



# ASX Announcement

**For immediate release**

16 February 2011

## **Interim Result**

**Profit \$500 million**

**Solid demand for next generation Immunoglobulin products**

**Affirming full year guidance of 10% underlying<sup>1</sup> growth**

**- top of previously provided range**

**Dividend unchanged at 35 cents per share**

CSL Limited today announced a profit after tax of \$500 million for the six months ended 31 December 2010. This result included an unfavourable foreign exchange impact of \$47 million. Net profit after tax in the prior comparable period was \$617 million, which included a one-off contribution from the sale of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>).

## **KEY ITEMS**

### **Financial**

- Sales revenue \$2.1 billion, up 7% on an underlying<sup>1</sup> basis when compared to the six months ended 31 December 2009
- Reported net profit after tax \$500 million
- Research and Development expenditure of \$143 million
- Cash flow from operations of \$408 million
- On market share buyback 33% complete, \$300 million spent
- Earnings per share of 91.5 cents
- Interim dividend unchanged at 35 cents per share, unfranked, payable on 8 April 2011

### **Operational**

- New large scale biotech facility announced and under construction in Australia
- Berinert<sup>®</sup> (C1-Esterase Inhibitor), now licensed in 30 countries
- Immunoglobulins
  - Privilgen<sup>®</sup> (10% liquid intravenous immunoglobulin)
    - Solid demand
    - Transition program from Carimune<sup>®</sup> well advanced
  - Hizentra<sup>®</sup> (20% liquid subcutaneous immunoglobulin)
    - US FDA approval to extend shelf life from 18 to 24 months

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<sup>1</sup> Excludes the one-off contribution from the sale of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>) in the prior comparable period and the impact of foreign exchange movements in the period under review.

- Transition program in the US from Vivaglobin® well progressed
- GARDASIL® (Human Papillomavirus Vaccine)
  - Australian TGA approval for males up to age 26 for the prevention of external genital lesions
  - US Food and Drug Administration (FDA) approval for the prevention of anal cancer and anal intraepithelial neoplasia in males and females 9 through 26 years of age.

Dr McNamee, CSL's Managing Director, said "Our underlying business has continued to grow. We have reached a number of important milestones in the development of our existing portfolio that will support continued growth. These include licensing into new geographic and patient markets. Given the challenges of currency headwinds, Government healthcare reforms and continuing weak economic conditions in a number of countries where we operate, this is a noteworthy achievement.

"The success of our novel A (H<sub>1</sub>N<sub>1</sub>) influenza or 'swine flu' vaccine, Panvax®, in the prior comparable period was a one-off contribution and, as foreshadowed, resulted in a decline in our headline profit.

"Our portfolio of immunoglobulins performed particularly well. Transition programs to new generation products, Privigen® and Hizentra®, are well underway and construction of additional production capacity to accommodate growth is complete. Applications for approval of this additional capacity have been submitted to the US Food and Drug Administration," Dr McNamee said.

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

Commenting on CSL's outlook, Dr McNamee said "Trading conditions in the second half of this financial year are expected to remain similar. The Company remains well positioned with a broad portfolio of products, a global market reach, and a very strong balance sheet.

"At the Annual General Meeting in October 2010 we provided guidance for a net profit after tax of between \$980 million and \$1,030 million, at fiscal 09/10 exchange rates. We now anticipate the result to be at the top of this range which represents a ~10%

growth in underlying<sup>2</sup> profit when compared to the full year 2010. Using current exchange rates, net profit after tax for FY2011 is expected to be approximately \$950 million, recognising that there are a number of items that fall unevenly between the first half and second half of the financial year," Dr McNamee said.

In compiling the Company's financial forecasts for the year ending 30 June 2011 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>3</sup> below. To assist investors in determining the impact of movement in key currency pairs, we have provided with our results materials a foreign currency sensitivity analysis. The materials have also been posted on the Company's website [www.csl.com.au](http://www.csl.com.au)

## BUSINESS REVIEW

### Results overview

**CSL Behring** sales of US\$1.6 billion grew 8% on a constant currency<sup>4</sup> basis when compared to the six months ended 31 December 2009. Sales contribution from the immunoglobulins product portfolio underpinned this growth.

Immunoglobulins grew 22% in constant currency<sup>4</sup> terms of which approximately half was driven by volume growth with the balance coming from a shift in sales mix and demand for Hizentra<sup>®</sup>, the Company's next generation subcutaneous immunoglobulin. Privigen<sup>®</sup> (10% liquid intravenous immunoglobulin) now accounts for almost 60% of immunoglobulin sold. A proportion of the growth in sales of immunoglobulin is attributed to the withdrawal of a competitor from the market place. The length of time of this withdrawal is unknown.

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<sup>2</sup> Excludes the one-off contribution from the sale of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>) in the prior comparable period and the impact of foreign exchange movements in the period under review.

<sup>3</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, regulatory risk, litigation, the effective tax rate and foreign exchange movements.

<sup>4</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability



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The Critical Care segment, including Asian sales<sup>5</sup>, grew 5% in constant currency terms underpinned by volume growth of albumin, particularly in the US and China. Specialty products, primarily Berinert<sup>®</sup> P (C-1 esterase inhibitor), also made a significant contribution.

Haemophilia sales declined 2% in constant currency terms. Volume growth in plasma derived FVIII grew 5% but was offset by competitive pressure, particularly in European markets. Also contributing to the decline has been an increase in patients covered by Medicaid in the US giving rise to additional rebates payable by CSL Behring.

**CSL Biotherapies** sales of \$375 million grew 4% on an underlying<sup>6</sup> basis when compared to the six months ended 31 December 2009. The prior period included a one-off contribution of \$160 million from novel A (H<sub>1</sub>N<sub>1</sub>) influenza (swine flu) vaccine sales.

Underlying growth during the period was driven by the Australian plasma therapies business however this was offset by challenges in seasonal influenza vaccine arising from a delayed entry in the US market and our non-participation in the paediatric market.

## Business development

*Hizentra<sup>®</sup> (Immune Globulin Subcutaneous (Human) 20% Liquid)  
Extended shelf life*

On 18 August 2010 the US FDA approved a supplemental Biologics Licence Application to extend the shelf life of Hizentra<sup>®</sup>, Immune Globulin Subcutaneous (Human), 20% Liquid, from 18 month to 24 months. Hizentra<sup>®</sup> the first and only 20% subcutaneous immunoglobulin (SCIg) approved in the US by the FDA is also the first and only SCIg in the US that may be stored at room temperature.

Subcutaneous immunoglobulin replacement therapy provides patients with the convenience of self infusion in the comfort of their own home. This new formulation will

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<sup>5</sup> Adjusted to include CSL Behring critical care products sold in Asia by CSL Biotherapies.

<sup>6</sup> Excludes the one-off contribution from the sale of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>) in the prior comparable period and the impact of foreign exchange movements in the period under review.

further add to patient convenience through reduced infusion time and greater portability.

*Transition to Hizentra® well progressed*

CSL Behring recently announced that as a result of the strong uptake of Hizentra® in the US, Vivaglobin® will be discontinued in the United States by the end of calendar year 2011. CSL Behring will continue to manufacture Vivaglobin® for European and Canadian markets.

*New Biotech Facility*

On 16 July 2010 CSL announced a major biotechnology project at CSL's manufacturing site in Broadmeadows, Australia. The centrepiece of the project will be the creation of Victoria's first large scale biotechnology facility for the late stage development of new therapies for cancer, bleeding disorders and inflammation. Construction of the facility commenced in November 2010.

*Beriner® (C1-Esterase Inhibitor), now licensed in 30 countries*

On 27 January 2011 CSL Behring announced that it had been granted national marketing authorisation in Israel to market Beriner® for the treatment of acute hereditary angioedema (HAE) attacks in any body location. With this most recent approval Beriner® is now licensed in 30 countries, including Europe, Japan, North America, South America and Australia.

*ISCOMATRIX® adjuvant*

During the period CSL signed a worldwide research license and option agreement with Pfizer Inc., granting certain rights and options for the use of CSL's ISCOMATRIX® adjuvant. Building on the License and Option Agreement signed between CSL and Wyeth in 2006, and following the acquisition of Wyeth by Pfizer, this new agreement significantly expands the breadth of use of ISCOMATRIX® adjuvant in Pfizer's pipeline of investigational vaccine products for infectious diseases and other indications.

*Human Papillomavirus Vaccine - GARDASIL®<sup>7</sup>*

- In October 2010, the Australian Therapeutics Goods Administration (TGA) approved the extension of the indication for GARDASIL® to include males up to 26 years of age for the prevention of external genital lesions and infection caused by human papillomavirus (HPV).

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<sup>7</sup> GARDASIL® is a trademark of Merck & Co. Inc.

- In December 2010, the US FDA approved GARDASIL® for the prevention of anal cancer and anal intraepithelial neoplasia (AIN) grades 1, 2 and 3 (anal dysplasias and precancerous lesions) caused by HPV in males and females 9 through 26 years of age. CSL Biotherapies has submitted data to the Australian Therapeutic Goods Administration (TGA) to support the licensing of GARDASIL® in Australia for prevention of anal cancer and AIN, with approval expected mid calendar year 2011.
- In November 2010, CSL Biotherapies submitted an application in Australia for government funding of GARDASIL to include males on the National Immunisation Program.

**Corporate Responsibility Report**

On the 1<sup>st</sup> February, CSL released its second Corporate Responsibility Report, providing a comprehensive account of the Company's economic, social and environmental performance in 2009/10. The report details CSL's achievements and challenges across its corporate responsibility priority areas and is available on the Company's website [www.csl.com.au](http://www.csl.com.au)

**Share Buyback**

On 18 August 2010, CSL announced its intention to conduct an on-market share buyback of up to \$900 million<sup>8</sup>. Under the Australian Securities Exchange listing rules this buyback has a 12 month completion window. To date CSL has repurchased 8,921,270 shares for approximately \$300 million, representing ~33% of the intended repurchase program.

CSL's balance sheet remains very sound. Cash and cash equivalents totalled \$719 million as at 31 December 2010, with interest bearing liabilities totalling \$384 million.

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<sup>8</sup> CSL reserves the right to suspend, terminate or extend the buyback at any time.



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## New Director

CSL is pleased to announce the appointment of Ms Christine O'Reilly as a new Director of CSL, effective from 16 February 2011. For further information please see the separate ASX announcement.

Additional details about CSL's results are included in the Company's 4D 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

Half year ended December \$ Millions	Dec 2009 Reported	Dec 2009 Underlying <sup>9</sup>	Dec 2010 Reported	Dec 2010 CC <sup>10</sup>	Change %
<b>Sales</b>	<b>2,317</b>	<b>2,157</b>	<b>2,116</b>	<b>2,300</b>	<b>7.0%</b>
Other Revenue / Income	98	98	75	78	
<b>Total Revenue / Income</b>	<b>2,415</b>	<b>2,255</b>	<b>2,191</b>	<b>2,378</b>	
<b>Earnings before Interest, Tax, Depreciation &amp; Amortisation</b>	<b>874</b>	<b>751</b>	<b>719</b>	<b>784</b>	<b>4.4%</b>
Depreciation/Amortisation	78	78	83	88	
<b>Earnings before Interest and Tax</b>	<b>796</b>	<b>673</b>	<b>636</b>	<b>696</b>	<b>3.4%</b>
Net Interest Expense / (Income)	(15)	(15)	(11)	(11)	
Tax Expense	194	157	147	160	
<b>Net Profit after Tax</b>	<b>617</b>	<b>531</b>	<b>500</b>	<b>547</b>	<b>3.0%</b>
Interim Dividend (cents)	35.00		35.00		
Basic EPS (cents)	106.34		91.45		

<sup>9</sup> Excludes the one-off impact of pandemic influenza vaccine (H<sub>1</sub>N<sub>1</sub>).

<sup>10</sup> Constant currency removes the impact of exchange rate movements to facilitate comparability.