



# ASX Announcement

For immediate release

18 August 2010

## Full Year Result

**Profit \$1,053 million (\$1,240m at constant currency<sup>1</sup> up 22%<sup>2</sup>)**

**Cash Flow from Operations \$1,168 million up 14%**

**New share buyback announced – up to \$900 million<sup>3</sup>**

**Final dividend 45 cents per share up 13%**

CSL Limited today announced a profit after tax of \$1,053 million for the twelve months ended 30 June 2010. This result included an unfavourable foreign exchange impact of \$187 million. On a constant currency (cc<sup>1</sup>) basis, operational net profit after tax grew 22% after excluding one-off non-operational items<sup>2</sup> in fiscal 2009, as previously disclosed.

## KEY ITEMS

### Financials

- Total sales revenue of \$4.5 billion up 10% at cc
  - Global sales and fill & finish activities relating to CSL's pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>), totalled \$235 million
- Reported net profit after tax of \$1,053 million (\$1,240 million at cc up 22%<sup>2</sup>)
  - Foreign currency headwind of \$187 million
- Research and Development investment of \$317 million up 10% at cc
- Cash flow from operations of \$1,168 million up 14%
- Strong Balance Sheet - cash on hand \$1,001 million, borrowings \$462 million
- Final dividend 45 cents per share, up 13%, partially franked to 11%, payable on 8 October 2010. Total ordinary dividends for the year were 80 cents per share up 14% on the previous year.

### Capital Management

- On-market share buyback complete ~\$1.8 billion returned to shareholders
- New on-market share buyback announced, up to \$900 million<sup>3</sup>
- Dividend payout ratio lifted to 43%.

<sup>1</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability.

<sup>2</sup> Comparative period of fiscal 2009 excludes one-off non-operational items, as previously disclosed, relating to the discontinuation of the Talecris merger and certain tax items.

<sup>3</sup> CSL reserves the right to suspend or terminate the buyback at any time.

**Operational**

- Australian fractionation agreement renewed to 31 December 2017
- Privigen® – Transition well underway
- Berinert® (C1-Esterase Inhibitor)
  - US FDA grants marketing approval, product launched
  - European approvals extended
  - Australian TGA approval, Notice of Compliance received from Health Canada
  - Product now registered in 28 countries
- Hizentra™ (Subcutaneous IG 20% Liquid)
  - US FDA approved, product launched
  - First 20% subcutaneous immunoglobulin therapy
- GARDASIL® (Human Papillomavirus Vaccine)
  - Merck & Co., Inc., data on use by females aged 27 – 45
  - US FDA approval for males aged 9 - 26 for genital warts
  - Data to Australian TGA for males aged 9 - 26 for external genital lesions and infections

Dr McNamee, CSL's Managing Director, said "This is a strong operational result in a period of currency headwinds, rigorous competition and significant healthcare reform around the world. Whilst certain markets have been subdued in line with the broader economic environment, underlying medical demand for CSL's plasma therapies reflects the importance of these life saving products.

"Following the World Health Organisation (WHO) announcements regarding the 2009 influenza pandemic, CSL's global sales of H<sub>1</sub>N<sub>1</sub> Influenza or 'Swine Flu' Vaccine, together with related fill and finish activities, provided a significant contribution. CSL's clinical trials played an important role in assisting Governments around the world in determining their vaccine immunisation policy. Pandemics are rare time-critical events and CSL responded swiftly to the WHO declared emergency," Dr McNamee said.

**OUTLOOK (at 09/10 exchange rates)**

Commenting on CSL's outlook, Dr McNamee said "The WHO recently announced that the world is no longer in phase 6 of an influenza pandemic alert and has moved into the post-pandemic period.

“Notwithstanding the absence of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>) sales in fiscal 2011 and the impacts of US and European healthcare reforms and austerity measures, CSL’s underlying operational profit<sup>4</sup> growth is again expected to be solid, largely underpinned by ongoing growth in demand for plasma therapies.

“CSL is one of the world’s largest manufacturers and distributors of plasma therapies, our reach and extensive portfolio of products provides the company with a robust, broad base of earnings.

“Our Immunoglobulin strategy is evolving well and sales will benefit from a continuing shift in product mix towards Privigen<sup>®</sup> (10% liquid intravenous immunoglobulin) and the recently launched Hizentra<sup>®</sup>, our next generation product for subcutaneous delivery of immunoglobulin. Developing specialty product sales such as Berinert<sup>®</sup> (C1-Esterase Inhibitor) and continuing to expand into markets such as Canada, Russia and China will further contribute to growth in 2011.

“In compiling our financial forecasts for the year ending 30 June 2011 we have determined a number of key variables which may have a significant impact on guidance and these have been included below<sup>4</sup>.

“For the 2010/11 financial year we anticipate net profit after tax of between \$980 and \$1,030 million, at fiscal 09/10 exchange rates. Although slightly less than 2009/10, this represents a growth of up to ~10% on the underlying operational profit<sup>5</sup>, largely reflecting CSL’s global plasma therapeutics business which is expected to deliver this growth. Foreign exchange rate movements may impact this forecast and to assist investors we have provided a foreign currency sensitivity analysis with our results materials.

“Finally, CSL continues to maintain a robust balance sheet, supported by strong cashflows and excellent growth prospects. Against this background, the Board of

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<sup>4</sup> Key variables which may have a significant impact on guidance include material price and volume movements on core plasma products, competitor activity, changes in healthcare regulations and reimbursement policies, royalties arising from the sale of Human Papillomavirus vaccine, implementation of the company’s influenza strategy and plasma therapy life cycle management strategies, enforcement of key intellectual property, the risk of regulatory action or litigation, the effective tax rate and foreign exchange movements.

<sup>5</sup> Underlying operational profit for fiscal 2010 excludes contribution from sale of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>), plus related fill and finish activities, to illustrate growth in underlying business.

Directors have decided to increase the dividend payout ratio to 43%. The Board also decided to return up to \$900m of capital, in excess of the company's current needs, by way of an on-market share buyback," Dr McNamee said.

## BUSINESS REVIEW

### Results overview

**CSL Behring** sales totalled \$3.5 billion, with product sales growing 10% on a constant currency basis when compared to the twelve months ended 30 June 2009. Sales contribution from across the product portfolio has underpinned this growth.

Immunoglobulins grew 12% in constant currency terms, largely driven by a sales mix shift in the company's multiple immunoglobulin product portfolio. An ongoing transition to the company's new generation 10% liquid immunoglobulin, Privigen<sup>®</sup>, was complemented by strong take up of Vivaglobin<sup>®</sup> (Subcutaneous Immunoglobulin), a product which provides patients with the convenience of self administration. The ramp up in sales under the relatively new Canadian supply contract further boosted growth. Immunoglobulin pricing did not materially change.

The Critical Care segment grew 5% in constant currency terms (9% including the Group's Asian sales which are reported within the Biotherapies business) underpinned by volume growth of albumin, particularly in the US and emerging markets. Specialty products, primarily Haemocomplettan<sup>®</sup> P, Berinert<sup>®</sup> P and Beriplex<sup>®</sup> P/N, also made a significant contribution.

Haemophilia sales grew 8% in constant currency terms, mainly driven by product demand in the US for Helixate<sup>®</sup> and Humate<sup>®</sup> P. New contracts in Europe and the commencement of coagulation product sales in Russia, particularly Beriate<sup>®</sup>, further contributed to sales growth.

**CSL Biotherapies** total sales \$958 million grew 21% on a constant currency basis when compared to the twelve months ended 30 June 2009.

Sales of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>), together with related fill and finish activities, contributed \$235 million to sales. This was partially offset by the decline in GARDASIL<sup>®</sup> vaccine sales to \$47 million for the financial year, down \$138 million when

compared to the prior comparable period. This decline is consistent with immunisation 'catch-up' programs in Australia drawing to a close as previously foreshadowed. Seasonal influenza vaccine sales totalled \$124 million for the period. Contributions from Intragam® P (Liquid 10% Immunoglobulin) in Australia and albumin in China also contributed to sales growth.

In Australia this year, CSL's 2010 seasonal influenza vaccine was associated with an increased rate of febrile reactions in children, predominantly under the age of 5, shortly after vaccination, compared to previous seasons. In response, we informed doctors and immunisation providers about the reactions, inserted new warnings and precautions into prescribing information and voluntarily retrieved remaining doses of our paediatric influenza vaccine. To prepare for the 2010/2011 Northern Hemisphere influenza season, CSL worked closely with government authorities and distribution partners to determine the most responsible action to take in the US and Europe.

Appropriate age restrictions have been decided in these markets which is being supported by communication to health professionals. The increased rate of reactions observed in Australia this season were unexpected and not consistent with our experience in previous seasons. Extensive investigations undertaken by CSL and Australia's Therapeutic Goods Administration to date have not yet identified an explanation. Scientific investigations are continuing.

**Intellectual Property Licensing** revenue of \$112million was down 22% on a constant currency basis. Royalty contribution from Human Papillomavirus Vaccines largely accounted for the decline, with receipts this year of \$102m.

### **Business development**

#### *Australian fractionation agreement*

On 23 December 2009, CSL signed an agreement with the Australian National Blood Authority to supply the Australian community with plasma therapeutics. The new Agreement, as previously announced, commenced on 1 January 2010 and will run for a total of eight years until 31 December 2017, subject to the satisfactory completion of a review against specified criteria to be undertaken in year five.

#### *Russia – Plasma therapy agreement with GSK*

During October 2009, CSL reached an agreement with GlaxoSmithKline (GSK) to initiate a strategic alliance in the territories of the Russian Federation. Under the terms of the agreement, GSK will distribute and promote certain CSL Behring products in

Russia and the Commonwealth of Independent States. The first therapeutics to have received regulatory approval in Russia are Beriate® and Mononine®, coagulation factors VIII and IX respectively.

#### *Privigen®*

In April 2010 the US Food and Drug Administration (FDA) approved a supplemental Biologics License Application to extend the shelf life for Privigen®, Immune Globulin Intravenous (Human), 10% Liquid, from 24 to 36 months. The approval makes Privigen the first liquid intravenous immunoglobulin in the US that can be stored at room temperature throughout its entire 36-month shelf life.

#### *Hizentra™*

In March 2010, the US FDA granted marketing approval for Hizentra™, Immune Globulin Subcutaneous (Human), 20% Liquid, for treating patients diagnosed with primary immunodeficiency. Hizentra is the first 20% subcutaneous Immunoglobulin approved in the US by the FDA and provides patients with the convenience of self infusion in the comfort of their own home. This new formulation, manufactured at the company's Bern facility in Switzerland, will further add to patient convenience by reducing infusion time.

#### *EVOGAM®*

During the year, CSL Biotherapies submitted a registration dossier to the Therapeutics Goods Administration (TGA) for EVOGAM®, a high-yielding chromatographically purified 16% immunoglobulin for subcutaneous use.

#### *Helixate®*

In August 2009, the US FDA approved Helixate® FS for routine prophylaxis in children with Haemophilia A up to 16 years old who do not have pre-existing joint damage.

#### *Beriner®*

- In October 2009, the US FDA approved Beriner®, (C1-Esterase Inhibitor, Human) for the treatment of acute abdominal or facial attacks of hereditary angioedema, a rare and serious genetic disorder, in adult and adolescent patients. Beriner® is the first and only therapy approved for this indication in the US.
- In December 2009, CSL completed a mutual recognition program in Europe.

- On 1 June 2010, CSL received Notice of Compliance from Health Canada for Berinert® for the treatment of acute abdominal or facial attacks of hereditary angioedema.
- In January 2010, Berinert® was approved by the Australian TGA for treatment of acute attacks in patients with hereditary angioedema. The product is now licensed in 28 countries worldwide.

#### *Human Papillomavirus Vaccine*

- Merck & Co. Inc. has submitted efficacy data to the US FDA for females aged 27-45
- Data has been submitted to the US FDA and European Regulatory Authorities to include the prevention of anal cancer and its precursor AIN (anal intraepithelial neoplasia).
- In October 2009 the US FDA approved the use of GARDASIL in males aged 9 through 26 years of age for the prevention of genital warts (condylomata acuminata) caused by HPV types 6 and 11.
- Data has also been submitted to the Australian TGA supporting GARDASIL for use in males aged 9-26 years (currently 9-15 years) for the prevention of external genital lesions and infection caused by HPV types 6, 11, 16 & 18. CSL Biotherapies received a positive recommendation at the June 2010 ACPM (Australian Committee for Prescription Medicines) meeting, and is awaiting final TGA approval.
- CSL Biotherapies plans to also submit data to the Australian TGA for anal cancer and its precursor AIN (anal intraepithelial neoplasia) in the coming months, with approval anticipated mid 2011.

#### **Share Buyback**

During the period under review the company conducted a share buyback of 54,863,000 shares. This represented approximately 9% of CSL's shares on issue. The buyback concluded in April 2010 having returned approximately \$1.8 billion to shareholders.

CSL today announced its intention to conduct a further on-market buyback of up to \$900 million<sup>6</sup>. This represents approximately 5% of shares currently on issue.

CSL's balance sheet remains very sound. Cash and cash equivalents totalled \$1.0 billion as at 30 June 2010, with interest bearing liabilities totalling \$462 million.

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<sup>6</sup> CSL reserves the right to suspend or terminate the buyback at any time.



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Additional details about CSL's results are included in the Company's Appendix 4E statement, Investor Presentation slides and webcast, all of which can be found on the company's website [www.csl.com.au](http://www.csl.com.au)

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## Group Results

Full year ended June \$ Millions	June 2009 Reported	Adj. <sup>7</sup>	June 2009 Underlying	June 2010 Reported	June 2010 cc <sup>8</sup>	Change %
<b>Sales</b>	<b>4,622</b>		<b>4,622</b>	<b>4,456</b>	<b>5,080</b>	<b>10%</b>
Other Revenue / Income	417	190	227	171	190	
<b>Total Revenue / Income</b>	<b>5,039</b>	<b>190</b>	<b>4,849</b>	<b>4,627</b>	<b>5,270</b>	
<b>Earnings before Interest, Tax, Depreciation &amp; Amortisation</b>	<b>1,550</b>	<b>23</b>	<b>1,527</b>	<b>1,514</b>	<b>1,784</b>	<b>17%</b>
Depreciation/Amortisation	182		182	157	173	
<b>Earnings before Interest and Tax</b>	<b>1,368</b>	<b>23</b>	<b>1,345</b>	<b>1,357</b>	<b>1,611</b>	<b>20%</b>
Net Interest Expense / (Income)	(2)	(7)	5	(22)	(21)	
Tax Expense	224	(96)	320	326	392	
<b>Net Profit after Tax</b>	<b>1,146</b>	<b>126</b>	<b>1,020</b>	<b>1,053</b>	<b>1,240</b>	<b>22%</b>
Total Ordinary Dividend (cents)	70.00			80.00		
Final Dividends (cents)	40.00			45.00		
Basic EPS (cents)	192.51			185.77		

<sup>7</sup> One-off non operational items relating to the discontinuation of the Talecris merger and certain tax items.

<sup>8</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability