

15 October 2008

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

Peter Turvey Company Secretary

## CSL Limited Chairman's Address Annual General Meeting – 15 October 2008

"I am very pleased to be able to report that continuing demand for our plasma products and the strong uptake of the GARDASIL® vaccine against cervical cancer in Australia and on international markets have combined to deliver an excellent annual result for CSL.

"CSL Group net profit after tax from continuing operations increased 30% on the previous year to \$702 million and would have been up 45% if not for adverse foreign currency movements. Cash flow from operations grew strongly by 49% to \$715 million.

"Underpinning this, global demand for our plasma therapies continues to grow as we enter new markets, develop new therapies and find new indications for existing therapies.

"In February 2008, we launched PRIVIGEN® in the US. This new generation 10% liquid intravenous immunoglobulin is set to become a driver of margin expansion and value. PRIVIGEN® is the first proline-stabilised liquid intravenous immunoglobulin requiring no refrigeration or reconstitution.

"This of course means that PRIVIGEN® is much more convenient to store and is available for immediate use which is a significant benefit to physicians and their patients.

"More than 26 million doses of the GARDASIL® vaccine have been distributed by our licensee, Merck & Co. Inc., and CSL has received \$167 million in royalty payments from international sales last financial year. In addition, the free national immunisation program in Australia generated sales of \$227 million.

"Following US Food and Drug Administration approval of CSL's AFLURIA® influenza vaccine in September 2007, this product has now been launched in the US. The Company's influenza vaccine is now registered and marketed as a finished product in 26 countries. Capital works recently completed at our Melbourne production facility will provide the extra capacity required for market expansion.

"Another important milestone recently achieved was the decision by the United States District Court, in August 2008, to lift the Consent Decree that had been imposed on our Kankakee manufacturing facility in January 1997, prior to our acquisition, due to certain quality issues. The lifting of a Consent Decree has previously been rarely achieved and therefore the efforts of a large number of people working at the Kankakee site are to be congratulated.



"Investing in research and development is an essential part of our strategy for growth and increased by 18% this year to \$225 million. In 2008-2009, we expect our R&D investment to increase to between \$265 and \$275 million.

"The Managing Director will go into greater detail on the operation of each of our businesses including our Global Research and Development programmes shortly.

#### **TALECRIS**

"On 13 August 2008, CSL announced an agreement to acquire, for US\$3.1 billion, Talecris Biotherapeutics, one of the world's leading manufacturers and suppliers of plasma-derived therapies. Based in North Carolina in the US, Talecris has plasma fractionation facilities, as well as 56 plasma collection centres.

"It is expected that the acquisition will bring substantial benefits to patients and significant gains to CSL shareholders. The combined entity can achieve efficiencies that are not available to either business on their own and will facilitate the provision of more output of high quality plasma products to patients in the USA and Europe. This will be achieved by delivering additional scale-efficient manufacturing facilities with a high quality workforce operating as a further centre of excellence, and strengthening CSL's manufacturing spine.

"By the integration of all manufacturing sites in the CSL Behring Group, the number and yield of plasma products from each litre of plasma will be maximised.

"The acquisition will also enhance our position in key countries including the US by providing a platform to increase diversity and volume of product sales to the benefit of patients in those markets.

"We expect synergies of approximately US\$225 million per annum to be realised progressively over the first three years from the time of closing the transaction. The net result of this will be that CSL Behring will become a stronger competitor in its most significant global markets.

"This acquisition will be funded through a mix of equity, cash and debt, the level of each designed to strike a balance between earnings per share accretion and the management of financial risk resulting in a pro forma gearing post acquisition of 26%.

"To achieve this, an underwritten institutional placement of \$1.75 billion was undertaken together with a Share Purchase Plan to eligible shareholders. The balance will be made up of company cash reserves and syndicated debt which will replace the acquisition bridge facility.



"In order to protect the Company against currency risk, the proceeds from the institutional equity placement in mid August was converted to US dollars at an average rate of 87 cents.

"Your Board was also very pleased with the result of the Shareholder Share Purchase Plan which was announced to the ASX on 19 September 2008.

"The Company raised a total of approximately \$145 million, which will form part of the funding arrangements for CSL's proposed acquisition of Talecris. The issue price for each new CSL share issued under the Plan was \$36.75, the same price as offered under the institutional placement. This price represented an 8% discount to the volume weighted average price of CSL shares traded on the Exchange in the previous 15 days prior to the date the offer closed. These new shares have also participated in the fully franked final dividend paid to shareholders on 10 October 2008.

"Some shareholders expressed concern that they could only acquire up to \$5,000 worth of CSL shares under the Plan. The reason for this was that the Australian Securities and Investments Commission requires that shareholders may only acquire a maximum of \$5,000 worth of shares in any 12 month period where such offer follows on from an overnight institutional placement in which a Prospectus is not completed.

"As advised in the Plan Booklet, the Company is also pleased to be able to donate on your behalf nearly \$120,000 to the Australian Red Cross, being the excess sum resulting from rounding down to the nearest whole number of CSL shares.

"As announced to the Australian Securities Exchange on 13<sup>th</sup> October 2008, and as expected, the US Federal Trade Commission has requested additional information about the Talecris transaction. Shareholders will continue to be kept informed about material developments in the acquisition process including the timing of the closing of the transaction which remain subject to the approval of various anti-trust authorities. If US anti-trust approvals are not forthcoming by 13 August 2009, then a break fee of US\$75 million is payable to the owners of Talecris.

#### CLIMATE CHANGE AND ENVIRONMENTAL RESPONSIBILITY

"I would now like to take this opportunity to address CSL's approach to its environmental responsibilities including climate change. The serious challenges posed by climate change have driven substantial changes in Government policy and regulation over the past 12 months. The Company has been able to maintain its record of strict compliance with environmental laws and is well prepared for new mandatory reporting of greenhouse gas emissions.

"The Company has also been closely monitoring the development of the Carbon Pollution Reduction Scheme in Australia. As currently proposed,



the direct emissions from our facilities are well below the levels that will trigger the need for greenhouse gas permits.

"Indirect effects of the Scheme and other related policy changes are likely to result in modest increases in energy prices, supply costs and environmental management fees. The Company does not expect the increases to be significant. This, however, is based on the premise that the Federal Government will have regard to implementing a scheme that does not unduly disadvantage Australian manufacturers.

"In Europe, the Company's facilities are not captured in the EU's Emission Trading Scheme, the second phase of which commenced this past year. Similarly, in the US we have no exposures to trading schemes but continue to monitor government discussion and proposals in relevant states.

"In considering the broader range of risks associated with climate change, it is our view that the Company's exposure is minimal in the short to medium term. We do however remain diligent in our ongoing assessment of these risks and in our efforts to continually reduce the environmental impacts of our operations. Not only does this assist in cost containment, it is an important demonstration of our commitment to corporate responsibility and sustainability.

"Over a number of years, we have focused on implementing process changes at our manufacturing sites to use natural resources more efficiently and reduce waste and emission rates. Over the last four years, for each unit of plasma processed, we have been able to reduce the amount of water used and greenhouse gas emitted by more than a third.

"I encourage you to read about some of our environmental initiatives in this year's Annual Report and to review the Company's performance in our first comprehensive global environmental report which will be available on our website in November this year. Our goals for the coming year include the setting of global environmental targets, continued reduction of energy and water consumption and waste, ongoing assessment of climate change risk within the Group and informing our stakeholders of our environmental performance.

## SHARE PURCHASE OFFERS BY THIRD PARTIES AT PREDATORY PRICES

"Earlier this year CSL shareholders were approached by a third party attempting to purchase their shares at well below real market prices. This prompted the Company to issue a warning to all shareholders.

"The Australian Shareholder's Association has also raised this as a concern and suggested that the Company set up a facility that enables shareholders with small holdings to sell their shares, free of brokerage and at market value. We believe this has merit and the Company is now investigating how such a process could be cost effectively introduced.



"Shareholders will be kept informed about the progress of this initiative.

#### **OUTLOOK**

"At the end of the first quarter of the current financial year, I am pleased to advise the Company performance is consistent with our expectations.

"At the time of announcing our full year's result in August we indicated an expectation for stable market conditions and growing contribution from royalties associated with the international sales of GARDASIL®. For the 2008/09 fiscal year, we expect net profit after tax to be at the upper end of our range of between \$810 and \$850 million at constant currency – subject to a number of variables outlined at the time of the Announcement of the Company's Annual Results and which are, amongst others, material price and volume movements on core plasma products, changes in healthcare regulations and reimbursement policies and royalties arising from the sale of GARDASIL® by Merck.

"If currency rates on 13 October 2008 were to apply for the balance of the financial year, the net profit after tax range referred to earlier would be in the order of \$935 million to \$1.01 billion. The Managing Director will address the sensitivity to further fluctuations in his presentation.

"We continue to be mindful of movements in foreign currency exchange rates. Shareholders wanting to assess the impact of such movements can refer to the Company's website where we provided detailed guidance on how movements in key currency pairs impact upon the Company's results.

#### DIVIDEND

"The Board has declared a final dividend of 23 cents per share fully franked, an increase of 26% on the same period last year. Dividend cheques were mailed to shareholders on 10<sup>th</sup> October.

#### THE CSL BOARD

"In respect to matters affecting the Board, may I first acknowledge the very significant twelve year commitment by Mr Ken Roberts to the growth of CSL. Mr Roberts has been a Director since February 1996 and Chairman of the Human Resources Committee from when it was initially formed. Mr Roberts has decided not to seek re-election at this meeting.

"During the time of Ken's chairmanship of the Human Resources Committee, the Company's operations have expanded from being totally Australian-based to an Australian Company which receives 80% of its revenues overseas.



'As part of that transition, human resource policies and initiatives have been of vital importance, and as Chairman of the Human Resources Committee his role and the execution of it has been very important.

"So Ken, may I offer you my personal thanks as well as those of the Board for your very valuable contribution over the past 12 years.

"In September this year we welcomed Mr David Anstice to the Board and he will offer himself for election at this meeting. Mr Anstice was a senior executive of Merck and Co, Inc, for many years retiring on 1 September 2008. Mr Anstice has served at various times as President of Merck Human Health for the US, Canada, Europe, Japan and Asia and is Chairman and President of the University of Sydney USA Foundation. Before moving to the US, Mr Anstice was Managing Director of Merck, Sharp and Dohme Australia, responsible for Merck's business in Australia as well as being Vice-President of the Australian Pharmaceutical Manufacturers Association. Mr Anstice is an Australian citizen and is an Adjunct Professor in the Faculty of Economics and Business at Sydney University.

#### **OUR THANKS TO MANAGEMENT AND STAFF**

"Our continuing strong business performance and international delivery of life-saving medicines are the end result of the skills of many people – in research and development, manufacturing, business development, sales and marketing, capital works and a range of essential support services.

"May I, on behalf of your Board of Directors, congratulate management and staff around the world for CSL's achievements in another successful year for the Company."

Elizabeth Alexander, AM Chairman

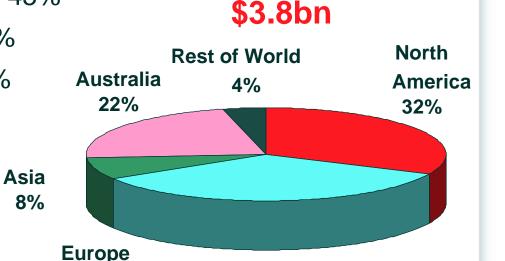


# CSL Limited Annual General Meeting 15 October 2008



## **Highlights - Financial**

- Total revenue \$3,794m up 15%
  - GARDASIL® royalty of \$167m
  - Australian GARDASIL® sales \$227m
- NPAT \$702m up 30%
  - Includes adverse currency impact of \$78m
  - NPAT at constant currency\* up 45%
- R&D expenditure of \$225m up 18%
- Operating cashflow \$715m up 49%
- EPS \$1.28\*\* up 30%
- Final dividend 23 cents (franked 100%)



**Global Revenue** 

34%



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

<sup>\*\*</sup> After restating comparative period for 3:1 share split undertaken 24 October 2007

## Human Health Business Unit Performance

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



## **CSL Behring**

Sales US\$2,526m (A\$2,822m)

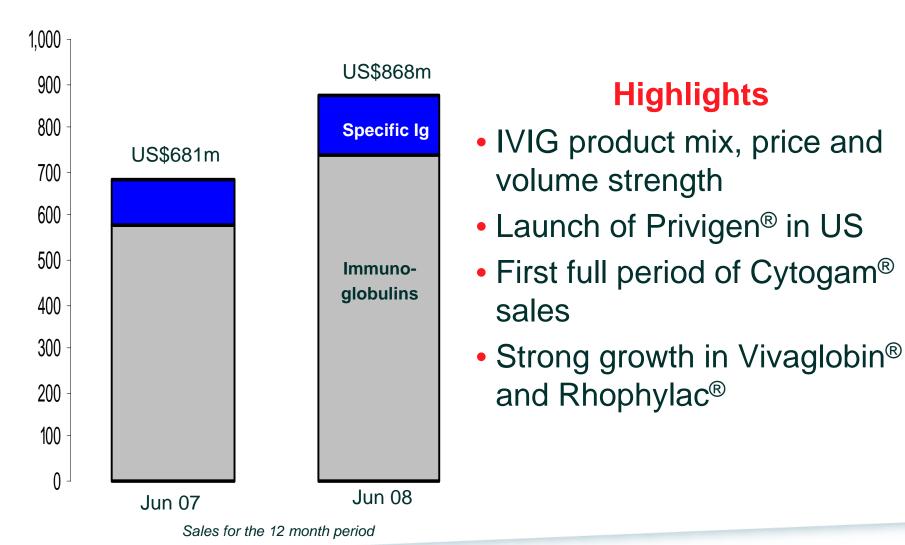
- Up 22% in \$US or 15% at constant currency
- Volume growth ~10%

## EBITDA US\$799m, EBITDA margin ~32%

- Strong contribution from core and specialty products
- Strong growth in intercontinental sales
- Optimizing product mix

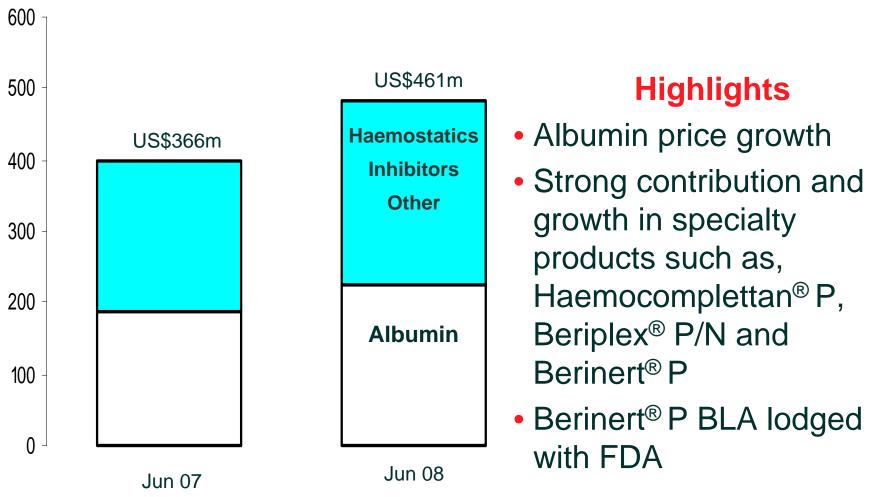


## Immunoglobulins sales - Up 28% in \$US Up 23% at Constant FX





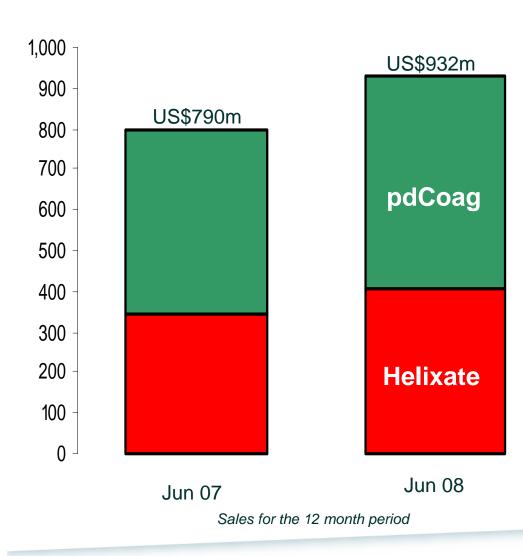
## Critical Care Sales - Up 26% in \$US Up 16% at Constant FX



Sales for the 12 month period



## Haemophilia sales - Up 18% in \$US Up 10% at Constant FX



## **Highlights**

Haemate® P /Humate-P®

- US patient uptake
- Increasing ITT sales in Europe
- Helixate<sup>®</sup>
  - US patient growth
  - UK contract win back



## **CSL Bioplasma**

## Sales A\$253m up 20%

- Strong Albumin sales in China
- Taiwanese Toll fractionation commenced
- 7% increase in plasma collected by ARCBS for fractionation in Australia
- Biostate® approved for vWD in New Zealand
  - Recommended for approval by ADEC & TGA in Australia
- Phase III trials for 10% IVIG and 16% sub-cut IVIG to improve patient convenience and reduce treatment costs advanced.



## **CSL Biotherapies**

Sales A\$481m up 52%

## **GARDASIL®**

Strong GARDASIL® sales in Australia - \$227m

- 'Catch-up' program well advanced
- NZ program expected to commence in September 2008

## Influenza Vaccine – US Launch

Approval and launch of US Influenza vaccine - Afluria®

US Phase IV clinical end-point study fully recruited

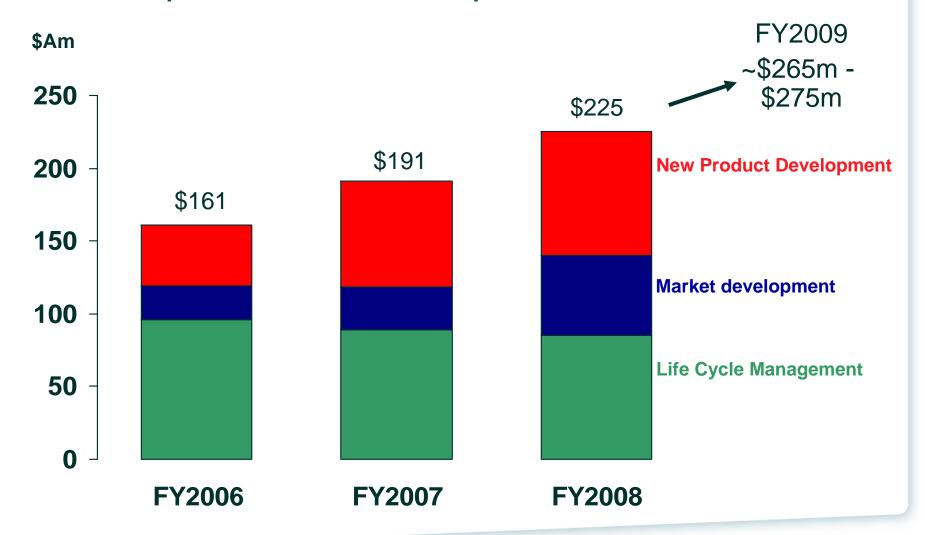
Completion of expanded 40m dose per season facility

US FDA approval granted July 2008



## **R&D Investment**

Growth in new product and market development





## **R&D Highlights – New Products**

#### **Replacement Therapies**

- Privigen approved by the EMEA on April 25
- IgPro20 subcutaneous 20% IgPro phase III's ongoing
- Berinert® P (C1 Esterase Inhibitor) BLA submission
- Beriplex® P/N approved in Western Europe
- Fibrinogen BLA submission
- Animal studies data for recombinant FVIIa Albumin Fusion Proteins for extended half life

#### **Reconstituted HDL**

Acute coronary syndrome – reformulation activities

#### Influenza

Panvax® - pandemic influenza vaccine approved by TGA



<sup>\*</sup> Partnered programs

## **R&D Highlights – New Products**

## Immunomodulators (ISCOMATRIX® Adjuvant)

- December 2007 Merck added 2 additional licences
- Clinical programs continuing
- Influenza ISCOMATRIX® Vaccine Phase IIa completed

## **Therapeutic Proteins**

- CSL360 mAb for Acute Myeloid Leukaemia Phase I ongoing
- GM-CSFR mAb for Rheumatoid Arthritis licensed to MedImmune/AZ – Phase I initiated
- IL-13R MAb for asthma partnership with Merck Phase I planned



## **CSL Limited**

# Acquisition of Talecris Biotherapeutics Holdings Corp.

**Enhancing a World Leading Plasma Therapeutics Business** 



## **Acquisition Summary**

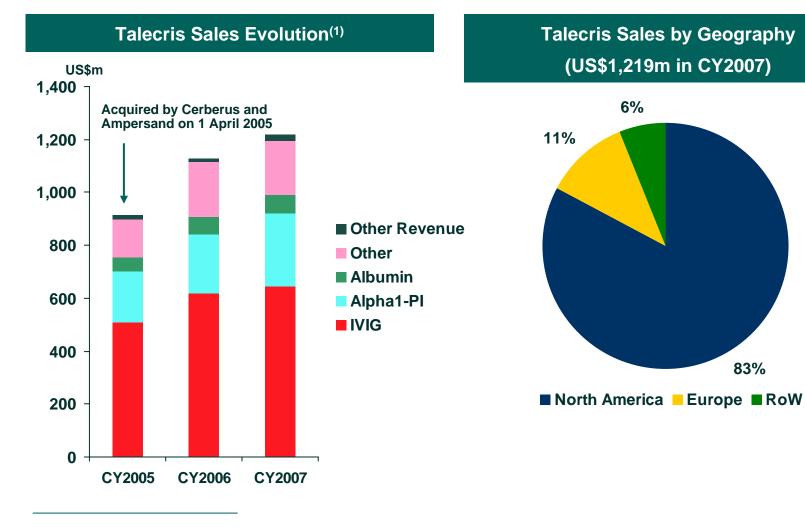
- Agreement signed to acquire Talecris, a leading manufacturer and marketer of plasma-derived protein therapies, from current owners, Cerberus and Ampersand
  - Cash purchase price of US\$3,100m (A\$3,483m)<sup>(1)</sup> less any net debt that may be assumed by CSL
  - Extension of plasma supply agreement
  - Agreement reached after thorough due diligence and exclusivity period
- Closing of the acquisition is subject to customary regulatory approvals including approval from anti-trust authorities

Complementary Acquisition that Makes CSL a Stronger Competitor and Delivers Substantial Benefits to Patients

(1) A\$1.00 = U.S.\$0.89 applied throughout these materials, unless otherwise indicated



## **Talecris Historical Sales**







83%

## **Strategic Rationale**

## Substantial Benefits to Patients

- Improved patient access to plasma products through increased supply
- Enhanced focus on R&D
- Improved market reach, service and support leading to earlier identification, diagnosis and treatment of patients

## Significant Gains to

Making CSL a stronger competitor

**CSL Shareholders** 

- Reduction of manufacturing bottlenecks and enhanced production capacity
- Additional, scale-efficient manufacturing facilities
  - A further centre of excellence
  - Improve balance of manufacturing between US and Europe
- Integration between manufacturing sites
  - Maximise products/yield per litre
- Enhanced portfolio of leading plasma and recombinant products
  - Liquid IVIG, Gamunex<sup>®</sup>, and Alpha1-PI therapy, Prolastin<sup>®</sup>
- Enhanced positions in key geographies, including the US
- More flexible, higher capacity and highly efficient plasma collection business
- A highly optimised supply chain to ensure timely, adequate, secure and reliable supply at lowest cost



## **Profit Improvement Initiatives**

### **Overview**

- Detailed integration plan developed
- Synergies expected to be realised progressively over three years from closing (weighted towards years 2 and 3)
- Associated one-off restructuring costs of approximately US\$120m to be incurred over 12 to 15 months from closing

### **Breakdown of Synergies**

Plasma Collection (1/3)  Creating a more efficient combined plasma collection network

Optimised Manufacturing (1/3)

- Optimise manufacturing operations via intermediates transfers
- Maximise yield of plasma proteins from each litre of plasma

Other Functions (1/3)

- Consolidate corporate functions
- Creating the optimum structure for the combined commercial effort
- Enhanced R&D portfolio and opportunities

Synergies And Improved Operational Execution Expected to Contribute approximately US\$225m p.a.



## **Funding**

- Up-front cash purchase price and transaction costs funded through mix of equity ~50%, available cash ~11% and new debt ~39%
  - Institutional equity placement raised A\$1,747m
  - Share purchase plan raised A\$145m
  - Proceeds from equity raising used to purchase US\$1,600m (A\$1,841m)
  - Available cash of approximately US\$360m (A\$450m)
  - New bank facility to fund balance of purchase price and transaction costs (US\$1,220m)
- Results in pro forma gearing of 26%<sup>(1)</sup> and Net Debt/EBITDA of 1.5x<sup>(2)</sup>, before any synergies



<sup>(1)</sup> Pro forma as at 30 June 2009. Assume transaction closes 30 June 2009 and based on forecast balance sheet as at 30 June 2009.

<sup>(2)</sup> Pro forma as at 30 June 2009. EBITDA based on CSL standalone for the year ended 30 June 2009.

## **Regulatory Process**

- Merger between two of the larger global manufacturers of plasma therapies
  - The transaction will require regulatory approvals including, among others, approval by the US Federal Trade Commission (FTC) which has requested additional information about the transaction as expected
- US\$75m break fee (approximately A\$0.18 per CSL share) is payable to the vendors, under certain circumstances, if anti-trust approvals are not forthcoming within 12 months
- CSL will work diligently to assist all the relevant agencies in their reviews of the acquisition



## **Group Outlook for FY2009**

#### Foreign Exchange (post tax)

FY09 Est.

Translation\* +ve \$125m-\$160m at 13 October 08 rates

Transaction Nil USD/CHF ~1.11

Total +ve \$125m - \$160m

#### Net profit after tax

NPAT FY2009 at constant currency\*\*

Est. foreign currency NPAT impact

(NPAT FY2009 at 13 Oct rates)

\$810m - \$850m

+ve \$125m - \$160m

\$935m - \$1,010m)

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® by Merck, sales of GARDASIL® 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> See company website for new foreign exchange sensitivity table

<sup>\*\*</sup> Analyst August 2008 consensus estimates on GARDASIL® royalties used in FY2009 forecast Excludes interest on equity raising

# CSL Limited Annual General Meeting Appendix



## Foreign Exchange Sensitivity

Translation sensitivity to 1% movement in key currency pairs

## <u>Translation impact - 9 months to June '09 NPAT</u>

	13 Oct	1% rate change
	Rates	9 months to June '09
<ul><li>AUD/USD*</li></ul>	0.68	+/- \$2.2m
<ul><li>AUD/EUR</li></ul>	0.50	+/- \$2.6m
<ul><li>AUD/CHF</li></ul>	0.77	+/- <u>\$2.1m</u>
		\$6.9m

Translation impact for 1Q FY2009 minimal

