**CSL Limited** 45 Poplar Road Parkville Victoria 3052 Australia T +613 9389 1911 F +613 9389 1434 www.csl.com.au



14 October 2009

To: The Manager Companies Company Announcements Office Australian Securities Exchange

Dear Sir/Madam

#### Chairman's Address and Managing Director's Presentation

Please find attached copies of the Chairman's Address and Managing Director's presentation slides to be presented at CSL's Annual General Meeting which commences at 10.00 a.m. today.

Yours faithfully

Edward Bailey Company Secretary

#### **CSL Limited**

#### Chairman's Address Annual General Meeting – 14 October 2009

"I am pleased to report that, in an extraordinary period of foreign exchange volatility and global economic upheaval, strong international growth in demand for our plasma products and significant continuing revenues from both sales and royalties of the GARDASIL vaccine against cervical cancer underpin the impressive result achieved by CSL this year.

"CSL Group revenues were up by 32% to \$5.04 billion and net profit after tax increased 63% on the previous year to reach \$1.15 billion. Underlying operational profit was up 45% to \$1.02 billion, after adjusting for several one-off beneficial items. Cash flow from operations grew 49% to \$1.03 billion. CSL remains well positioned with a very strong balance sheet.

"Australia's national immunisation program against cervical cancer generated \$159 million in GARDASIL sales this year. This has been a highly successful public health campaign with more than 70% of females aged 12 to 26 now vaccinated. CSL also received royalty payments of \$161 million from the international sales of human papillomavirus vaccines.

"The Group's capital expenditure during the year totaled \$286 million, an increase of approximately 30%, and underpins a number of growth initiatives. In Marburg, we are in the process of validating new aseptic filling and lyophilisation suites that will support the future growth in coagulation and critical care products. We also completed a new state-of-the-art testing laboratory for plasma donation in Knoxville, Tennessee.

"Following the US launch of Privigen in 2008, this year we opened a new Privigen facility in Bern and a further facility is now well advanced. This new generation 10% liquid intravenous immunoglobulin is set to become a key driver of margin expansion and value. Privigen is a proline-stabilised liquid intravenous immunoglobulin. Since Privigen does not require refrigeration or reconstitution, it is much more convenient to store and is available for immediate use which is a significant benefit to physicians and their patients.

"These investments and others ensure CSL is well placed to meet expected demand for therapies going forward.

"The CSL Group continues to pursue market expansion opportunities. Recently, the United States Food and Drug Administration granted marketing approval for Berinert, C1-Esterase Inhibitor, for the treatment of acute abdominal or facial attacks of hereditary angiodema, a rare and serious genetic disorder, in adult and adolescent patients. Also, CSL Behring has recently appointed GlaxoSmithKline Russia to distribute and promote certain products from CSL Behring's extensive product portfolio in Russia.



"As one of the leading global influenza vaccine manufacturers, CSL responded quickly to the global pandemic influenza threat this year developing a novel Type A (H1N1) influenza vaccine that commenced clinical trials in July. The purpose of this and other clinical studies being undertaken is to establish an optimum vaccine dose for protection against this new strain of influenza.

"On 11 September, CSL announced that preliminary data from the first study of its candidate H1N1 vaccine, published as an original article in the New England Journal of Medicine, demonstrated a robust immune response in healthy adults after a single unadjuvanted 15 microgram dose. The study also showed that the vaccine has a tolerability profile consistent with seasonal influenza vaccines and that the immune response remained consistently strong irrespective of age.

"Following this, in mid September, the Australian Therapeutic Goods Administration and the United States Food and Drug Administration registered CSL's H1N1 vaccine.

"In addition, CSL has clinical studies underway examining the performance of the H1N1 vaccine in children and we look forward to sharing this data when it becomes available.

"The Australian Government has ordered 21 million doses of the vaccine. CSL also has a contract with the US Department of Health and Human Services to provide vaccine with the initial order valued at US\$180 million.

"On 18 September 2009, the Australian Government announced that the H1N1 vaccine ordered by the Government will be available for a national vaccination campaign and has encouraged Australians to protect themselves and their families against the pandemic influenza by getting vaccinated, particularly those at most risk of severe outcomes from this disease. Persons who wish to be vaccinated should consult with their healthcare professional.

"The development and manufacture of CSL's H1N1 vaccine has been a global effort, as vaccine destined for the US is currently being filled and finished in our Marburg facility in Germany, and will soon include fill and finish activity at our Kankakee facility in the US. Such collaboration across CSL's manufacturing and supply chain network is a true reflection of CSL's commitment to develop and produce life-saving medicines essential to the health of many thousands of people around the world.

"Achieving equity of access to the H1N1 vaccine for developing countries remains a major global challenge, and we commend the World Health Organisation for its leadership on this very important issue.

"As the only manufacturer of influenza vaccine in the Southern Hemisphere, we have a unique role to play in not only helping to protect the health of Australians, but also those in our region.

"I am pleased to announce today, CSL is donating 3 million doses of H1N1 vaccine to the World Health Organisation for use in priority low-income countries in the South and Western Pacific as well as South East Asia.



"We will continue to work with the WHO and other partners to identify further ways in which we can help expand access to this very important vaccine.

"As part of CSL's continuing efforts to grow its influenza vaccine business internationally, CSL is pleased that CSL Biotherapies, Inc. recently secured an agreement with Merck & Co, Inc for Merck to act as CSL's exclusive distributor of CSL's seasonal influenza vaccine, Afluria, in the United States commencing from the 2011 influenza season. CSL is committed to providing influenza vaccine to the United States and is now able to leverage Merck's extensive sales network in meeting that commitment and in making Afluria available to more people in the United States in future influenza seasons. This is another milestone in our companies' shared history of close collaboration in the area of vaccine development and distribution.

"In relation to CSL Bioplasma, negotiations are progressing with the National Blood Authority for a new Plasma Products Agreement and we are confident that CSL Bioplasma will continue to provide ongoing specialised plasma products and other value-added services to the National Blood Authority in collaboration with the Australian Red Cross Blood Service.

"CSL congratulates the Australian Red Cross Blood Service in its continuing efforts to support the Australian blood system and is pleased that their efforts and those of their donors is being recognised in this "Year of the Blood Donor 2009".

"CSL's research and development investment continues to be an essential element in our strategy for growth and increased 38% to \$312 million this year. Our R&D investment includes a product development focus on new treatments for life-threatening diseases, market development aimed at maximising opportunities for existing products, and life-cycle management to ensure existing products remain competitive through a continuous improvement program.

#### TALECRIS

"It was on 13 August 2008 that CSL announced an agreement to acquire Talecris Biotherapeutics, Inc, a leading manufacturer and marketer of plasmaderived therapies, from the owners Cerberus Partners, L.P. and Ampersand Ventures. The Talecris acquisition was subject to regulatory approvals, including approval from US anti-trust authorities.

"On 25 May 2009, the US Federal Trade Commission filed a complaint in the US Federal District Court challenging CSL's proposed acquisition. CSL fundamentally disagreed with the FTC case which had not recognised that 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, after careful consideration, 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.

"As a result, on 9 June 2009, both Talecris and CSL announced they had mutually agreed to terminate their merger. 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 of the termination of the transaction has been a non-recurring net profit after tax of \$79 million.

"CSL has recently been served with a number of lawsuits filed in the 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. These actions were filed by individual private hospital groups but all seek status to proceed as class actions on behalf of all persons similarly situated. CSL believes these lawsuits are unsupported by fact and without merit. CSL is an aggressive competitor in all markets and takes great pride in its commitment to delivering life-saving therapies to its customers. CSL will robustly defend against these lawsuits.

"In June 2009, CSL announced an on-market share buyback of up to 54,863,000 shares, approximately 9% of shares on issue. Our shareholders will benefit from improved investment return ratios, such as on earnings per share and return on equity. The buyback returns funds received from shareholders last year to support our acquisition of Talecris.

"As at 12 October 2009, CSL has repurchased 23,518,839 shares for approximately \$758 million, which represents approximately 43% of the intended maximum number of shares to be repurchased.

#### CORPORATE RESPONSIBILITY

"Turning now to Corporate Responsibility.

"This year we launched our Code of Responsible Business Practice.

"The Code sets out CSL's principles for ethical and responsible business practice, which are drawn from our ongoing commitment to conducting our business with integrity and to contributing to the economic, social and environmental well-being of our communities.

"This Code replaces the former CSL Code of Conduct and underpins our policies and practices worldwide. It has been developed to ensure that all of our employees, and the organisations we deal with, know what is expected of them. It will also play an important role in ensuring that our stakeholders continue to have the utmost confidence in the integrity of our practices.

"This year CSL also published its first Global Environment Report outlining the Company's performance with respect to greenhouse gas emissions, water use and waste management. We now have 5 years of data showing year-on-year



reductions in the rates at which we use natural resources and generate byproducts in the manufacture of our medicines.

"Since 2004/2005, our plasma manufacturing facilities have reduced water consumption and greenhouse gas emissions per unit of plasma production by more than 30%. We have also been successful in reducing our waste intensity by 20%.

"We continue to look for innovative ways to reduce our carbon footprint and other environmental impacts through capital works, equipment upgrades and process changes, and to embed environmental considerations into our decisionmaking processes.

"We are closely monitoring climate change policy developments to assess how emerging regulations might impact our business, and remain well prepared for new greenhouse gas reporting regimes being introduced around the world. CSL is not captured in any existing emission trading schemes.

"In considering physical and other risks arising from climate change, it continues to be our view that the Company's exposure is minimal in the short to medium term. We were this year acknowledged for our disclosures on relevant information on climate change strategy, management and practices by being included in the Australian Climate Disclosure Leadership Index.

"In addition to fulfilling our environmental responsibilities, we also increased our contributions to the community this year to help address social issues relevant to our business.

"In addition to the donation of H1N1 influenza vaccine outlined earlier, CSL initiated several programs to help facilitate greater access to medicines for those in need. Most significant was our announcement of a new \$US 3 million partnership with the World Federation of Haemophilia to expand access to haemophilia therapies in developing countries. Each year for the next three years, CSL Behring will donate two million units of Factor VIII concentrate to the World Federation of Haemophilia s well as provide financial support.

"Closer to home, I'm sure none of us forgets the tragic events of Black Saturday and its aftermath. The most devastating bushfire in Victoria's history saw an unprecedented show of public support for those who lost their lives, homes and communities. Our staff responded immediately, not just in Australia but all around the world, and together we contributed a total of \$412,760 to the Victorian Bushfire Fund to help those affected.

"This year we also increased our contributions to the local communities where our manufacturing facilities and plasma collection centres are located, and stepped up our efforts to support science in schools and support our next generation of medical research leaders. I encourage you to read about these initiatives in this year's Annual Report and on the company's website.



#### <u>OUTLOOK</u>

"At the end of the first quarter of the current financial year, I can advise the Company is trading consistently with our expectations.

"At the time of announcing our full year's result in August, we indicated an expectation of continuing growth in the demand for plasma therapies with sales benefiting from a product mix change with a shift towards Privigen. Following the successful rollout of the human papillomavirus vaccine program in Australia, sales of GARDASIL are expected to decline substantially with the catch-up program drawing to a close. However, the novel H1N1 influenza vaccine is expected to provide a strong contribution this year.

"For the 2009/2010 fiscal year, we expect net profit after tax to be between \$1.16 billion and \$1.26 billion at 2008/2009 exchange rates. However, if currency rates on 9 October 2009 were to apply for the balance of the fiscal year, the net profit after tax range referred to earlier would be in the order of \$970 million to \$1.070 billion.

"The outlook is subject of course to a number of variables outlined at the time of the announcement of the Company's annual results, including material price and volume movements on core plasma products, changes in health care regulations and reimbursement policies, royalties from the sale of human papillomavirus vaccines, sales of GARDASIL in Australia, and the fulfilment of novel H1N1 influenza vaccine orders.

#### DIVIDEND

"The Board has declared a final unfranked dividend of 40 cents per share with dividend cheques mailed to shareholders on 9 October. Total ordinary dividends for the year were 70 cents per share, up 52% on the previous year.

"As shareholders would know, franking is a function of Australian derived profits. As CSL's business grows successfully offshore our ability to provide fully franked dividends declines. During the 2008/2009 fiscal year approximately 80% of CSL Group sales were derived offshore. Our Australian businesses and the royalty income from global Human Papillomavirus vaccine sales attract Australian tax. It is CSL's present intention that franking credits generated from these activities will be passed on to shareholders as and when they are generated. We do not, however, expect to be able to frank the interim dividend for the 2009/2010 fiscal year. The decision on franking of the final dividend for the 2009/2010 fiscal year will be taken after the completion of the 2009/2010 fiscal year final accounts.

#### OUR THANKS TO MANAGEMENT AND STAFF

"CSL develops and produces life-saving medicines essential to the health of many thousands of people around the world. For continuing success in this



satisfying work, we depend on the commitment, skills and experience of our talented international workforce.

"On behalf of your Board of Directors, I would like to convey our appreciation of all that management and staff around the world have achieved this year to deliver another strong result for the company.

> Elizabeth Alexander, AM Chairman





### **Disclaimer**

#### Forward looking statements

The materials in this presentation speak only as of the date of these materials, and include forward looking statements about our financial results and estimates, business prospects and products in research that involve substantial risks and uncertainties, many of which are outside the control of, and are unknown to, CSL. You can identify these statements by the fact that they use words such as "anticipate," "estimate," "expect," "project," "intend," "plan," "believe," "target," "may," "assume," and other words and terms of similar meaning in connection with any discussion of future operating or financial performance. Among the factors that could cause actual results to differ materially are the following: the success of research and development activities, decisions by regulatory authorities regarding whether and when to approve our drug applications as well as their decisions regarding labeling and other matters that would affect the commercial potential of our products; competitive developments affecting our current growth products; the ability to successfully market new and existing products in Australia and other countries; difficulties or delays in manufacturing; trade buying patterns, fluctuations in interest and currency exchange rates; legislation or regulations throughout the world that affect product production, distribution, pricing, reimbursement or access; legal defense costs, insurance expenses, settlement costs and the risk of an adverse decision or settlement relating to product liability, patent protection or governmental investigations, growth in costs and expenses; and CSL's ability to protect its patents and other intellectual property throughout the world. The statements being made in this presentation do not constitute an offer to sell, or solicitation of an offer to buy, any securities of CSL.

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## **Highlights - Financial**

Total revenue \$5.04 billion up 32% (16% at constant currency\*)

• HPV royalties of \$161m

EBIT \$1.37 billion up 42% (21% at constant currency)

NPAT \$1.15 billion up 63%

Underlying operational profit \$1.02 billion up 45% - adjusted for

- Talecris merger discontinuation, favourable impact of \$79m
- Tax non-operational items, favourable impact \$47m
- Up 23% at constant currency

R&D expenditure of \$312m up 38%

Operating cashflow \$1.03 billion up 49%

On market share buyback announced ~9% of issued capital

EPS \$1.93 up 51% (underlying EPS \$1.71 up 34%)

Final dividend 40 cents (unfranked), up 52%

# Underlying Operational Profit up 45% (23% @ CC)



### Notes

Reported NPAT	\$1,146m
NPAT - non operational item	
- Merger discontinuation*	\$ 79m
- Tax non operational	<u>\$ 47m</u> \$126m
Underlying operational profit**	<u>\$1,020m</u>

\* Net impact arising from the discontinuation of the Talecris merger

## **Global Revenue \$5 Billion\***



\* Chart excludes revenues related to the discontinuation of the Talecris merger

### Human Health Business Unit Performance

- CSL Behring
- Other Human Health
  - CSL Bioplasma
  - CSL Biotherapies
  - CSL Research & Development

# **CSL Behring**

- Sales US\$2,781m (A\$3,786m)
  - Product sales up 17% at constant currency\* (cc)
- EBITDA margin ~34%, up ~3% at cc
- Strong contribution from core and specialty products
- Optimizing product mix
  - Privigen<sup>®</sup> conversion
  - Vivaglobin<sup>®</sup> take-up
- Privigen<sup>®</sup> IG Lab Module 1 plant approved
- RiaSTAP<sup>™</sup> approved January 2009

## CSL Behring – Product sales up 17% in CC terms

US\$2,781m



## **CSL Bioplasma**

Sales A\$334m up 32% (23% at constant currency) Strong Albumin demand and improved pricing in China Australian sales up 8% Biostate<sup>®</sup> approved for von Willebrands disease in Australia Clinical trials on Intragam<sup>®</sup> 10 NF completed

Dossier submitted to TGA
 Phase III trial - subcutaneous IG for use in Aust. & NZ
 Negotiation of the Aust. Fractionation Agreement underway

## **CSL Biotherapies**

Sales A\$502m up 5%

GARDASIL® Australia / New Zealand

GARDASIL® sales in Australia \$159m

>75% of females aged 12 to 26 now vaccinated

New Zealand sales of \$26m

Influenza sales \$124m, up 60%

Dispensing and packaging facilities completed at Kankakee site

• US FDA approved August 2009

US sales of just under 4 million doses, launched into Germany

In-licensed vaccines and pharmaceuticals product growth

Q-Vax<sup>®</sup> manufacturing facility opened at Broadmeadows site

# Pandemic Influenza Vaccine H<sub>1</sub>N<sub>1</sub>

Significant orders

US Department of Health and Human Services

• Initial order US\$180m vaccine

Australian Department of Health and Ageing

• Order for 21 million doses (15 mcg)

Initial industry yields lower than anticipated

Extensive clinical program underway

**Excellent Progress** 

- Pivotal NEJM publication
- US FDA & Australian TGA Approved (Sept 09)

Australian program launched 30 September 2009

## **R&D Investment**

#### Growth in new product and market development



# **R&D Highlights**

IgPro20

Phase 3 completed and BLA submitted to FDA April 2009
 RiaSTAP<sup>™</sup>

 FDA approval Jan 2009 and EU submission Feb 2009 Berinert<sup>®</sup>

• US FDA approved Oct 2009

**Recombinant Factor IX-FP** 

- Lead clone selected and manufacturing cell line established Reconstituted HDL
  - Reformulation complete and clinical candidate selected



### **Group Outlook for FY2010**

Foreign Exchange (post tax)

FY10 Est.
-ve \$100m
<u>-ve \$80m – \$90m</u>
-ve \$180m – \$200m

Net profit after tax NPAT FY2010 at constant currency *Up 14-24% on FY09 underlying operational profit* Est. foreign currency NPAT impact *(NPAT FY2010 at current rates*)

\$1,160m - \$1,260m

-ve \$180m - \$190m \$970m - \$1,070m)

Outlook statements are subject to: Material price and volume movements on core plasma products, unforeseen competitor activity, changes in healthcare regulations and reimbursement policies, royalties\* arising from the sale of GARDASIL<sup>®</sup> by Merck, sales of GARDASIL<sup>®</sup> in Australia, 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.

<sup>\*</sup> Refer Appendix (Foreign Currency Sensitivity)

### **CSL Growth Strategy**

#### Market Development

Influenza H<sub>1</sub>N<sub>1</sub> Privigen<sup>®</sup> Pro20 Specialty products RiaSTAP<sup>™</sup> Zemaira<sup>®</sup> Cytogam<sup>®</sup> vWF Beriplex<sup>®</sup> etc Expanded geographies HPV ISCOMATRIX® adjuvant Technology partnering

**Royalties &** 

Licensing

#### Novel Products

Biotech rCoag CSL 360

Plasma rHDL

#### Global Specialty Bio- pharmaceutical Company

Plasma sector growth Global focus Growth in R&D investment New products – unmet medical needs

**Financial Strength** Identify Complementary Assets CSĽ

### CSL Limited Annual General Meeting Appendix



# **Foreign Exchange Sensitivity**

Translation sensitivity to 1% movement in key currency pairs

### Translation impact - 9 months to June '10 NPAT

	9 Oct Rates	1% rate change 9 months to June '10
<ul> <li>AUD/USD*</li> </ul>	0.90	+/- \$1.0m
• AUD/EUR	0.61	+/- \$2.9m
<ul> <li>AUD/CHF</li> </ul>	0.92	+/- <u>\$3.0m</u>
		\$6.9m