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CSL

# ASX Announcement

**For immediate release**

18 February 2021

# CSL Delivers a Strong Half Year Result of $1.8 Billion[1] Net Profit

CSL delivered a strong first half result for 2021 with reported net profit after tax of $1,810 million, up 44% at CC[2] reflecting:

- Solid growth in our core immunoglobulin portfolio led by HIZENTRA®
- Successful transition to own distribution model in China
- Strong growth in the leading HAE product HAEGARDA®
- Exceptionally strong performance by Seqirus
- CSL's diversified portfolio and resilient business model in the midst of COVID-19 pandemic
- Full financial recognition of contracted income for UQ COVID-19 vaccine in first half, after program termination

- Earnings per share $3.98, up 44% at CC[2]
- Interim dividend[3] of US$1.04 per share, up 9%
  - Converted to Australian currency, the interim dividend is approximately A$1.34 per share down 9%
- FY21 net profit after tax is anticipated to be in the range of approximately $2,170 million to $2,265 million at constant currency

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces a reported net profit after tax of $1,810 million for the six months ended 31 December 2020. This result is an increase of 45% (or 44% on a constant currency basis[2]) compared to the previous corresponding period.

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[1] All figures are expressed in US dollars unless otherwise stated.

[2] Constant currency (CC) removes the impact of exchange rate movements, facilitating comparability of operational performance. For further detail please refer to CSL's Financial Statements for the Half Year ended December 2020 (Directors' Report).

[3] For shareholders with an Australian registered address, the interim dividend of US$1.04 per share (approximately A$1.34) will be unfranked for Australian tax purposes and paid on 1 April 2021. For shareholders with a New Zealand registered address, the interim dividend of US$1.04 per share (approximately NZ$1.44) will be paid on 1 April 2021. The exchange rates will be fixed at the record date of 5 March 2021. All other shareholders will be paid in US$. CSL also offers shareholders the opportunity to receive dividend payments in US$ by direct credit to a US bank account.

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"I am pleased to report a strong result in an unprecedented time of uncertainty during the most severe pandemic of our lifetime" said CSL Chief Executive Officer and Managing Director Mr Paul Perreault.

"Guided by our values, our 27,000 dedicated employees remained focused on delivering on our promise to patients and public health. Our people and business model both demonstrated tremendous agility and resiliency in this most challenging of environments."

"Our core franchise, the immunoglobulin portfolio, has continued to perform well led by our market leading subcutaneous product HIZENTRA®. HIZENTRA® sales grew strongly, up 19% reflecting the benefits of home administration and the continued strong uptake for the treatment of the debilitating neurological disorder CIDP (Chronic Inflammatory Demyelinating Polyneuropathy). Our intravenous product PRIVIGEN®, grew only modestly, tempered by pandemic-driven supply constraints."

"Albumin sales grew at a strong 93%[2], largely reflecting the successful transition to our own distribution model in China. Albumin sales in China now reflect a more normalised level with the new distribution model expected to help improve our participation in the value chain and strengthen sales, marketing and our distribution network," Mr Perreault said.

"Sales of our transformational therapy for patients with Hereditary Angioedema (HAE), HAEGARDA®, increased 16%[2] with new patients continuing to take up the innovative therapy."

"Our influenza business Seqirus, delivered an exceptionally strong performance, more than doubling earnings before interest and tax to $693 million. This was achieved by significant growth in seasonal influenza vaccines driven by record demand and the ongoing shift to Seqirus' differentiated and high value product portfolio."

"In the half, we also announced plans to construct a new world-class biotech manufacturing facility in Australia as a further sign of our promise in providing safe and effective influenza vaccines around the world. The state-of-the-art facility will use cell-based technology to produce influenza vaccines for use in both influenza pandemics and seasonal vaccination programs – and will be the only cell-based influenza vaccines facility in the Southern Hemisphere," Mr Perreault said.

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## OPERATIONAL HIGHLIGHTS

### CSL Behring

- Total revenue +9%[2]
- HIZENTRA® +19%[2]
- Albumin +93%[2] (GSP impact[4])
- HAEGARDA® +16%[2]

### Seqirus

- Total revenue +38%[2]
- Seasonal influenza vaccine sales up 44%[2]
- FLUAD® QIV launched in the US
- Re-launch of business in Germany
- Fill and finish capacity expanded
- MF59 sales to US government
- Support provided for COVID-19 vaccines including MF59 supply

### Innovation & Development

- PRIVIGEN® for CIDP launched in Japan
- HAEGARDA® US FDA approval for HAE in patients 6+years
- uniQure announced data from Phase III trial of EtranaDez
- IDELVION® 21 day extended dosing option approved in Japan
- CSL112 (ApoA-1) Phase III study (AEGIS-II) >11,500 patients enrolled
- CSL346 (Anti-VEG-B) diabetic kidney disease Phase II study initiated
- Commencement of aQIVc Phase 2 study
- Pre-clinical assessment of mRNA technology for influenza

### People & Culture

- CSL named among world's best employers by Forbes magazine for the 4th consecutive year
- Key leadership appointments:
  - Joy Linton – Chief Financial Officer
  - Mark Hill – Chief Digital Information Officer

### Efficiency

- Ongoing investment in major capital projects at all manufacturing sites to support future growth

[4] GSP – transition to a new business model in China

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- State-of-the-art new immunoglobulins facility completed in Bern, Switzerland
- 17 new plasma collection centres opened in the US in the first half

**Response to COVID-19**

COVID-19 continues to present challenges for CSL's employees, its supply chains and the collection of plasma, an essential raw material used in the production of many of CSL's therapies. CSL products are critical to sustaining patients' lives, and because of this its plasma collection centers and manufacturing facilities are classified as 'essential services', remaining operational during the pandemic.

Since the beginning of the pandemic, CSL has pursued R&D projects where capabilities, expertise and technologies can be leveraged in the fight against COVID-19. These include multiple programs and partnerships spanning vaccines, monoclonal antibodies and plasma therapies.

The first half results include one-off contributions received for the Company's efforts to develop a COVID-19 vaccine with the University of Queensland. Despite strong Phase 1 data, there were mitigating issues for which there was no easy solution in the timeframes required, resulting in the program being halted and the Australian Government order cancelled.

Prior to being cancelled, CSL had rapidly re-deployed and recruited 400 personnel from other priority projects, undertaken extensive retooling of biotech facilities across two sites in Melbourne and produced 300,000 finished doses for the planned Phase 3 clinical trial. In addition, advanced preparations were underway to launch a 28,000 cohort Phase 3 clinical trial across multiple continents, as well as significant at-risk scale-up production activities (including the manufacture of bulk vaccine that when finished would have made approximately 11 million doses) to support the Australian Government contract, and the potential to distribute a successful vaccine through international mechanisms such as the COVAX facility.

In parallel to the UQ program, CSL had also entered into an agreement with the Australian Government to manufacture 30 million doses of the Oxford University/AstraZeneca COVID-19 vaccine candidate.

Following the cessation of the UQ candidate, CSL turned its attention to accelerating the manufacture of the Oxford University/AstraZeneca COVID-19 vaccine candidate and

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supply an additional 20 million doses ahead of the original schedule. Manufacturing is well underway and the first doses are planned for release in late March 2021.

As a founder of the CoVIg-19 Plasma Alliance, CSL has made good progress with its partners on developing a plasma-derived hyperimmune for treating among the most severe complications resulting from COVID-19. A global Phase 3 clinical trial has nearly completed and CSL is producing trial lots at our Swiss facility. If successful, this will become another viable option for hospitalised COVID-19 patients.

**OUTLOOK *(at FY20 exchange rates)***

Commenting on CSL's outlook, Mr. Perreault said, "Demand for CSL's core plasma, and influenza vaccine products remains robust."

"Seqirus is performing well as strong demand for influenza vaccines together with our differentiated products portfolio will see it deliver another strong profitable year. Consistent with the seasonal nature of the business we anticipate, however, a loss in the second half of the year."

"COVID-19, however, will continue to have an impact on CSL. Our plasma collections have been adversely affected during the pandemic. To combat this, we have implemented a number of initiatives to increase plasma collections and introduced a customer fulfilment process to ensure the equitable distribution of medicines to patients."

"We remain the industry leader in opening new plasma collection centres and investing in future innovation - positioning CSL to emerge strongly when the COVID-19 crisis recedes."

"The additional work we have been doing on COVID-19 vaccines in Australia has resulted in significant opportunity costs to our standard business and manufacturing operations and the re-prioritisation of some R&D projects. Subsequently, there will be an increase in operations and R&D spend in the second half as we restart projects and build them back to scale.

"Our people continue to work exceptionally hard to undertake the COVID-19 vaccine work without compromising the production of our core life-saving therapies – influenza vaccines and plasma and recombinant protein therapies.

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"We're proud that we've been able to meet our existing global commitments while leveraging our unique position and capabilities in Australia, resulting in what will be a significant contribution to the COVID-19 vaccine effort.

"CSL's net profit after tax for FY21 is anticipated to be in the range of approximately $2,170 million to $2,265 million at constant currency, representing growth over FY20 of up to 8%," Mr. Perreault concluded.

In compiling the company's financial forecasts for FY21, a number of key variables that may have a significant impact on guidance have been identified and these have been included in the footnote[5] below.

Authorised for lodgment by:

Fiona Mead
Company Secretary

**FURTHER INFORMATION**

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 CSL's website www.csl.com A glossary of medical terms can also be found on the website. For further information, please contact:

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[5] Key variables that could cause actual results to differ materially include: the success and timing of research and development activities; decisions by regulatory authorities regarding approval of our products as well as their decisions regarding label claims; competitive developments affecting our products; the ability to successfully market new and existing products; difficulties or delays in manufacturing; ability to collect plasma; trade buying patterns and fluctuations in interest and currency exchange rates; legislation or regulations that affect product production, distribution, pricing, reimbursement, access or tax; acquisitions and divestitures; research collaborations; litigation or government investigations; and CSL's ability to protect its patents and other intellectual property.

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# Group Results

| Half year ended December<br>US$ Millions | Dec 2019 Reported | Dec 2020 Reported | Dec 2020 at CC[6] | Change % |
|---|---|---|---|---|
| **Sales** | **4,709** | **5,596** | **5,512** | **17%** |
| Other Revenue / Income | 202 | 143 | 141 | |
| **Total Revenue / Income** | **4,911** | **5,739** | **5,653** | **15%** |
| **Earnings before Interest, Tax, Depreciation & Amortisation** | **1,836** | **2,638** | **2,599** | **42%** |
| Depreciation/Amortisation/Impairment | (204) | (280) | (279) | |
| **Earnings before Interest and Tax** | **1,632** | **2,358** | **2,320** | **42%** |
| Net Interest Expense | (71) | (107) | (77) | |
| Tax Expense | (313) | (441) | (449) | |
| **Net Profit after Tax** | **1,248** | **1,810** | **1,794** | **44%** |
| Interim Dividend | 0.95 | 1.04 | | 9% |
| Earnings Per Share | 2.75 | 3.98 | 3.95 | 44% |

[6] Constant currency removes the impact of exchange rate movements to facilitate comparability of operational performance. For further details, please refer to CSL's Financial Statements for the Half Year ended December 2020 (Directors' Report).