined 10% at constant currency. The prior comparable period included a payment from CSL's licensee Janssen

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<sup>7</sup> The Group has recognised a deferred tax asset relating to current year Seqirus losses in the UK on the expectation that the business will generate future taxable profits.

Biotech Inc. to develop and commercialise CSL362, a product used to treat patients with acute myeloid leukaemia.

## **CAPITAL MANAGEMENT**

### *Share Buyback*

In October 2015, CSL announced its intention to conduct an on-market share buyback of up to A\$1 billion. To date, CSL has purchased approximately 9.1 million shares for approximately A\$924 million, representing about 92% of the intended buyback program.

### *Capital management foreshadowed during FY17*

CSL's balance sheet remains very sound and appropriately geared. The current cost of debt is at historic lows. Following the completion of the current buyback, which has approximately A\$76 million remaining, the Board of Directors will consider a further on-market share buyback program of approximately A\$500 million.

During the first half of fiscal 2017, CSL intends to approach the US private placement market to raise approximately US\$500 million as part of the company's overall capital management program.

## **CHANGES TO CSL BOARD**

Dr. Tadataka "Tachi" Yamada KBE has been appointed a Director of the Company, effective 1 September 2016. Mr John Akehurst has indicated his intention to retire from the CSL Board of Directors at the conclusion of the Company's Annual General Meeting on 12 October 2016. For further information please see the separate ASX announcement which was issued today.

## **DIVIDENDS**

CSL will offer shareholders the opportunity to receive dividend payments in US dollars by direct credit to a US bank account. This option will be available for the 2016 final dividend payment (payment date 7 October 2016). Shareholders who wish to avail themselves of this payment option for the 2016 final dividend payment must provide their valid US bank account details by the dividend record date which is 14 September 2016.

US bank account details can be provided:

- Online at [www.investorcentre.com](http://www.investorcentre.com). If not already an existing user, shareholders must create a login in order to provide their payment instruction;
- By calling our Share Registry, Computershare Investor Services, on 1800 646 882 (within Australia) or +61 (03) 9415 4178 (outside Australia);
- By writing to the Share Registry at Computershare Investor Services, GPO Box 2975, Melbourne VIC 3001 and providing the relevant particulars including your SRN or HIN.

#### **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 [www.csl.com.au](http://www.csl.com.au). 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 years ended June US\$ Millions	FY15 Reported	FY16 Reported	FY16 Reported @CC <sup>#</sup>	FY16 NVS-IV <sup>8</sup> @CC	FY16 Underlying <sup>9</sup> at CC	Change %
<b>Sales</b>	<b>5,459</b>	<b>5,909</b>	<b>6,210</b>	<b>284</b>	<b>5,926</b>	<b>8.6%</b>
Other Revenue / Income	169	220	225	62	163	
<b>Total Revenue / Income</b>	<b>5,628</b>	<b>6,129</b>	<b>6,435</b>	<b>346</b>	<b>6,089</b>	<b>8.2%</b>
<b>Earnings before Interest, Tax, Depreciation &amp; Amortisation</b>	<b>1,939</b>	<b>1,658</b>	<b>1,818</b>	<b>(294)</b>	<b>2,112</b>	<b>7.7%</b>
Depreciation/Amortisation	181	220	233	27	206	
<b>Earnings before Interest and Tax</b>	<b>1,758</b>	<b>1,438</b>	<b>1,585</b>	<b>(321)</b>	<b>1,906</b>	<b>7.1%</b>
Gain on Acquisition		176	176	176		
Net Interest Expense / (Income)	44	58	57	3	54	
Tax Expense	335	314	347	(32)	379	
<b>Net Profit after Tax</b>	<b>1,379</b>	<b>1,242</b>	<b>1,357</b>	<b>(116)</b>	<b>1,473</b>	
NVS-IV one-off (gain)/costs	22	(90)	(90)	(90)	0	
<b>Underlying Net Profit after Tax</b>	<b>1,401</b>	<b>1,152</b>	<b>1,267</b>	<b>(206)</b>	<b>1,473</b>	<b>5.2%</b>
Total Dividend (US\$)	1.24	1.26				
Final Dividend (US\$)	0.66	0.68				3.0%
Reported EPS (US\$)	2.92	2.69				(8.0%)
Underlying <sup>9</sup> EPS (US\$)	2.97				3.19	7.4%

<sup>8</sup> Novartis influenza vaccines acquisition as from 31 July 2015

<sup>9</sup> Underlying excludes financials relating to the Novartis influenza vaccines business (NVS-IV)



<sup>(#)</sup> 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**

<b>Reported net profit after tax</b>	<b>US\$1,242.4m</b>
Translation currency effect (a)	US\$85.5m
Transaction currency effect (b)	US\$(7.7m)
Foreign Currency losses (c)	US\$37.2m
<b>Constant currency net profit after tax *</b>	<b>US\$1,357.4m</b>

**a) Translation Currency Effect NPAT \$85.5m**

Average Exchange rates used for calculation in major currencies (twelve months to June 16/June 15) were as follows: USD/EUR (0.90/0.82); USD/CHF (0.98/0.94).

**b) Transaction Currency Effect NPAT \$(7.7m)**

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 Effect NPAT \$37.2m**

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

**Underlying Net Profit after Tax at Constant Currency**

At the time of the 2015 results CSL provided guidance to the market excluding the Novartis Influenza business (NVS-IV) that was acquired by the Group on 31 July 2015. Guidance to the market was presented excluding the anticipated financial performance of NVS-IV given the uncertainty around that performance at the time of the publication of the 2015 results.

There are three elements that bridge the constant currency result noted above to the Underlying Net Profit after Tax at constant currency:

**d) Operational Performance NVS-IV NPAT (\$205.5m)**

Operational performance of the NVS-IV business – the business recorded a Net Loss after Tax of \$205.5m

**e) One off items NPAT (\$86.6m)**

One off items comprise acquisition and integration costs that were incurred during the year. Acquisition costs include professional fees and travel. Integration costs are those costs incurred in bringing the acquired business into the CSL Group, these include salary costs, professional fees and travel. Together acquisition and integration costs are \$86.1m after tax – these costs have been charged to the income statement of the Group.

**f) Gain on acquisition NPAT \$176.1m**

The acquisition gave rise to a gain as the fair value of net assets acquired was greater than the consideration paid. Full details of the gain are included in the financial statements in Note 1b.

<b>Constant currency net profit after tax *</b>	<b>US\$1,357.4m</b>
Operational performance of NVS-IV (d)	US\$205.5m
One-off items (e)	US\$86.6m
Gain on acquisition (f)	US\$(176.1m)
<b>FY16 underlying constant currency NPAT</b>	<b>US\$1,473.4m</b>

**Summary Sales**

Reported sales	US\$5,909.5m
Currency effect	US\$300.1m
Constant currency sales (Group)	US\$6,209.6m
NVS-IV sales	US\$283.8m
Underlying FY16 Sales	US\$5,925.8m

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

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# CSL Limited 2016 Full Year Result

17 August 2016



The CSL logo, consisting of the letters "CSL" in a bold, red, sans-serif font, positioned in the bottom right corner of the slide.

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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; 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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# Financials

Revenue US\$6.1 billion

- *Underlying<sup>1</sup> revenue up 8.2% @CC<sup>2</sup>*      *Guidance ~7% @CC*

EBIT US\$1,438 million

- *Underlying EBIT up 7% @CC*

NPAT US\$1,242 million

- *Underlying NPAT up 5.2% @CC*      *Guidance ~5% @CC*
- *NVS-IV NPAT (\$116m)*      *Guidance (~\$90-120m)*

EPS US\$2.69

- *Reported EPS down 8.0%*
- *Underlying EPS up 7.4% @CC*

Research & Development investment US\$614 million

Final dividend increased to US\$0.68, up 3% on PCP, unfranked

3 1. *Underlying excludes financials relating to the Novartis influenza vaccines business (NVS-IV). NVS-IV was acquired on 31 July 2015*  
2. *Constant Currency (CC) removes the impact of exchange rate movements to facilitate comparability of operational performance. See end note for further detail.*

# Highlights

## CSL Behring

- Product sales up 10% @ constant currency
- Idelvion<sup>®</sup> (rFIX-FP) approved by US FDA, EMA and Health Canada
- Afstyl<sup>®</sup> (rFVIII-SC) approved by US FDA
- Respreeza<sup>®</sup> (AATD) approved by the EMA
- New Privigen<sup>®</sup> (IVIG) manufacturing facility approved by US FDA

## Influenza (Seqirus)

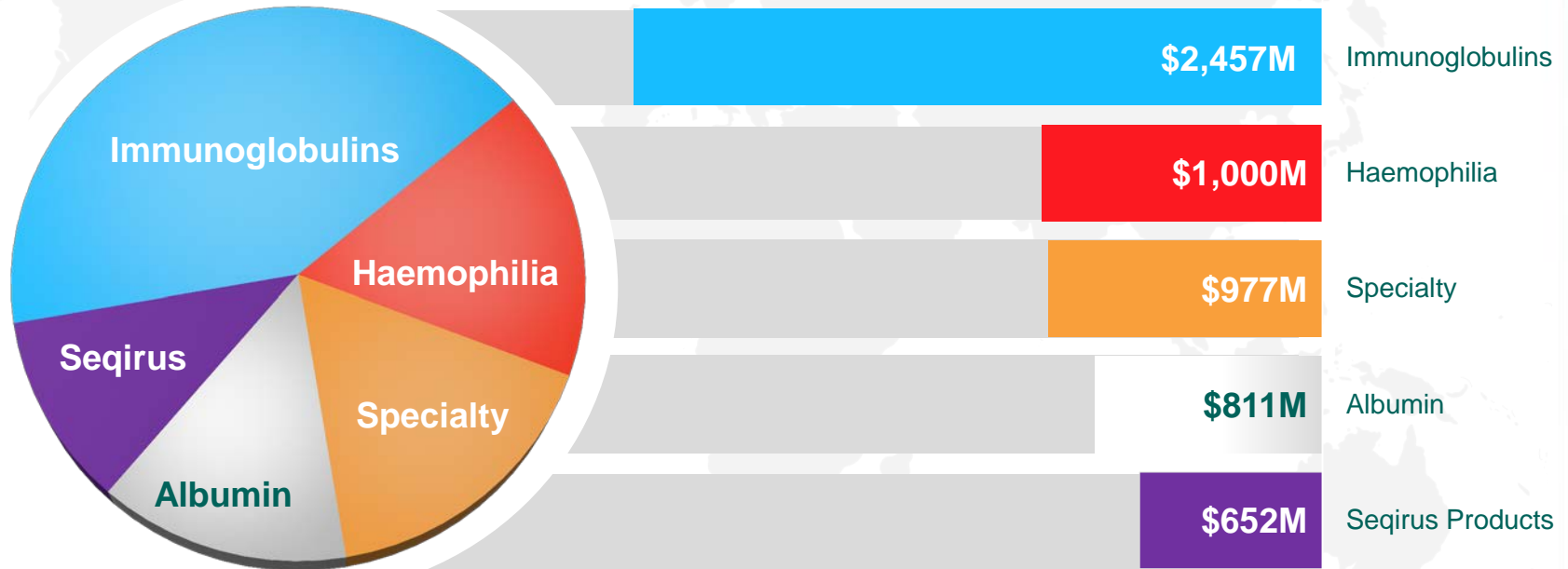
- Novartis influenza vaccines acquisition closed 31 July 2015
- 'Seqirus' launched – No 2 global influenza vaccine manufacturer
- Flud<sup>™</sup> approved by US FDA
- Flucelvax Quadrivalent<sup>™</sup> approved by US FDA
- Afluria Quad<sup>™</sup> approved by Australian TGA

## Capital Management

- A\$1 billion share buyback<sup>1</sup> ~92% completed<sup>2</sup>

# Group Sales

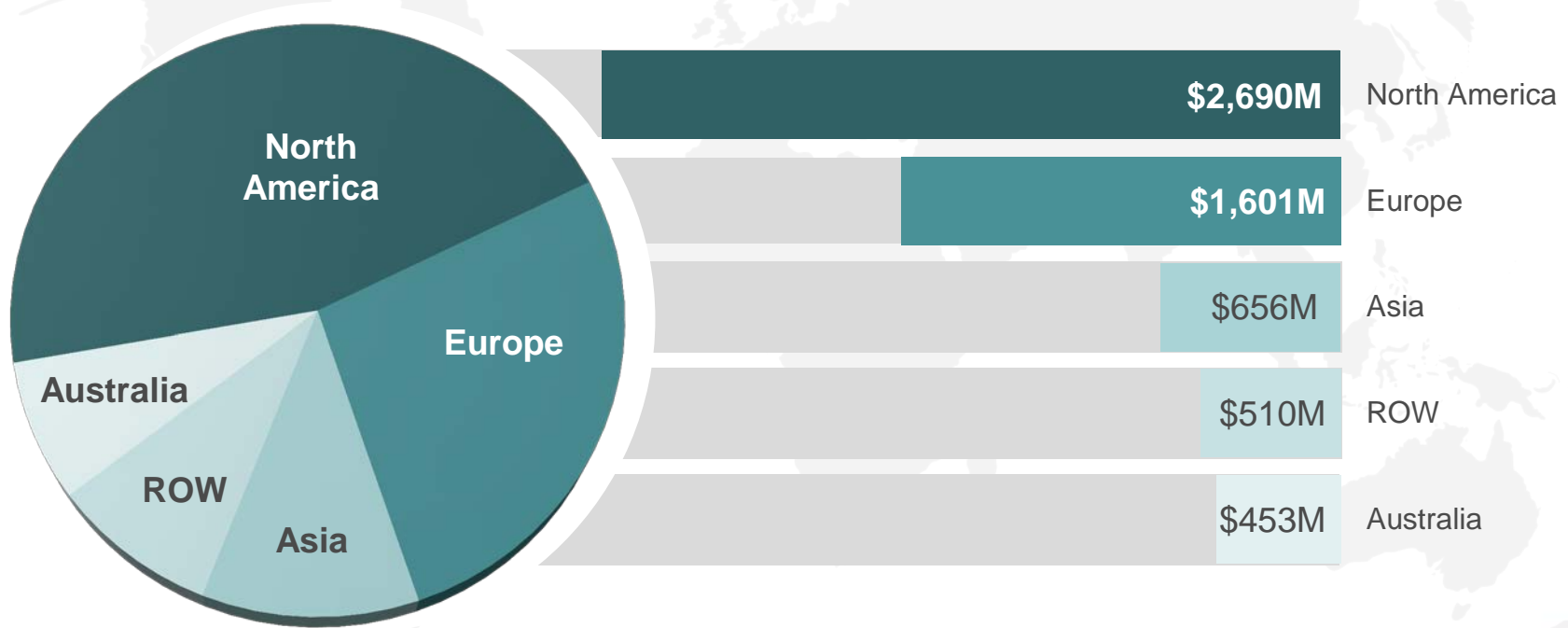
CSL FY16 Sales US\$5.9B



**Broad portfolio of products**

# Broad Sales Reach

CSL FY16 Sales US\$5.9B



# Looking Forward into FY17<sup>1</sup>

**NPAT growth<sup>2</sup> ~ 11% @ CC<sup>3</sup>**  
**EBITDA growth<sup>2</sup> ~14% @ CC**  
**EPS growth to exceed NPAT growth**

Revenue expected to grow ~9% @ CC

- Continued strong demand for plasma therapy products
- Full year rCOAGs sales contribution
- Seqirus fully participating in a normal flu season

Investing for the future

- New capacity to support growth
- Enterprise Process Management initiative
- Planning for CSL112 (apoA-I) Phase III continuing

Capital management

- New ~A\$500m share buyback foreshadowed
- New ~US\$500m US private placement

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

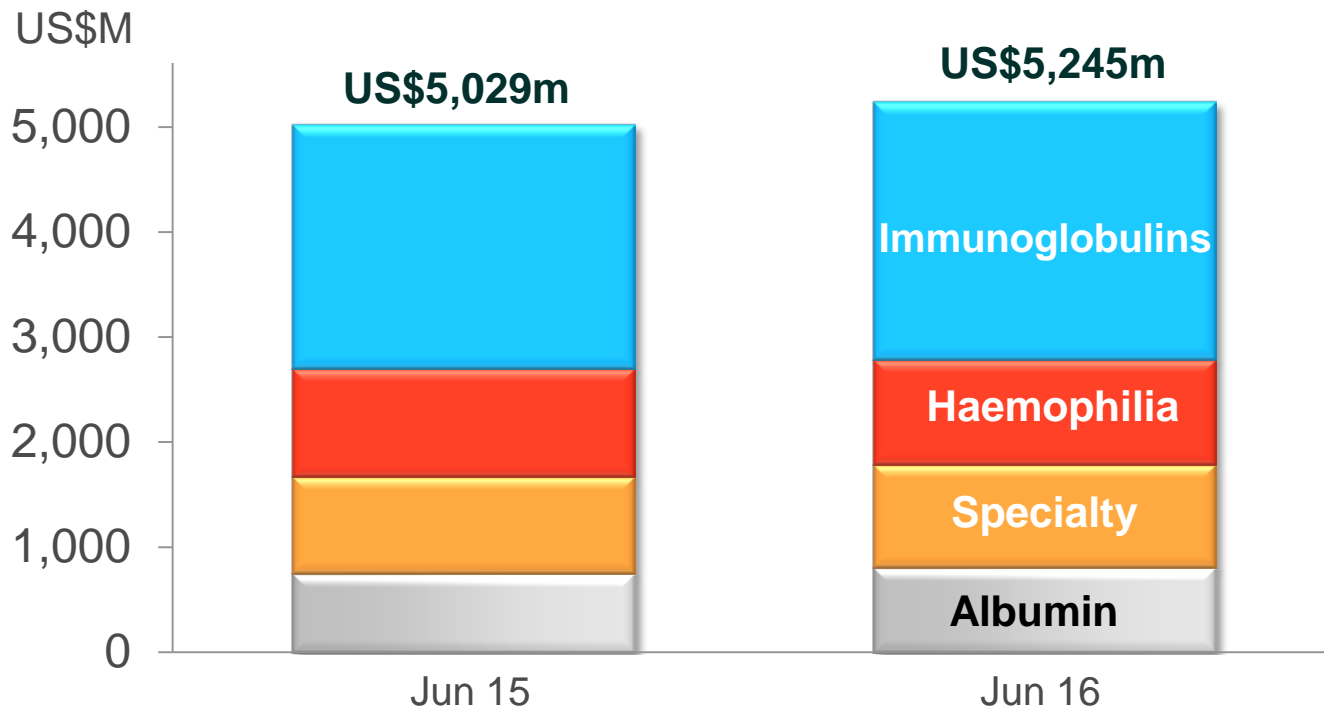
<sup>2</sup> Excludes one-off gains and costs (net US\$90m) relating to the acquisition of NVS-IV during FY2016 – see appendix for detail

<sup>3</sup> Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability

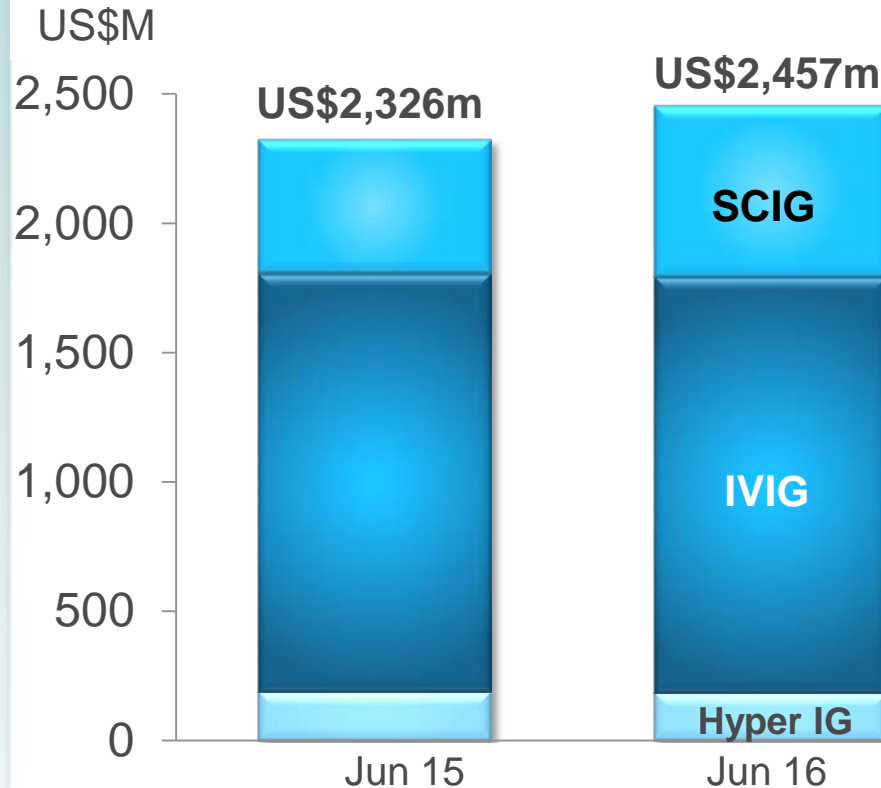




## *Business Unit Performance*



*Reported sales for the 12 month period*



Reported sales for the 12 month period

## Highlights

SCIG – Hizentra® up 31%

- Significant increase in new patient starts in both US and EU
- Strong specialty pharmacy growth driven by at home treatment

IVIG – Privigen® up 7%

North America

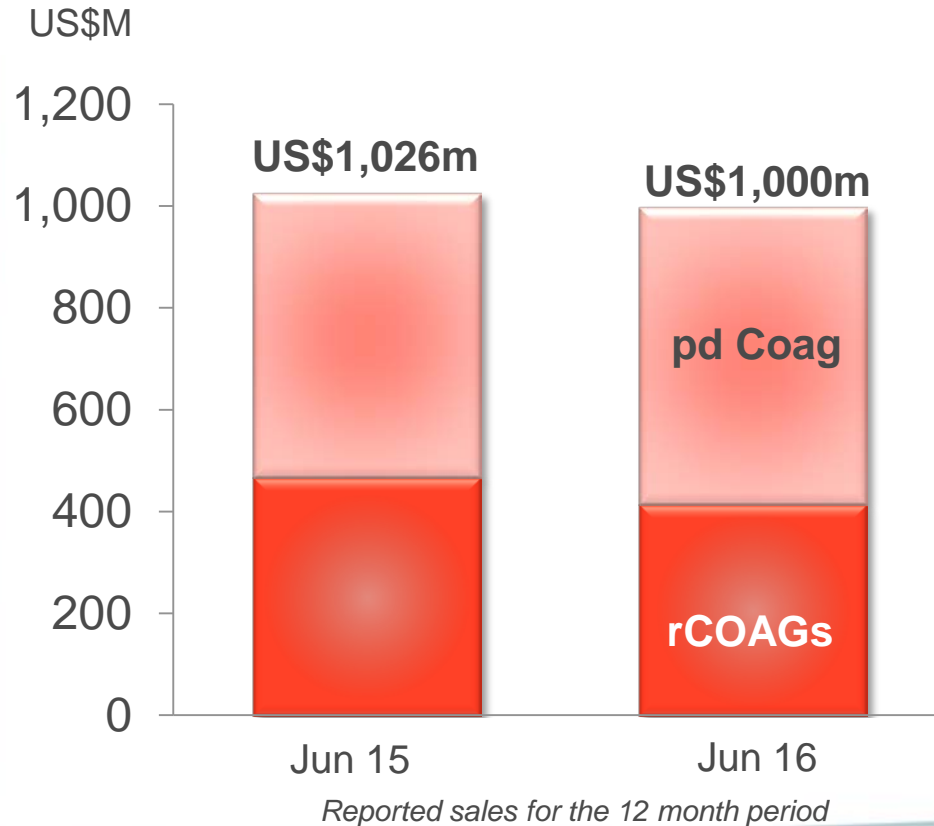
- Maintained share in competitive hospital setting
- Grew share in the non-acute setting

Europe

- Growth in France & UK driven by neurology
- Introduction of IG IsoLo® well received

Australia

- Privigen® launched



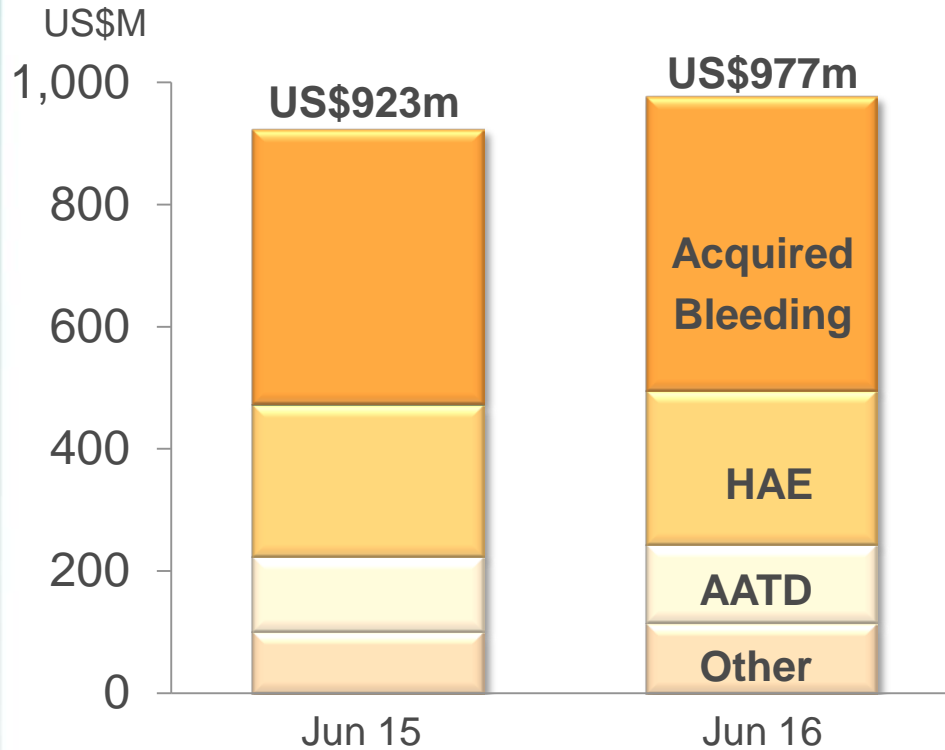
## Highlights

### pdCOAGs

- Solid growth in Humate®
- Growth in Beriate® driven by Eastern European and global tenders
- Volume growth in developing markets

### rCOAGs

- Volumes declined driven by the competitive environment for rFVIII



*Reported sales for the 12 month period*

## Highlights

### Kcentra<sup>®</sup> / Beriplex<sup>®</sup>

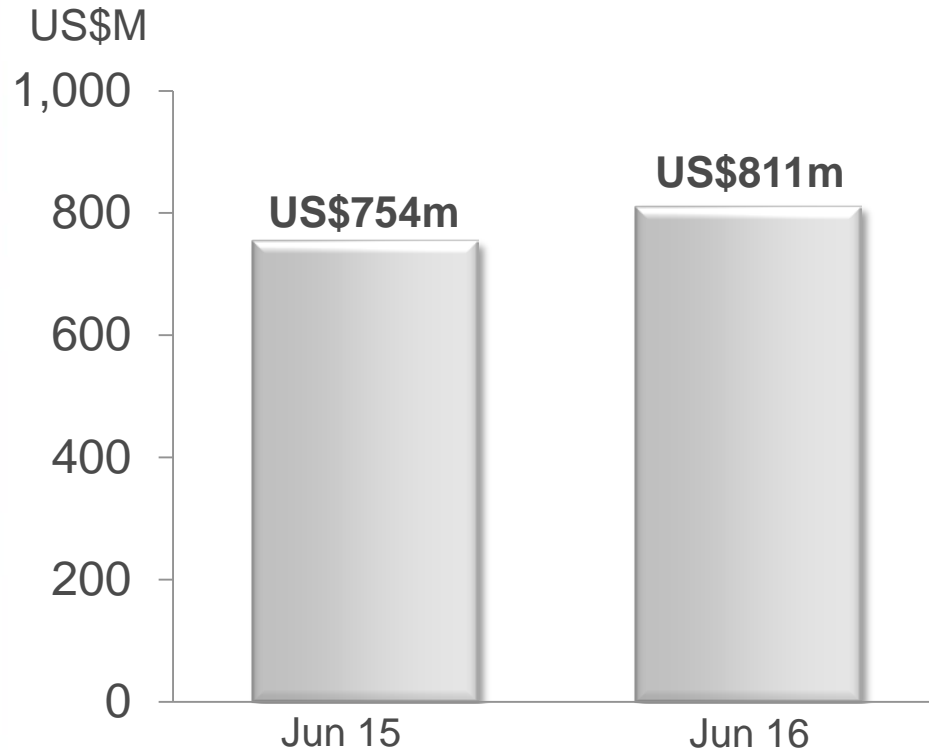
- Sales up strongly in the US due to increased focus and commercial investment

### Beriner<sup>®</sup> P

- New patient starts in the US up 9%
- Increasing awareness and diagnosis in EU

### Zemaira<sup>®</sup> / Respreeza<sup>®</sup>

- Launched in EU



*Reported sales for the 12 month period*

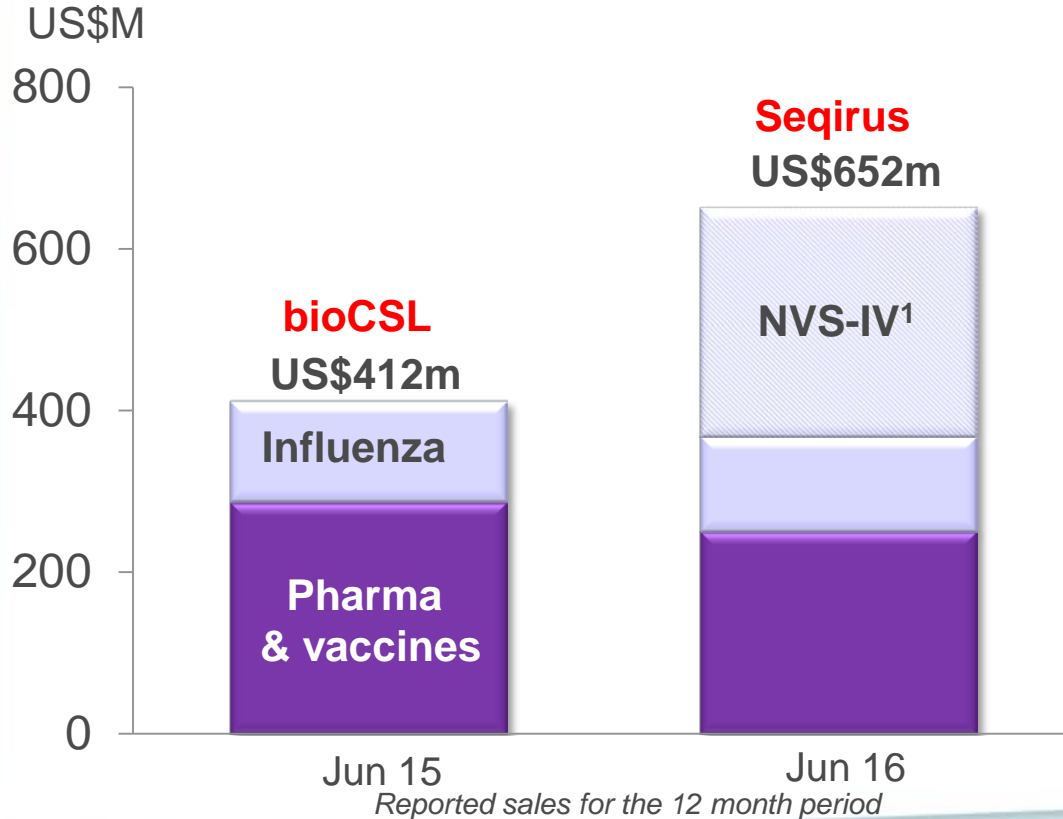
## Highlights

### China

- 26% sales growth
- Continued strong sales momentum
- Extensive distribution network

### US

- Solid demand
- Expansion of integrated delivery networks and large hospital contracts contributing to majority of growth



## Highlights

- FY16 includes 11 months from NVS-IV
- Mild 2015/16 northern hemisphere influenza season
- TIV portfolio in FY16
- In-license product fluctuation

## Operations

- Integration substantially complete
- Enhanced efficiency, sharing of best practices
- New formulation facility in Liverpool

## Product launches

- Recent US launch of Flucelvax Quadrivalent™ and Fluad™
  - Full year impact from FY18
- Seqirus influenza vaccines 1<sup>st</sup> to market in the US

## Clinical trials

- Fluad™: quadrivalent in elderly and paediatric
- Afluria Quad™: paediatric



Segment Revenue \$123m, down 10% @CC

- PCP includes license payment relating to CSL 362

HPV royalties \$120m, up 14% @CC

- Registration of 9-valent HPV vaccine in US by Merck

CSL362 (anti-IL-3Ra mAb)

- Exclusive worldwide license with Janssen Biotech to develop and commercialise CSL362
- Phase 2 AML study commenced by Janssen Biotech July 2015
- Commitment to exploratory study in SLE (Lupus) patients

## Idelvion® (rIX-FP)

- rIX-FP Phase III efficacy data supports 7-14 day dosing
- Extension study supports dosing interval of up to 21 days for prophylaxis in appropriate patients
- Adult and pediatric indications approved in Canada, US and EU

## Afstyla® (rVIII-SingleChain)

- Phase I/III data supports twice weekly prophylaxis
- Prophylaxis treatment demonstrates long-lasting efficacy in paediatric patients
- Adult and paediatric indications approved in US in May 16
- Application submitted to the European authorities in Dec 15

## Hizentra® (SCIG)

- Hizentra® flexible dosing registration in US
- Hizentra® CIDP pivotal study recruitment completed

## Beriplex<sup>®</sup> (Prothrombin Complex Concentrate)

- Phase III study in Japan nearing completion
- Orphan Drug Designation received in Japan in March 16

## Beriner<sup>®</sup>/CSL830 (C1 Esterase Inhibitor)

- CSL830 (subcut) pivotal Phase III study successfully completed
- Beriner<sup>®</sup> approved for use in paediatric patients in the US in July 16
- Anti-FXIIa mAb pre-clinical development in HAE completed

## Zemaira<sup>®</sup>/Respreeza<sup>®</sup> (Alpha1-Proteinase Inhibitor)

- Respreeza<sup>®</sup> approved by EMA in August 15

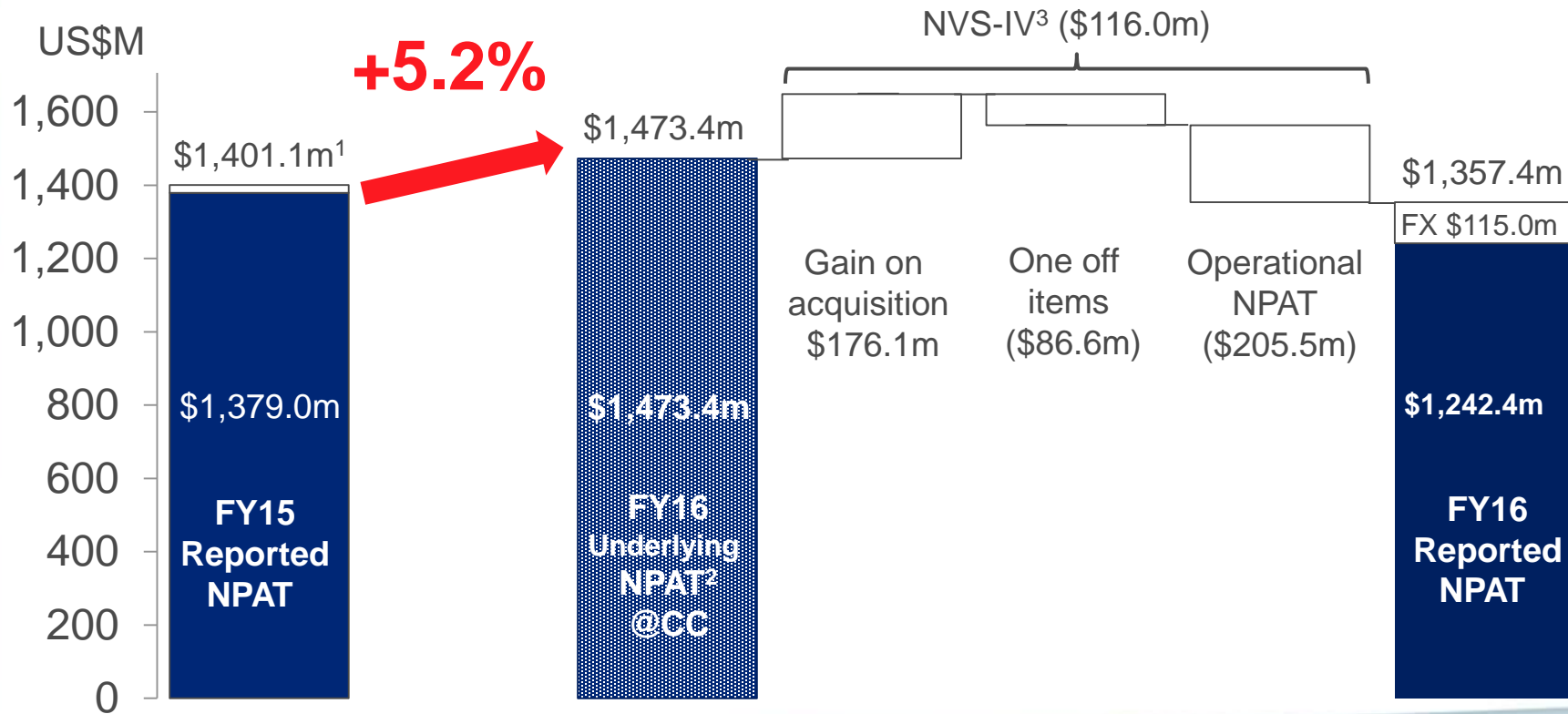
## CSL112 (Apolipoprotein A-I)

- AEGIS-I Phase IIb study completed
- Planning for Phase III continuing



# *Financials*

# FY16 Profit Growth

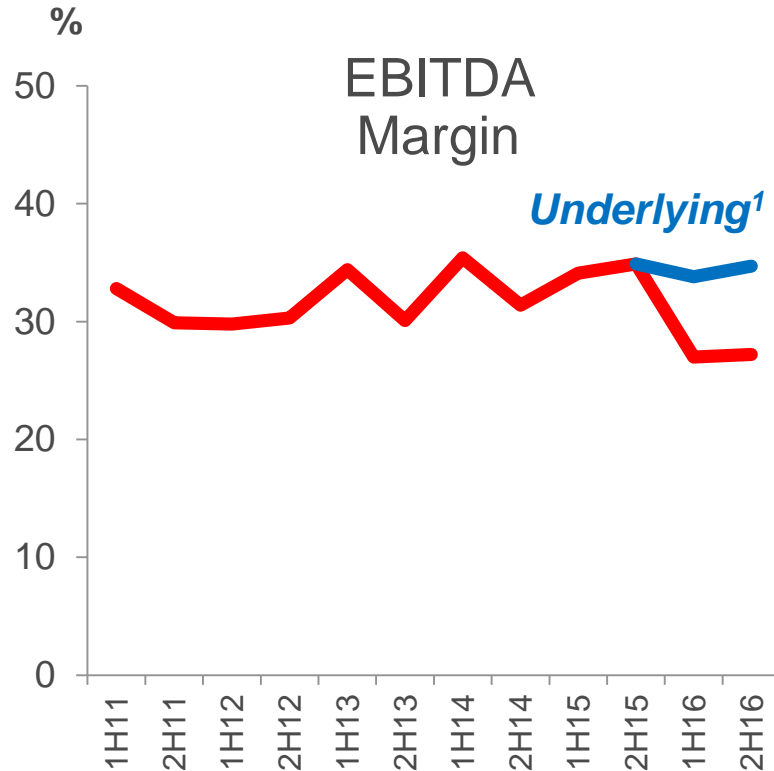


1. Excludes \$22.1m Novartis influenza vaccines business NVS-IV acquisition costs

2. Underlying excludes financials relating to the Novartis influenza vaccines business (NVS-IV)

3. NVS-IV was acquired on 31 July 2015

# Margin Development



## FY16

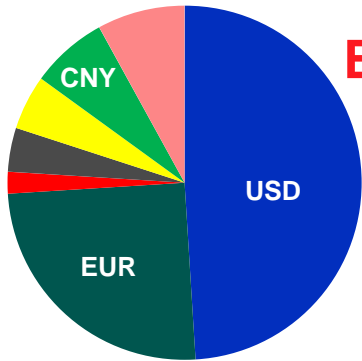
- Margin impacted by NVS-IV acquisition & commercial operations preparation for rCOAG launches

## Outlook<sup>2</sup>

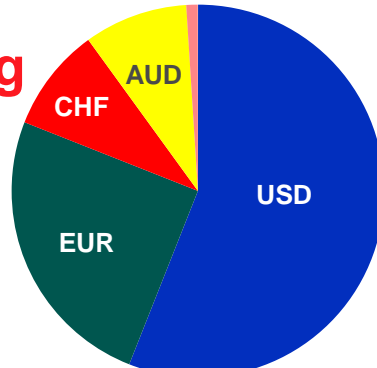
- Margin to benefit from transitioning to CSL's rCOAGs
- Helixate<sup>®</sup> sales to extend beyond supply contract expiry
- Seqirus turnaround

# Currency Exposure

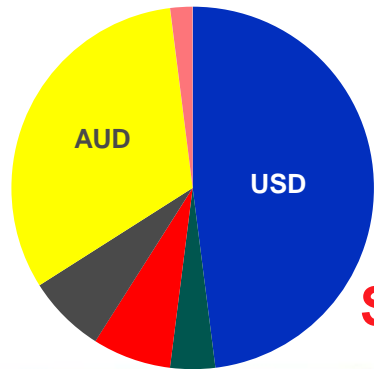
## CSL Behring



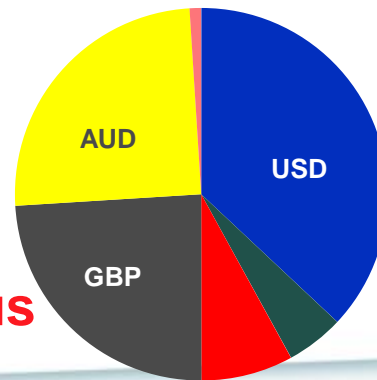
*Inflows*



*Outflows*



## Seqirus



## CSL Behring

- Balance in USD & Euro flows
- Lengthy period between flows

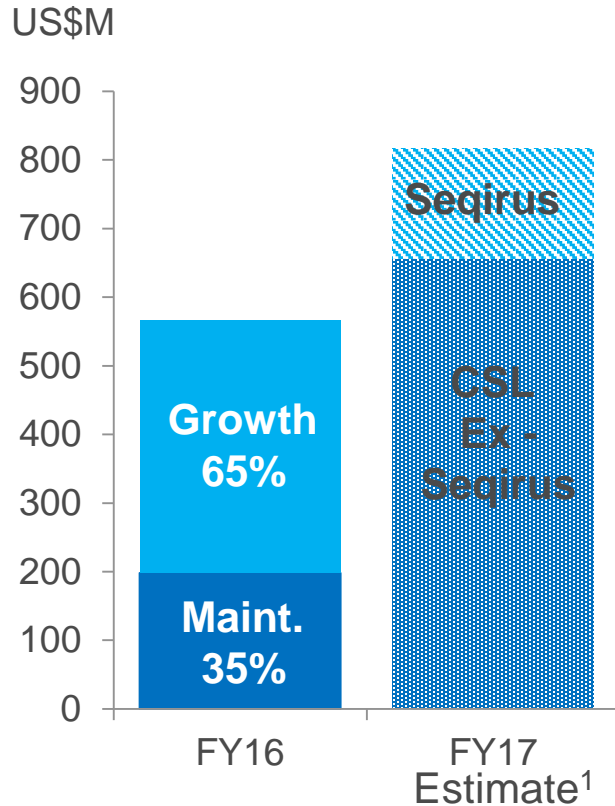
## Seqirus

- Balance to improve as Flucelvax volumes increase
- Influenza sales skewed for 1H - outflows more even through year
- FX composition will change with discontinuation of TSAs

## Group

- Hedge material known contracts
- FX impact<sup>1</sup> in FY17 ~(\$35m) at current rates

# Capital Expenditure



## Seqirus – *Establishment*

- Liverpool – new formulation facility
- New IT platform

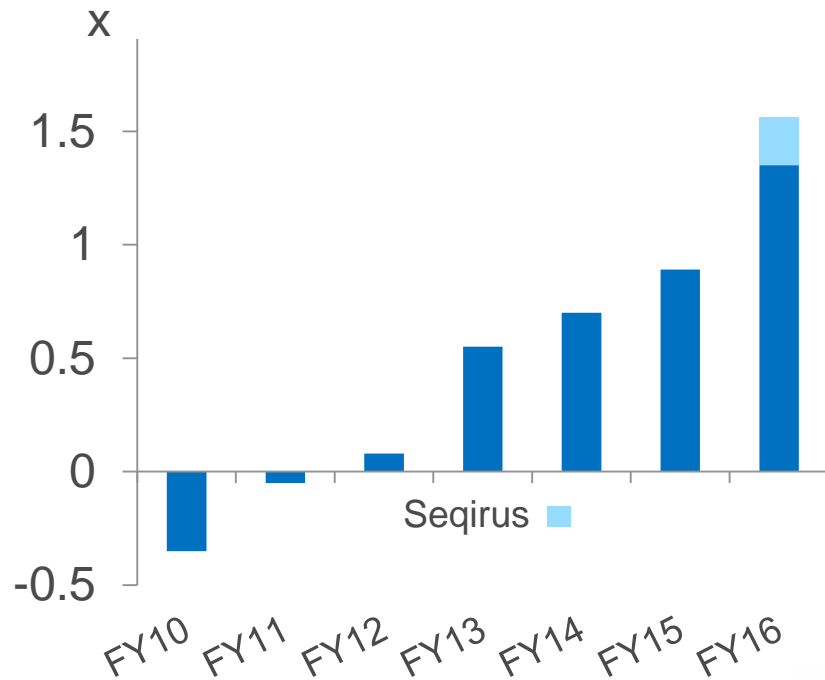
## CSL Behring - *Growth*

- Marburg – new base fractionation
- Bern – warehousing & logistics & filling line
- Kankakee – new base fractionation
- Lengnau – new rCOAG manufacturing
- Broadmeadows – new albumin manufacturing
- EPM initiative



# Effective Capital Management

## Net Debt/EBITDA



- Appropriate balance sheet leverage beneficial to shareholders
- NVS-IV acquisition lifts Net Debt to EBITDA ratio
- Cost of debt at historic lows
- Strong group cash generation
- Debt coverage well below debt covenants
- Net interest coverage 32x

# Looking Forward<sup>1</sup>

**NPAT growth<sup>2</sup> ~ 11% @ CC<sup>3</sup>**  
**EBITDA growth<sup>2</sup> ~14% @ CC**  
**EPS growth to exceed NPAT growth**

Notable items:

- Gross margin – modest growth with full year of rCOAG contributions
- D&A – increase in capex to support CSL Behring growth, establishment of Seqirus and EPM initiative
- Interest – funding for capex, buyback, Seqirus financing costs
- Effective tax rate – product mix shift leading to ~20 to 22% ETR
- Seqirus – continue to anticipate breakeven in FY18

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

<sup>2</sup> Excludes one-off gains and costs (net US\$90m) relating to the acquisition of NVS-IV from FY2016 – see appendix for detail

<sup>3</sup> Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability

# CSL Strategy for Profitable Growth

## Future Growth Pipeline

- CSL 112 – new treatment paradigm in ACS
- CSL 830 – HAE
- Pipeline antibodies
- Targeted business development

## Growth Drivers

Seqirus


CSL  
Behring

- Drive Seqirus business to profitability
- Successfully launch pipeline vaccines
- Launch & grow recombinant coagulation factors
- Maintain leadership in Ig and albumin
- Grow high-margin specialty products

## Core Plasma

- Relentless commitment to lowest cost base
- Remain ahead of the demand curve
- Organic growth of core plasma products

**Sustained  
Financial  
Performance**



# CSL Limited 2016 Full Year Result

17 August 2016

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



# Group Results

Full year ended June US\$ Millions	FY15 Reported	FY16 Reported	FY16 Reported @CC <sup>3</sup>	FY16 NVS-IV <sup>1</sup> @CC	FY16 Underlying <sup>2</sup> @CC	Change %
<b>Sales</b>	<b>5,459</b>	<b>5,909</b>	<b>6,210</b>	<b>284</b>	<b>5,926</b>	<b>8.6%</b>
Other Revenue / Income	169	220	225	62	163	
<b>Total Revenue / Income</b>	<b>5,628</b>	<b>6,129</b>	<b>6,435</b>	<b>346</b>	<b>6,089</b>	<b>8.2%</b>
<b>Earnings before Interest, Tax, Depreciation &amp; Amortisation</b>	<b>1,939</b>	<b>1,658</b>	<b>1,818</b>	<b>(294)</b>	<b>2,112</b>	<b>7.7%</b>
Depreciation/Amortisation	181	220	233	27	206	
<b>Earnings before Interest and Tax</b>	<b>1,758</b>	<b>1,438</b>	<b>1,585</b>	<b>(321)</b>	<b>1,906</b>	<b>7.1%</b>
Gain on Acquisition		176	176	176		
Net Interest Expense / (Income)	44	58	57	3	54	
Tax Expense	335	314	347	(32)	379	
<b>Net Profit after Tax</b>	<b>1,379</b>	<b>1,242</b>	<b>1,357</b>	<b>(116)</b>	<b>1,473</b>	
NVS-IV one off (gain)/costs	22	(90)	(90)	(90)	0	
<b>Underlying Net Profit after Tax</b>	<b>1,401</b>	<b>1,152</b>	<b>1,267</b>	<b>(206)</b>	<b>1,473</b>	<b>5.2%</b>
Total Dividend (US\$)	1.24	1.26				
Final Dividend (US\$)	0.66	0.68				3.0%
Reported EPS (US\$)	2.92	2.69				(8.0%)
Underlying <sup>2</sup> EPS (US\$)	2.97				3.19	7.4%

1. Novartis influenza vaccines acquisition as from 31 July 2015

2. Underlying excludes financials relating to the Novartis influenza vaccines business

3. Constant Currency (CC) removes the impact of exchange rate movements to facilitate comparability of operational performance. See end note for further detail.

# CSL Behring Sales

Full year ended June US\$ Millions	FY15	FY16	FY16 CC <sup>1</sup>	Change %
<b>Immunoglobulins</b>	<b>2,326</b>	<b>2,457</b>	2,571	11%
<b>Haemophilia</b>				
- <i>Recombinants</i>	468	415	434	(7%)
- <i>Plasma</i>	558	585	634	14%
<b>Specialty</b>	<b>923</b>	<b>977</b>	1,021	11%
<b>Albumin</b>	<b>754</b>	<b>811</b>	848	12%
<b>Total Product Sales</b>	<b>5,029</b>	<b>5,245</b>	5,508	10%
<i>Other sales (mainly plasma)</i>	18	12		
<i>Total Sales</i>	5,047	5,257		

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

# Financial Appendix

## CSL GROUP

Full Year ended June US\$ Millions	FY16 Actual	FY17 Guidance <sup>1</sup>
<b>Reported Revenue</b>	6,129	~9% growth @CC <sup>2</sup>
<b>Reported EBITDA</b>	1,658	
NVS-IV one-offs <sup>3</sup>	91	
Underlying EBITDA	1,749	~14% growth @CC
<b>Reported Net Profit after Tax</b>	1,242	
NVS-IV one-offs <sup>4</sup>	(90)	
Underlying NPAT	1,152	~11% growth @CC
 FX Impact <sup>5</sup>		 ~(\$35M)

1 For forward looking statements, refer to Legal Notice on page 2

2 Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability. See end note for further detail.

3 Comprises one-off acquisition related costs of \$91m (@EBIT line)

4 Comprises gain on acquisition ~US\$176.1m & one off acquisition related costs of \$86.6m (@NPAT line)

5 Assumes current rates remain steady for the remainder of the year

(#) 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**

<b>Reported net profit after tax</b>	<b>US\$1,242.4m</b>
Translation currency effect (a)	US\$85.5m
Transaction currency effect (b)	US\$(7.7m)
Foreign Currency losses (c)	US\$37.2m
<b>Constant currency net profit after tax *</b>	<b>US\$1,357.4m</b>

#### **a) Translation Currency Effect NPAT \$85.5m**

Average Exchange rates used for calculation in major currencies (twelve months to June 16/June 15) were as follows: USD/EUR (0.90/0.82); USD/CHF (0.98/0.94).

#### **b) Transaction Currency Effect NPAT \$(7.7m)**

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 Effect NPAT \$37.2m**

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



## Underlying Net Profit after Tax at Constant Currency

At the time of the 2015 results CSL provided guidance to the market excluding the Novartis Influenza business (NVS-IV) that was acquired by the Group on 31 July 2015. Guidance to the market was presented excluding the anticipated financial performance of NVS-IV given the uncertainty around that performance at the time of the publication of the 2015 results.

There are three elements that bridge the constant currency result noted above to the Underlying Net Profit after Tax at constant currency:

### d) Operational Performance NVS-IV NPAT (\$205.5m)

Operational performance of the NVS-IV business – the business recorded a Net Loss after Tax of \$205.5m

### e) One off items NPAT (\$86.6m)

One off items comprise acquisition and integration costs that were incurred during the year. Acquisition costs include professional fees and travel. Integration costs are those costs incurred in bringing the acquired business into the CSL Group, these include salary costs, professional fees and travel. Together acquisition and integration costs are \$86.1m after tax – these costs have been charged to the income statement of the Group.

### f) Gain on acquisition NPAT \$176.1m

The acquisition gave rise to a gain as the fair value of net assets acquired was greater than the consideration paid. Full details of the gain are included in the financial statements in Note 1b.

<b>Constant currency net profit after tax *</b>	<b>US\$1,357.4m</b>
Operational performance of NVS-IV (d)	US\$205.5m
One-off items (e)	US\$86.6m
Gain on acquisition (f)	US\$(176.1m)
<b>FY16 underlying constant currency NPAT</b>	<b>US\$1,473.4m</b>

### Summary Sales

Reported sales	US\$5,909.5m
Currency effect	US\$300.1m
Constant currency sales (Group)	US\$6,209.6m
NVS-IV sales	US\$283.8m
Underlying FY16 Sales	US\$5,925.8m

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



# CSL Limited

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