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CSL

# ASX Announcement

**For immediate release**

19 August 2009

## Full Year Result
## Reported Profit $1.15 billion up 63%
## Underlying Operational Profit[1] $1.02 billion up 45%
## (23% at constant currency)
## Cash Flow from Operations $1.03 billion

CSL Limited today announced a profit after tax of $1.15 billion for the twelve months ended 30 June 2009, up 63% when compared to the twelve months ended 30 June 2008. Underlying operational profit (adjusted for currency movements, the impact of discontinuing the Talecris merger and non-operational tax items) grew 23%.

### KEY ITEMS

**Financial**

- Total revenue of $5.04 billion, up 32%;
  - Up 16% on a constant currency basis;
  - Human Papillomavirus (HPV) vaccine royalties of $161 million;
  - GARDASIL® (HPV vaccine) – Australian/New Zealand sales $185 million;
- Reported net profit after tax grew 63% to $1.15 billion; this includes -
  - Favourable foreign currency impact of $156 million;
  - Favourable net impact of Talecris merger discontinuation of $79 million;
  - Favourable non-operational tax items $47 million;
- Research and Development expenditure of $312 million, up 38%;
- Cash flow from operations of $1.03 billion, up 49%;
- On market share buyback announced of approximately 9% of share capital;
- Earnings per share of $1.93, up 51%;
- Final dividend 40 cents per share, unfranked, payable on 9 October 2009. Total ordinary dividends for the year were 70 cents per share up 52% on the previous year.

**Operational**

- Plasma Therapies
  - Privigen® (10% liquid intravenous immunoglobulin) manufacturing facilities rollout on track – new manufacturing facility approved by US and European regulators;
  - Market development of specialty plasma therapies.

[1] Excludes one-off beneficial items to facilitate comparison. Items excluded - earnings and costs associated with discontinuing the Talecris merger and non-operational tax items.

- GARDASIL®
  - Merck & Co., Inc., submitted data to the US FDA for males aged 9 – 26 and females aged 27 – 45;
  - Merck phase III trial on 9-valent HPV vaccine;
  - US HPV patent, covering license for GARDASIL®, granted to 2026.
- Influenza
  - Expanded influenza vaccine facility approved by US FDA;
  - Seasonal Influenza vaccine business grew 60% to $124 million;
  - Significant orders for Novel A ($H_1N_1$) influenza vaccine - 'Swine Flu'
    - Clinical trials underway.

Dr McNamee, CSL's Managing Director, said "This is a powerful result for CSL, derived in an extraordinary period of foreign exchange volatility and global economic upheaval. This year we benefited from favourable movements in foreign exchange, in contrast to the past four years of currency 'head winds'.

"Global demand for plasma therapies continues to be robust. Our Privigen® manufacturing facility rollout is on track and our new facility in Switzerland is now approved.

"Over the last few months we received significant orders from the Australian and US Governments for Swine flu vaccine. CSL has vigorously pursued the development of a vaccine and commenced manufacturing in order to meet demand for this important medicine. CSL has commenced clinical trials to determine dosage. These trials are now well underway.

"GARDASIL® royalties continue to make an excellent contribution and CSL's US patent position protects our intellectual property through to 2026," Dr McNamee said.

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

Commenting on CSL's outlook, Dr McNamee said "There are a number of components of our expected result in fiscal year 2010 worth highlighting. Growth in demand for plasma therapies is expected to continue. Sales will benefit from a product mix change with a shift towards Privigen®.

"Following the successful rollout of the HPV vaccine program in Australia by the Commonwealth Government, sales of GARDASIL® are expected to substantially decline as the catch up programs draw to a close.

"Orders for Novel A ($H_1N_1$) influenza or 'Swine Flu' vaccine are expected to provide a strong contribution to the fiscal year 2010 result.

"In compiling our financial forecasts for 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[2] arising from the sale of Human Papillomavirus vaccine, sales of GARDASIL® in Australia, fulfilment of Novel A ($H_1N_1$) influenza vaccine orders, 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.

"For the 2009/10 fiscal year we expect net profit after tax of between $1,160 million and $1,260 million, at 08/09 exchange rates. This represents 14 - 24% growth on the underlying operational profit for fiscal year 2008/09. Given the volatile foreign exchange environment we have provided with our results materials a foreign currency sensitivity analysis to assist investors in determining the impact of movement in key currency pairs," Dr McNamee said.

## BUSINESS REVIEW

### Results overview

**CSL Behring** product sales grew 38% to $3.7 billion (17% in constant currency terms) when compared to the twelve months ended 30 June 2008. Strong contribution from immunoglobulins and critical care products have underpinned the growth.

Immunoglobulins grew 26% in constant currency terms with vigorous growth in Privigen®, consistent with the company's transition program in favour of liquid over lyophilised presentations. Vivaglobin® (subcutaneous Immunoglobulin), a product which provides the convenience of immunoglobulin self administration, attracted significant patient growth.

[2] FY2009 HPV royalty revenue used for FY2010 forecast

Volume and price growth and, above all, product mix contributed to global growth in immunoglobulin sales. Specialty products Rhophylac® (Anti-D) and Tetagam® P (Tetanus) also boosted sales.

The Critical Care segment grew 18% in constant currency terms underpinned by volume growth of albumin, particularly in the US and emerging markets. Specialty products, primarily Haemocomplettan® P, Beriplex® P/N and Berinert® P, also made a significant contribution.

Haemophilia sales grew 8% in constant currency terms, after adjusting for short term supply issues with Monoclate-P® as indicated at the half year result. Total sales volume grew by 11% with pricing 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 Bioplasma** sales were up 32% to $334 million driven by strong demand and improved pricing for albumin in China. Demand for plasma therapies from Hong Kong, Singapore and Taiwan was also strong. Australian sales grew by 8%.

**CSL Biotherapies** sales were up 5% to $502 million. Growth in influenza vaccine sales into the Northern Hemisphere was offset by reduced Australian sales of GARDASIL®. The current period included GARDASIL® sales into the Australian and New Zealand markets of $159 million and $26 million respectively, compared with a total of $227 million in the prior comparable period arising from strong demand during the initial take-up by women in the 18-26 year old cohort. Influenza vaccine sales totalled $124 million for the period, up 60% compared to the prior comparable period.

**Other Revenue / Income** grew 69% to $417 million, the key driver being a $157 million foreign exchange gain arising from the conversion back to Australian dollars of US$1.5 billion of funds held on deposit in anticipation of closure of the Talecris Biotherapeutics acquisition.

**Business development**

*Talecris*

On 13 August 2008, CSL signed an agreement to acquire Talecris Biotherapeutics, Inc., a leading manufacturer and marketer of plasma-derived protein therapies, from owners

Cerberus Partners, L.P. and Ampersand Ventures. The close of the acquisition was subject to regulatory approvals, including the approval from US anti-trust authorities.

On 25 May 2009, the US Federal Trade Commission (FTC) filed a complaint in the US Federal District Court challenging CSL's proposed acquisition. CSL fundamentally disagreed with the FTC's case as the FTC had not recognised the combination would be pro-competitive, provide significant efficiencies that would improve the supply of biotherapies and be beneficial to the patient community.

Notwithstanding this position, CSL's Board of Directors did not believe that entering into a protracted litigation process with its inherent risks, substantial costs and lengthy distraction of CSL management, would be in the best interests of the company's stakeholders.

On 9 June 2009, both Talecris and CSL announced they had mutually agreed to terminate their merger agreement. Transaction and termination costs associated with the proposed acquisition have been more than offset by a foreign exchange benefit arising from selling forward into Australian dollars approximately US$1.5 billion held on deposit in anticipation of acquiring Talecris. The net financial impact to CSL has been a non-recurring net profit after tax of $79 million.

CSL has recently been served with two lawsuits filed in US courts alleging that CSL and a competitor had conspired to restrict output and artificially increase the price for plasma derived therapies in the US. Both actions were filed by individual private hospital groups but were filed as class actions. CSL believes these lawsuits are unsupported by fact and without merit and will robustly defend against these suits.

*Share Buyback*

On 9 June 2009, CSL announced its intention to conduct an on-market share buyback of up to 54,863,000 shares[3]. This represents approximately 9% of the company's current shares on issue. To-date CSL has repurchased 8,543,419 shares for approximately $268 million, representing 15.6% of the intended maximum number of shares to be repurchased.

*GARDASIL® – Human Papillomavirus Vaccine*

During the period under review, CSL's licensee Merck made a number of announcements regarding cervical cancer vaccine, GARDASIL®. They have submitted data to the US FDA seeking to expand the GARDASIL® label claim to include adult women aged 27 - 45 and males aged 9 - 26. The US FDA has since recommended that Merck submit additional data

[3] CSL reserves the right to suspend or terminate the buyback at any time

when the 48 month female study has been completed. Merck has also announced that they are in phase III trials for a 9-valent vaccine. GARDASIL® is a quadrivalent vaccine.

In addition, during the period a US patent for HPV virus like particles was issued jointly to CSL and the University of Queensland, which is licensed to Merck and will drive royalties from the sale of GARDASIL® until 2026.

*Privigen®*

The company has a modularised plan to increase manufacturing capacity of Privigen® (10% liquid intravenous immunoglobulin). The first facility with a capacity of 3 million grams per annum has been in production throughout the year. The US FDA has approved the company's new facility, with a design capacity of 10 million grams per annum. Construction of an additional facility, with the same design capacity of 10 million grams per annum, has commenced with operations anticipated to begin in 2011.

The company's Privigen® strategy is to accommodate increasing global patient demand for IVIG as well as progressively migrating patients from Sandoglobulin® / Carimune® to liquid Privigen®. Privigen® is the first and only proline stabilised IVIG that is ready for immediate use, not requiring refrigeration or reconstitution during its shelf life.

*Subcutaneous immunoglobulin*

On 1 May 2009, CSL Behring announced that it had submitted a biologics license application to the US Food and Drug Administration 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. The company's current subcutaneous immunoglobulin, Vivaglobin®, was launched into the US markets in March 2006 and has received strong patient take up.

*Specialty Plasma Products*

The company's 'maximising revenue per litre' objective moved forward with market development in a number of specialty products.

- RiaSTAP™ (fibrinogen) - In January 2009 the US Food and Drug Administration (FDA) granted marketing approval for RiaSTAP™, the first and only treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, a rare and potentially life threatening bleeding disorder.

- Berinert® - EU mutual recognition procedure completed December 2008. CSL Behring is currently addressing questions raised by the US FDA that relate to the manufacturing process and clinical data.
- Beriplex® – US trial initiated. European expansion ongoing.
- Zemaira™ – US patient base expanding, European registration clinical trial recruitment proceeding.

*Influenza*
Initial sales of influenza vaccine, manufactured at CSL's expanded facility in Parkville, Victoria, were made into the USA. CSL Behring also lodged a Biologics License Application supplement seeking approval of the recently completed dispensing and packaging facilities in the US, at the company's Kankakee site. This facility will further enhance manufacturing capabilities and assist in meeting anticipated growth in US demand.

During the period CSL's influenza vaccine was launched into Germany and a vaccine tender was won in Hong Kong.

*Pandemic Influenza Vaccine $H_1N_1$ - 'Swine Flu'*
On 29 May 2009, CSL signed a contract with the U.S. Department of Health and Human Services (HHS) to provide Novel A ($H_1N_1$) influenza vaccine. The vaccine will be manufactured at Parkville. The new vaccine will be tested in US clinical trials funded by HHS. The initial order under the contract will be for an amount of US $180 million.

CSL has also received an order from the Australian Department of Health and Ageing to supply 21 million (15 mcg) doses of Novel A ($H_1N_1$) influenza vaccine. Australian clinical trials to determine dosage commenced in mid July with initial results expected during September 2009.

*Q-Vax®*
On 1 July 2009, CSL's new Q-Vax® manufacturing facility at the company's Broadmeadows site in Melbourne, was officially opened, following approval by the Australian Therapeutics Goods Administration. Q-Fever is primarily an occupational disease of people working in the meat and livestock industry.

*Corporate Responsibility*
In December 2008, CSL published its first global environment report which presents four years of performance data from its five manufacturing sites. Highlighted in the report are significant improvements in the rate at which CSL consumes natural resources and generates by-products in the manufacture of plasma therapies.

In February 2009, CSL released a new Code of Responsible Business Practice, setting out the company's principles for ethical conduct and its commitment to sustainable development. This Code replaces the former CSL Code of Conduct.

In April 2009, CSL announced a new $US3 million partnership with the World Federation of Haemophilia (WFH). Each year for the next three years, CSL Behring will donate two million units of Factor VIII to help the WFH expand access to haemophilia therapies in developing countries and will also provide additional financial support.

In June 2009 CSL made a submission to the Carbon Disclosure Project, reporting that climate change does not pose any significant risks to operations in the short to medium term and outlined the company's efforts to reduce its carbon footprint in the interests of sustainability.

Details regarding CSL's corporate responsibility initiatives can be found on the company website.

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# Group Results

| Full year ended June | June 2009 $m | June 2008 $m | Change % |
|---|---|---|---|
| **Sales** | **4,622.4** | **3,556.7** | |
| Other Revenue / Income | 417.0 | 246.7 | |
| **Total Revenue / Income** | **5,039.4** | **3,803.4** | **32%** |
| **Earnings before Interest, Tax, Depreciation & Amortisation** | **1,549.8** | **1,108.4** | **40%** |
| Depreciation/Amortisation | 181.6 | 141.8 | |
| **Earnings before Interest and Tax** | **1,368.2** | **966.6** | **42%** |
| Net Interest Expense / (Income) | (1.5) | 14.6 | |
| Tax Expense | 223.8 | 250.2 | |
| **Net Profit after Tax** | **1,145.9** | **701.8** | **63%** |
| Total Ordinary Dividends (cents) | 70.00 | 46.00 | |
| Final Dividend (cents) | 40.00 | 23.00 | |
| Basic EPS (cents) | 192.5 | 127.6 | |