

**CSL Limited** 

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# **ASX Announcement**

For immediate release 15 August 2023

# FY23 reported NPATA US\$2.61 billion<sup>1,2</sup> Up 20% at constant currency<sup>3</sup>

Strong Ig growth
Record level of plasma collections
CSL Vifor integration well advanced
Successful launch of gene therapy HEMGENIX®

#### FINANCIAL HIGHLIGHTS<sup>4</sup>

- Revenue \$13.31 billion, up 31% at CC<sup>3</sup>
- NPAT \$2.19 billion<sup>1</sup>, down 3%
  - NPAT \$2.44 billion<sup>1</sup> at CC<sup>3</sup>, up 8%
- NPATA \$2.61 billion<sup>1,2</sup>, up 10%
  - NPATA \$2.86 billion<sup>1,2</sup> at CC<sup>3</sup>, up 20%
- NPATA<sup>1,2</sup> earnings per share \$5.41<sup>2</sup>, up 6%
  - NPATA<sup>1,2</sup> earnings per share \$5.92 at CC<sup>3</sup> up 17%
- Final dividend<sup>5</sup> of US\$1.29 per share
  - o Total full year dividend US\$2.36, up 6%
  - Converted to Australian currency, the total full year dividend is approximately A\$3.59 per share, up 13%
- NPATA<sup>1,2</sup> for FY24 is anticipated to be in the range of approximately \$2.9 billion to \$3.0 billion at  $CC^3$

CSL Limited (ASX:CSL; USOTC:CSLLY) today announces a reported net profit after tax of \$2.19 billion<sup>1</sup> for the 12 months ended 30 June 2023, up 8% on a constant currency basis<sup>3</sup>. Underlying profit (NPATA) was \$2.61 billion<sup>1,2</sup>, up 20% on a constant currency basis to \$2.86 billion<sup>1,2,3</sup>.

Dr Paul McKenzie, CSL's Chief Executive Officer and Managing Director said, "Our strong performance in the 2023 financial year was delivered against a challenging operating environment. Our CSL Behring business rebounded strongly driven by exceptional growth in immunoglobulin sales and record plasma collections.

"While we have not been immune to inflation and currency headwinds, our focus on improving efficiencies across our global network of manufacturing sites has helped reduce the impact. We remained focused on executing on our strategy of delivering innovative medicines to best



serve our patients and protect public health. This, combined with the efforts of our people is now delivering positive momentum for CSL and our patients in more than 100 countries.

"During the period, we successfully completed the acquisition of Vifor Pharma. Whilst CSL Vifor has only been part of CSL for a short period, the integration is well advanced and the cost synergies are well on track.

"Undoubtedly a highlight during the period was treating the first patients with HEMGENIX®, after the FDA approved the first and only gene therapy for the treatment of adults with haemophilia B earlier in the year", Dr McKenzie concluded.

#### **PERFORMANCE**

### **CSL Behring**

Total revenue was \$9,290 million, up 12% when compared to the prior comparable period.

**Immunoglobulin** (Ig) product sales of \$4,675 million, increased 21%<sup>3</sup> with strong growth recorded across all geographies as global supply recovered strongly.

PRIVIGEN® (Immune Globulin Intravenous (Human), 10% Liquid) sales delivered strong growth of 29%³ as demand continues to recover from the pandemic with patient diagnosis and new patient starts steadily increasing.

HIZENTRA® (Immune Globulin Subcutaneous (Human), 20% Liquid) sales were up 12%³ as patient diagnosis rates continue to improve and new patients emerge.

Underlying demand for Ig continues to be strong due to significant patient needs in core indications – namely Primary Immune Deficiency, Secondary Immune Deficiency and Chronic Inflammatory Demyelinating Polyneuropathy (CIDP).

**Albumin** sales of \$1,109 million, were up 11%<sup>3</sup>. Sales in China were up strongly as COVID restrictions eased. Solid growth was also recorded in the US and Europe as supply improved.

Haemophilia product sales of \$1,193 million increased 8%<sup>3</sup>.

IDELVION®, CSL Behring's novel long-acting recombinant factor IX product, achieved strong growth of 13%³ as patient interactions with health care providers increased post COVID.

HEMGENIX®, the first and only gene therapy for haemophilia B was successfully launched in the US.

The haemophilia A market continued to be competitive resulting in a modest increase in sales for AFSTYLA®, a novel recombinant factor VIII product, and a decline in sales for plasma-derived products.



**Specialty products** sales of \$1,831 million, up 6%³ led predominately by demand for KCENTRA® and ZEMAIRA®.

KCENTRA® (4 factor prothrombin complex concentrate) recorded sales growth of 10%³, as social mobility increased post COVID.

ZEMAIRA® Alpha1-Proteinase Inhibitor (Human) sales were up 24%³ as supply returned.

#### **Plasma Collections**

Plasma collections were robust with plasma volumes up 31% and now at record levels.

Improved social mobility post-COVID, targeted marketing campaigns and enhanced digital initiatives to attract donors all contributed to this unprecedented growth.

The cost of collecting plasma, which includes donor compensation and labour, declined ~14% over the previous year and ~17% down from the peak in March 2022.

The significant increase in plasma supply underpins the company's ability to manufacture plasma products and enables CSL to meet the underlying patient demand for core plasma products.

#### **CSL Segirus**

Total revenue of \$2,031 million, was up 9%<sup>3</sup> driven by growth in seasonal influenza vaccines, in particular FLUCELVAX<sup>®</sup> which increased 30%<sup>3</sup>.

This growth was achieved against a backdrop of reduced rates of immunisation and highlights the strength of CSL Seqirus' strategy and its high value differentiated product portfolio.

#### During the period:

- A licence agreement was signed with Arcturus Therapeutics for next-generation mRNA vaccine technology
- 6 months+ age indication for FLUCELVAX® now approved in the US, Argentina, Canada, Taiwan, Australia & New Zealand
- The US Centers for Disease Control and Prevention recognised FLUAD® as a preferentially recommended seasonal vaccine option for adults aged 65+ years
- Fill and finish capacity expansion now fully operational at Holly Springs and Liverpool
- Good progress was made on construction of the new cell-culture influenza vaccine facility in Melbourne, expected to be operational in 2026.

# **CSL Vifor**

Total revenue was \$1,989 million representing approximately 11 months contribution since the business was acquired on 9 August 2022. This amounts to approximately 14% growth<sup>3,6</sup> compared to the 11 months in FY22 before CSL ownership, reflecting solid growth across all key product areas.



The integration of CSL Vifor is well advanced and the cost synergies are well on track.

During the period Injectafer® (ferric carboxymaltose) was approved in the US for the treatment of iron deficiency in adult patients with heart failure and Ferinject® was launched in China in April 2023.

#### **Expense Performance**

Research and development (R&D) expenses were \$1,232 million<sup>9</sup>, up 22%<sup>3</sup> when compared to the prior comparable period. The increase in expenses reflects the inclusion of CSL Vifor and progression of the pipeline.

Selling and marketing expenses (S&M) were \$1,454 million<sup>9</sup>, up 58%<sup>3</sup> in comparison to the previous year. The inclusion of CSL Vifor for the first time accounts for the increase in S&M expenses while other S&M expenses were held in line with the prior year.

General and administrative (G&A) expenses were \$907 million<sup>9</sup>, an increase of 27%<sup>3</sup> when compared to the prior comparable period. The increase in G&A expenses was related to the inclusion of CSL Vifor.

Depreciation, amortisation (D&A) expense and impairment was \$831 million<sup>9</sup>, up 27%<sup>3</sup> in comparison to the prior comparable period. The increase in D&A was largely due to the inclusion of CSL Vifor.

Net finance costs were \$406 million<sup>9</sup>, up 165%<sup>3</sup>. The increase in net finance costs was due to the debt associated with the acquisition of Vifor Pharma and higher interest rates.

## **Financial position**

Cashflow from operations was \$2,601 million, down 1%. Cash earnings growth was offset by growth of plasma collections.

Cash outflow from investing was \$11,843 million, up significantly when compared to the prior comparable period driven by the acquisition of Vifor Pharma.

CSL's balance sheet remains in a strong position with net assets of \$17,826 million.

Current assets decreased by 44% to \$9,259 million. The main driver was the cash payment relating to the acquisition of Vifor Pharma.

Non-current assets increased by 127% to \$26,975 million in comparison to the previous year. The increase is largely due to the acquisition of Vifor Pharma and the intangible assets recognised by the acquisition.

Current liabilities decreased by 35% to \$4,608 million. The decrease was mainly due to the reclassification of the 144A senior notes from current to non-current following the removal of a mandatory redemption feature on the close of the Vifor Pharma acquisition.



Non-current liabilities increased by 107% to \$13,800 million compared to last financial year. The increase was due to the draw down in bank borrowings in connection with the acquisition of Vifor Pharma in addition to interest-bearing liabilities and borrowings assumed on the acquisition of Vifor Pharma.

### **Innovation & Development**

Key highlights include:

- First patient dosed with FDA approved HEMGENIX® in the US, the first gene therapy for haemophilia B
- CSL112 (ApoA-1) Phase III study (AEGIS-II) was completed with results expected in early calendar 2024
- Garadacimab (Anti-FXIIa) for HAE, preparation for global regulatory submissions underway
- Global collaboration and license agreement signed with Arcturus Therapeutics for access to next-generation mRNA platform technology
- Adjuvanted Cell Culture Influenza Vaccine (aQIVc) on track to go into Phase III
- New state-of-the-art research and development centres opened in Marburg, Germany and Waltham, United States.
- CSL's new Global Headquarters and Centre for R&D opened in Melbourne, Australia

# **People & Culture**

- Appointment of Dr Paul McKenzie as new CEO & Managing Director, effective 6 March 2023
- Andy Schmeltz joined CSL as Head of CSL Behring, effective 30 June 2023 with Bill Campbell, Executive Vice President, Chief Commercial Officer to retire in December 2023
- Jeffrey Ball promoted to Chief Sustainability Officer, effective 1 July 2023
- Ken Lim promoted to Executive Vice President, Strategy and Business Development, effective 1 August 2023
- Kate Priestman appointed Head of Corporate and External Affairs, effective 11 September 2023.

#### **Efficiency**

- 12 new plasma collection centres opened
- Commenced roll-out of new RIKA plasmapheresis devices
- Continued advancement of digital transformation initiatives
- Additional base fractionation capacity completed and approved at Broadmeadows and Marburg facilities
- Multiple manufacturing yield initiatives underway.



# **Sustainability**

- Submitted direct and indirect emissions reduction targets to the Science Based Targets initiatives for validation and endorsement
- Reduced Scope 1 and Scope 2 greenhouse gas emissions due to an increased proportion of purchased electricity from renewable sources
- First of four waves of Scope 3 supplier communication has been completed, representing 8% of CSL's total Scope 3 emissions which revealed that all suppliers targeted have set SBTi or science-based aligned targets, or plan to set SBTi or sciencebased aligned targets by 2024
- New global corporate headquarters has been awarded a five-star rating from the Green Building Council of Australia
- Marburg manufacturing facility now procures 100% of its electricity from renewable sources

# Outlook

Commenting on CSL's outlook, Dr. McKenzie said, "The strong growth in our immunoglobulins franchise is expected to continue following record plasma collections in FY23.

"We have a number of initiatives underway to improve efficiencies which include a focus on optimising plasma collection costs, improving manufacturing yields and bringing new products to market, all of which will support the medium-term recovery in CSL Behring's gross margin.

"The launch of HEMGENIX® in the US last quarter will continue to deliver this paradigm-shifting treatment to the haemophilia B community in the US and Europe in the year ahead. Our R&D pipeline includes a number of late-stage programs nearing completion which will lead to more options for patients and protecting public health.

"We anticipate that CSL Seqirus will deliver another strong year driven by demand for its differentiated products. CSL Seqirus is progressing global registrations for its next-generation mRNA COVID vaccine.

"For CSL Vifor, we are focusing on unlocking the value and growth within this newly acquired business. Supporting our medium-term outlook, we are bringing together our research and development capabilities into the one R&D organisation. We are also combining nephrology and transplant therapeutic areas and have a number of patient blood management initiatives underway that leverages the strengths of CSL Vifor and CSL Behring.

"For FY24, revenue growth is anticipated to be approximately 9-11% over FY23 at constant currency<sup>3</sup>. CSL's underlying profit, NPATA<sup>1,2</sup> for FY24 is anticipated to be in the range of approximately \$2.9 billion to \$3.0 billion at constant currency<sup>3</sup>, representing growth over FY23 of approximately 13-17%<sup>7</sup>", Dr McKenzie concluded.

In compiling the company's financial forecasts for FY24, a number of key variables that may have a significant impact on guidance have been identified and these have been included in the endnote<sup>8</sup>.



# **FURTHER INFORMATION**

Additional details about CSL's results are included in the company's 4E 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.

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# **Group Results**

Full year ended June US\$ Millions	Jun 2022 Reported	Jun 2023 Reported	<b>Jun 2023</b> at CC <sup>3</sup>	Change %
Sales	10,136	12,776	13,270	31%
Other Revenue / Income	426	534	556	31%
Total Revenue / Income	10,562	13,310	13,826	31%
Earnings before Interest, Tax, Depreciation & Amortisation	3,595	3,900	4,240	18%
Depreciation/Amortisation/Impairment	(553)	(596)	(607)	10%
Other acquisition adjustments	40	353	346	
Earnings before Interest and Tax <sup>9</sup>	3,082	3,657	3,978	29%
Net Interest Expense	(147)	(406)	(390)	165%
Tax Expense <sup>9</sup>	(554)	(504)	(594)	7%
NPATA <sup>2</sup>	2,381	2,747	2,994	26%
Acquired intangible assets amortisation	(115(	(235)	(239)	
Other acquisition adjustments	(40)	(353)	(346)	
Income tax on the above adjustments	29	85	84	
Net Profit After Tax	2,255	2,244	2,493	11%
NPATA attributable to:				
<ul> <li>Shareholders of CSL Limited</li> </ul>	2,381	2,610	2,855	20%
- Non-controlling interest		137	139	
NPAT attributable to:				
<ul> <li>Shareholders of CSL Limited</li> </ul>	2,255	2,194	2,441	8%
- Non-controlling interest		50	52	
NPATA <sup>2</sup> earnings per share <sup>1</sup>	5.08	5.41		6%
Total Dividend (US\$)	2.22	2.36		6%



- <sup>1</sup> Attributable to CSL shareholders
- <sup>2</sup> Statutory net profit after tax (NPAT) before amortisation and impairment of acquired intellectual property, business acquisition and integration costs and unwind of the inventory fair value uplift.
- <sup>3</sup> Constant currency (CC) removes the impact of exchange rate movements, facilitating the comparability of operational performance. For further detail refer to CSL's Financial Statements for the Full Year ended June 2023 (Directors Report).
- <sup>4</sup> All figures are expressed in US dollars unless otherwise stated
- <sup>5</sup> For shareholders with an Australian registered address, the final dividend of US\$1.29 per share (approximately A\$1.97) will be paid on 4 October 2023. For shareholders with a New Zealand registered address the final dividend of US\$1.29 per share (approximately NZ\$2.13) will be paid on 4 October 2023. The exchange rates will be fixed at the record date of 12 September 2023. 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.
- <sup>6</sup> Eleven months to FY22 pre-CSL ownership and unaudited versus eleven months to FY23
- $^{7}$ % growth rates exclude the one-off gain from the sale of property in FY23 (NPATA \$44m)
- <sup>8</sup> 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.
- <sup>9</sup> Underlying results are adjusted to exclude impairment and amortisation of acquired intellectual property (\$235 million), business acquisition and integrations costs and unwind of the inventory fair value uplift.
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# General disclaimer

#### Non-IFRS

There are references to IFRS (International Financial Reporting Standards) and non-IFRS financial information in this document report. Non-IFRS financial measures are financial measures other than those defined or specified under any relevant accounting standard and may not be directly comparable with other companies' information. Non-IFRS financial measures are used to enhance the comparability of information between reporting periods, and enable further insight and a different perspective into the financial performance. Non-IFRS financial information should be considered in addition to, and is not intended to be a substitute for, IFRS financial information and measures. Non-IFRS financial measures are not subject to audit or review.