CSL

Press Release

21 February 2007

# Interim Result
# Strong profit from operations, up 46% to $257 million
# Full year profit guidance upgrade

CSL Limited today announced a profit after tax of $257 million for the six months ended 31 December 2006, up 46% when compared to the six months ended 31 December 2005.

The Board has increased the interim dividend by 75% to 49 cents per share, unfranked, reflecting the strength of the result and the confidence in the outlook for the full year.

## HIGHLIGHTS

### Financial

- Total revenue of $1.6 billion, up 10% when compared to the six months ended 31 December 2005;
- Net profit after tax grew 46% to $257m;
- Net operating cash flow of $187m;
- Earnings per share of $1.41, up 46%; and
- Interim dividend up 75% to 49 cents per share, unfranked, payable on 13 April 2007.

### Operational

- Strong trading performance by CSL Behring;
- Extension of Helixate® supply contract with Bayer until 2017 and final settlement with Sanofi Aventis arising from the acquisition of Aventis Behring in 2004;
- License and option agreement with Wyeth for ISCOMATRIX® adjuvant technology and the expansion of an existing agreement with Merck & Co, Inc;
- Chromatographic liquid IVIG filed with US Food & Drug Administration;
- Commonwealth Government funding of GARDASIL® in Australia;
- Acquisition of CytoGam®, a specialty CMV immunoglobulin used in organ transplantation; and
- Acquisition of Zenyth Therapeutics Limited completed.

Dr McNamee, CSL's Managing Director said, "The Company has had a very good first half. It's been a period of solid financial performance and a period of further strengthening the underlying business.

"Operational activities coupled with favourable trading conditions in international plasma therapies have produced strong growth in CSL Behring's operating margin. Sales of GARDASIL® by our licensee Merck & Co, Inc (Merck) are now producing royalty receipts and momentum appears to be building as the product is launched globally.

"Other operating highlights include extending the Helixate® supply contract with Bayer until 2017 and making a final settlement with Sanofi-Aventis, which draws to a conclusion the arrangements made in 2004 for the acquisition of Aventis Behring. We have also intensified our research focus on recombinant antibodies with the acquisition of Zenyth Therapeutics Limited and expanded our plasma therapies portfolio in the US with the acquisition of the CytoGam® product. Furthermore our proprietary adjuvant ISCOMATRIX® continues to attract interest around the globe with around 20 research and development programs incorporating ISCOMATRIX® currently underway."

"The company's solid performance has prompted the Board to substantially increase the dividend paid to shareholders to 49 cents per share, an increase of 75%," Dr McNamee said.

## BUSINESS REVIEW

### Results overview

**CSL Behring** sales grew 9% to $1.3 billion (10% in US dollar terms) when compared to the six months ended 31 December 2005. Solid performance across the plasma product portfolio in both core and specialty products have underpinned this performance.

Carimune® / Sandoglobulin® (Intravenous Immunoglobulin), Vivaglobin® (subcutaneous Immunoglobulin) and Humate®/Haemate® (von Willebrand disease therapies) performed particularly well. During the period immunoglobulin prices in Europe improved, drawing closer to US pricing. The growth of Vivaglobin®, which was launched into the USA in March 2006, reflects patient demand given the unique convenience of the product. Humate® / Haemate®, with its high ratio of ristocetin co-factor, have been in strong demand by patients with a need for von Willebrand's factor and Haemophilia-A patients in need of inhibitor therapy.

CSL Behring's sales growth, general market conditions and a continuing efficiency drive have underpinned an improved operating margin (earnings before interest and taxes) of

29%, up from 21% in the prior comparable period. The improved margin includes the residual inventory benefit of $12 million ($36 million in the prior comparable period), arising from the purchase of Aventis Behring in 2004.

**CSL Bioplasma** sales grew 12% to $103m which is attributable to an increased demand for albumin in Asia, particularly China, and the successful renewal of the New Zealand Toll based plasma fractionation contract.

**CSL Biotherapies** grew sales by 5% to $94m reflecting growth in influenza vaccine exports.

**Other Revenue** doubled to $49m reflecting for the first time a royalty of $21m earned from the global sales of GARDASIL® by CSL's licensee Merck. The growth also includes $17 million of interest earned on cash balances held during the period which will not be repeated in the second half following the acquisitions of CytoGam® and Zenyth Therapeutics Limited and the settlement with Sanofi-Aventis.

**Business development**

*Plasma Therapies*
In November 2006 after completing clinical trials, the company filed with the US Food and Drug Administration (US FDA) an application to market chromatographic liquid intravenous immunoglobulin. Work has commenced on a large-scale chromatographic purification plant at the company's Bern facility.

The company's subcutaneous immunoglobulin, Vivaglobin® launched into the US markets in March 2006 is receiving strong interest from primary immune deficient patients interested in a more convenient infusion method. The company has now commenced phase III clinical trials on a high yielding chromatographic version of Vivaglobin®.

*Helixate®*
In February this year, CSL concluded an agreement with Sanofi-Aventis that facilitated an extension of arrangements with Bayer for the supply of Helixate®, a recombinant Factor VIII product. The previous agreement with Bayer on Helixate® expired in 2009 with the new arrangement securing supply for a further eight years until 2017.

CSL agreed to pay Sanofi-Aventis the Contingent Payment of US$250m[1] and the Deferred Payment of US$65m[2] earlier than originally agreed when CSL acquired Aventis Behring in 2004. This agreement with Sanofi-Aventis enabled CSL to independently negotiate with Bayer the sublicensing terms of key intellectual property to secure the long-term supply of Helixate® and to facilitate the settlement of litigation against Bayer. A number of other outstanding matters that had remained unresolved with Sanofi-Aventis, stemming from the original 2004 acquisition of Aventis Behring, have also now been resolved and provided a non recurring profit during the period of $18 million after tax.

*ISCOMATRIX® adjuvant*

A worldwide license and option agreement was signed with Wyeth granting certain rights and options to Wyeth for use of CSL's ISCOMATRIX® adjuvant in a number of Wyeth's investigative vaccine programs. Under the terms of the agreement CSL could receive, over time, option and milestone payments as well as royalties on future product sales. CSL will supply all of Wyeth's requirements for ISCOMATRIX® adjuvant for development and commercialisation.

Further to the agreement with Merck announced in August 2005, the company had extended this agreement to include additional fields and vaccine candidates, again with the inclusion of upfront, option and milestone payments. Additionally Merck has now taken two product candidates, which include the ISCOMATRIX® adjuvant, into clinical trials, one in the USA and one in Europe

*GARDASIL® – Human Papillomavirus Vaccine*

On 8 June 2006, CSL's Licensee Merck, received approval from the US Food and Drug Administration (FDA) for GARDASIL® the only vaccine available in the US for the prevention of HPV types 16 and 18 related cervical cancer, for girls and women aged 9 to 26 years. GARDASIL® is also approved for the prevention of genital warts and low grade cervical lesions caused by HPV types 6, 11, 16 & 18.

At the end of calendar 2006 GARDASIL® was approved in 40 countries with applications under review with regulatory agencies in a further 50 countries.

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[1] *CSL had made provision for this Contingent Payment at the time of its full year result announcement in August 2006. CSL had agreed at the time of the acquisition of Aventis Behring in March 2004 to pay US$250m to Aventis (now Sanofi-Aventis) if the volume weighted average price of CSL's shares for any 60 consecutive trading day period during the six months commencing October 2007 exceeded A$35.00.*

[2] *CSL had agreed at the time of the acquisition of Aventis Behring to pay Aventis (now Sanofi-Aventis) on December 31 2007 the sum of US$65m as a deferred payment.*

*CytoGam®*

On 9 November 2006, CSL Behring acquired the plasma product 'CytoGam®', a specialty immunoglobulin enriched in antibodies against cytomegalovirus. The acquisition price was $153 million (US$120 million) in cash, of which $89 million (US$70 million) is subject to the achievement of specified milestones.

*Zenyth Therapeutics Limited*

On 10 November 2006, CSL concluded the acquisition of Zenyth Therapeutics Limited under a share scheme of arrangement for a total of $106 million, which included a cash balance and short term investments convertible to cash within Zenyth of $43 million. The acquisition strengthens CSL's research interests in recombinant antibodies and includes programs in the fields of cancer, immunology and inflammation.

*Australian Plasma Fractionation Review*

The Australian Commonwealth Minister for Health and Ageing released on 15 December 2006 a Review of Australia's Plasma Fractionation Arrangements. The recommendations within the report are currently being reviewed by State and Federal Governments.

*Pandemic Influenza*

On 30 January 2007, CSL announced new data from its pandemic influenza vaccine clinical trial program. The results will enable submission of a dossier to the Australian Therapeutic Goods Administration for the registration of the vaccine. The latest studies confirm that two doses of 30 micrograms of antigen with the addition of an aluminium adjuvant are required to produce a strong immune response against the H5N1 bird flu virus. Results of a subsequent study undertaken in infants, young children and the elderly are expected to be available later this year.

Whilst encouraged by the results, the company intends to continue research and development to enable the maximum number of vaccine doses to be produced in the shortest possible time. The goal is to develop a pandemic vaccine which uses the lowest dose of antigen, offer cross-protection against similar but non identical bird flu strains, and lasts as long as possible.

## OUTLOOK

Commenting on CSL's outlook, Dr McNamee said "We continue to anticipate stable to favourable market conditions for our plasma therapies business and growing contribution from receipts associated with the international sales of GARDASIL®.

"For the 2006/07 fiscal[3] year we have lifted our net profit after tax guidance to between $500 and $520 million. The key drivers for this upgrade include a strong launch of GARDASIL® by our licensee in the US and sales of GARDASIL® in Australia beginning this financial year; CSL Behring's trading performance and the Sanofi-Aventis settlement which boosted profit in the first half," Dr McNamee said.

For further information, please contact:

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[3] *This guidance is subject to a number of variables, including currency fluctuation and material price movements in core plasma products.*

# Group Results

| Half year ended December | December 2006 $m | December 2005 $m | Change % |
|---|---|---|---|
| **Sales** | **1,514.4** | **1,393.1** | |
| Other Revenue | 49.4 | 24.6 | |
| **Total Revenue** | **1,563.8** | **1,417.7** | **10%** |
| **Earnings before Interest, Tax, Depreciation & Amortisation** | **448.3** | **311.2** | **44%** |
| Depreciation/Amortisation | 57.6 | 50.3 | |
| **Earnings before Interest and Tax** | **390.7** | **260.9** | **50%** |
| Net Interest Expense | 3.8 | 9.0 | |
| Tax Expense | 129.6 | 75.5 | |
| **Net Profit after Tax** | **257.3** | **176.4** | **46%** |
| Interim Dividend (cents) | 49 | 28 | 75% |
| Basic EPS (cents) | 141.2 | 96.7 | 46% |