



# ASX Announcement

For immediate release

17 February 2010

## Interim Result

**Profit \$617 million up 23% (up 32% at constant currency<sup>1</sup>)**

**Cash Flow from Operations \$491 million up 10%**

CSL Limited today announced a profit after tax of \$617 million for the six months ended 31 December 2009, up 23% when compared to the six months ended 31 December 2008. This result included an unfavourable foreign exchange impact of \$46 million. Adjusting for this item, net profit after tax grew 32%.

## KEY ITEMS

### Financial

- Total sales revenue of \$2.3 billion, up 5% when compared to the six months ended 31 December 2008, up 12% at constant currency
- Reported net profit after tax up 23% to \$617 million, up 32% at constant currency
- Research and Development expenditure of \$147 million
- Cash flow from operations of \$491 million, up 10%
- On market share buyback 86% complete, ~\$1.5 billion spent
- Earnings per share of 106.3 cents, up 24%
- Interim dividend up 17% to 35 cents per share, unfranked, payable on 9 April 2010

### Operational

- Australian fractionation agreement renewed to 31 December 2017
- Berinert<sup>®</sup> (C1-Esterase Inhibitor)
  - US FDA grants marketing approval
  - European mutual recognition program completed
  - TGA approval, Notice of Compliance received from Health Canada;
- Hizentra<sup>™</sup> (Subcutaneous IG 20% Liquid)
  - License application submitted to the US FDA
- Afluria<sup>®</sup> (Influenza Virus Vaccine)
  - Agreement with Merck & Co., Inc for US distribution
  - US FDA approves for use in paediatric population
- Panvax<sup>®</sup> (Pandemic Influenza Vaccine)
  - Successful development and registration
- GARDASIL<sup>®</sup> (Human Papillomavirus Vaccine)
  - Merck & Co., Inc., submitted data to the US FDA for females aged 27 – 45

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



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Dr McNamee, CSL's Managing Director, said "This is a pleasing result in what has been a competitive trading environment.

Despite a currency headwind and the continuing impact of market dynamics, the underlying business remains sound. Demand for CSL's plasma derived therapies has continued with product development underpinning an improvement in product sales.

Sales of Novel A (H<sub>1</sub>N<sub>1</sub>) Influenza or 'Swine Flu' Vaccine provided a significant contribution and I'm proud to report that following the outbreak in April 2009 CSL rapidly conducted clinical trials that were first published in September 2009 in the New England Journal of Medicine. The data played an important role in assisting Governments around the world in determining their vaccine immunisation policy. In a time-critical event such as a pandemic this is a notable achievement," Dr McNamee said.

## **OUTLOOK (at 08/09 exchange rates)**

Commenting on CSL's outlook, Dr McNamee said "Demand growth for plasma derived therapies is expected to continue. CSL is well positioned with a broad portfolio of plasma derived proteins and an increasing demand for Vivaglobin<sup>®</sup> (subcutaneous delivery of liquid immunoglobulin) is expected.

"We continue to forecast a result, in line with previous guidance, for a net profit after tax of between \$1,160 million and \$1,260 million, at financial year 08/09 exchange rates. This represents 14 - 24% growth on the underlying operational profit. Furthermore, we now anticipate the result to be towards the upper end of this range. Using current exchange rates, net profit after tax is expected to be between \$970 million and \$1,070 million, recognising that there are a number of items that fall unevenly between the first half and second half of the financial year.

"In compiling our financial forecasts for the year ending 30 June 2010 we have determined a number of key variables which may have a significant impact on guidance, in particular, 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, successful implementation of the company's influenza expansion 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.

“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,” Dr McNamee said.

## **BUSINESS REVIEW**

### **Results overview**

**CSL Behring** total sales of \$1.8 billion grew 10% on a constant currency basis when compared to the six months ended 31 December 2008. Sales contribution from across the product portfolio has underpinned this growth.

Immunoglobulins grew 9% in constant currency terms, largely driven by product demand growth together with a shift in product mix. Sales of Vivaglobin® and Privigen® have been encouraging. Vivaglobin® (Subcutaneous Immunoglobulin), a product which provides the convenience of immunoglobulin self administration, attracted significant patient growth. Immunoglobulin pricing has generally remained stable.

The Critical Care segment grew 8% in constant currency terms underpinned by volume growth of albumin, particularly in the US and emerging markets. Specialty products, primarily Haemocomplettan® P and Berinert® P, also made a significant contribution.

Haemophilia sales grew 10% in constant currency terms, mainly driven by product demand growth. Pricing has been steady, albeit the total average price was affected by growth in lower priced emerging and tender markets.

Sale of plasma raw material declined consistent with the new supply contract with Talecris Biotherapeutics.

**CSL Biotherapies** sales grew 31% to \$528 million.

Sales of Novel A (H<sub>1</sub>N<sub>1</sub>) Influenza (Swine Flu) Vaccine contributed \$160 million to sales. This was partially offset by the decline in GARDASIL® sales to \$18 million for the first half of the financial year, down \$66 million when compared to the prior comparable period. This decline is consistent with immunisation ‘catch-up’ programs in Australia

drawing to a close. Seasonal influenza vaccine sales totalled \$91 million for the period, up 22% compared to the prior comparable period, arising from growth in the US and German markets. Strong contributions from Intragam® P (Liquid Immunoglobulin) in Australia and albumin in China also contributed to growth.

### **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-derived therapeutic products. The new Agreement, as previously announced, commenced on 1 January 2010 and will run for a total of eight years until 31 December 2017.

#### *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 in Russia, and the Commonwealth of Independent States, certain CSL Behring products. The first therapies to have received regulatory approval in Russia are Beriate® and Mononine®, coagulation factors VIII and IX respectively.

#### *Beriner®*

- On 12 October 2009, the US Food and Drug Administration (FDA) granted marketing approval for 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, where Beriner® is now approved in 23 countries.
- In January 2010, CSL received Notice of Compliance from Health Canada for Beriner® for the treatment of acute episodes of hereditary angioedema.
- In January 2010, Beriner® was approved by the Australian Therapeutic Goods Administration (TGA) for treatment of acute attacks in patients with hereditary angioedema.

*Subcutaneous immunoglobulin*

On 1 May 2009, CSL Behring announced that it had submitted a biologics license application to the US FDA requesting approval to market its 20% liquid formulation, subcutaneous immunoglobulin, for weekly replacement therapy in patients with primary immunodeficiencies. Subcutaneous immunoglobulin replacement therapy provides patients with the convenience of self infusion in the comfort of their own home. This new formulation will further add to patient convenience by reducing infusion time. CSL's current subcutaneous immunoglobulin, Vivaglobin<sup>®</sup>, was launched into the US markets in March 2006 and has received strong patient take up.

*Human Papillomavirus Vaccine*

Before the end of calendar 2009, Merck & Co., Inc., submitted end of study data to the US FDA seeking to expand the GARDASIL<sup>®</sup> vaccine label claim to include adult women aged 27 - 45.

Royalties on global sales of Human Papillomavirus Vaccine totalled \$58m for the half.

*Influenza*

On 11 November 2009, the US FDA approved Afluria<sup>®</sup>, influenza virus vaccine, for use in the paediatric population 6 months and older.

On 1 October 2009, CSL announced an agreement reached with Merck & Co., Inc., on rights to market and distribute Afluria<sup>®</sup> in the United States under an exclusive, six-year agreement effective 3 September 2009.

**Share Buyback**

On 9 June 2009, CSL announced its intention to conduct an on-market share buyback of up to 54,863,000 shares<sup>2</sup>. This represents approximately 9% of CSL's current shares on issue. To-date CSL has repurchased 46,952,545 shares for approximately \$1,497 million, representing 85.6% of the intended maximum number of shares to be repurchased.

CSL's balance sheet remains very sound. Cash and cash equivalents totalled \$956 million as at 31 December 2009, with interest bearing liabilities totalling \$459 million.

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<sup>2</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 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)

For further information, please contact:

**Media:**

Tim Duncan / Jo Lynch

Hintons

Telephone: +613 9600 1979

Email: [tduncan@hintons.com.au](mailto:tduncan@hintons.com.au)

[jlynch@hintons.com.au](mailto:jlynch@hintons.com.au)

**Investors:**

Mark Dehring

Head of Investor Relations

CSL Limited

Telephone: +613 9389 2818

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

## Group Results

| Half year ended December  | December<br>2009<br>\$m | December<br>2008<br>\$m | Change<br>% |
|---|-------------------------|-------------------------|-------------|
| <b>Sales</b>  | <b>2,317.4</b>          | <b>2,206.7</b>          | <b>5%</b>   |
| Other Revenue / Income  | 97.6                    | 158.2                   |             |
| <b>Total Revenue / Income</b>   | <b>2,415.0</b>          | <b>2,364.9</b>          | <b>2%</b>   |
| <b>Earnings before Interest, Tax, Depreciation &amp; Amortisation</b> | <b>874.4</b>            | <b>701.5</b>            | <b>25%</b>  |
| Depreciation/Amortisation   | 78.3                    | 75.3                    |             |
| <b>Earnings before Interest and Tax</b>                               | <b>796.1</b>            | <b>626.2</b>            | <b>28%</b>  |
| Net Interest Expense / (Income)                                       | (15.2)                  | (13.7)                  |             |
| Tax Expense   | 193.9                   | 138.0                   |             |
| <b>Net Profit after Tax</b>   | <b>617.4</b>            | <b>501.9</b>            | <b>23%</b>  |
| Interim Dividend (cents)  | 35.00                   | 30.00                   |             |
| Basic EPS (cents)   | 106.34                  | 85.44                   |             |