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# **ASX Announcement**

For immediate release

14 October 2020

### **CSL LIMITED 2020 ANNUAL GENERAL MEETING SPEECHES**

CSL Limited (ASX:CSL; USOTC:CSLLY)

Please find attached addresses to shareholders to be delivered by the Chair and the Chief Executive Officer at CSL Limited's Annual General Meeting today.

Shareholder attention is drawn to a revised FY21 outlook, details of which are provided in slide 9 of the attached presentation.

Net profit after tax is now expected to be approximately \$2.170 to \$2.265 billion at constant currency, implying a growth of 3 to 8%, which is a slight tightening of the range advised at the Company's results announcement in August. The low end of the range was previously zero, which has now been raised to 3%.

The meeting will be webcast at <a href="https://web.lumiagm.com/?fromUrl=362222588">https://web.lumiagm.com/?fromUrl=362222588</a>.

Authorised for release by

**Fiona Mead** 

**Company Secretary** 

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### CSL 2020 Annual General Meeting: Chair Address

Good morning Ladies and Gentlemen. Thank you for joining us today. There is a quorum present and I am delighted to open the meeting.

What a difference a year makes. This time last year we held - for the first time in the history of our company - an AGM outside of Melbourne, and during that week we recognised our 25<sup>th</sup> anniversary as a listed company on the Australian Securities Exchange.

Clearly there is a little less fanfare this year but as we move through our 26<sup>th</sup> year as a listed entity, we could not possibly have imagined ourselves hosting an AGM that is entirely dependent on the technology not failing! I do hope all of you – no matter where you are participating from -- are staying safe and healthy as we each continue to navigate through the disruption of the COVID-19 pandemic.

I would now like to introduce your Board of Directors and our Company Secretary who are all on line today:

- Mr. Paul Perreault, Managing Director
- Mr. Bruce Brook;
- Dr. Megan Clark;
- Professor Andrew Cuthbertson;
- Ms. Carolyn Hewson;
- Mr. Abbas Hussein;
- Ms. Marie McDonald;
- Ms. Christine O'Reilly;
- Mr. Pascal Soriot; and
- Ms. Fiona Mead, our Company Secretary who has already spoken.

As always, one of the Board's priorities is to ensure it has the capabilities and domain expertise to govern our complex, global business effectively.

This year we welcomed Carolyn Hewson and Pascal Soriot to the Board.

We are very pleased to have Carolyn and Pascal join us as they bring deep experience from their respective fields and will further contribute to the right balance of attributes, skills and diversity to support us in the delivery of best practice governance befitting a multi-national company such as ours.

Not only do we take a structured and rigorous approach to Board composition and succession, we apply this level of review throughout the organisation to ensure that we have an agile, best-in-class and principles-based management team reflecting our Values of Patient Focus, Innovation, Integrity, Collaboration and Superior Performance.

We also farewell Christine O'Reilly who will retire after 10 years of service to CSL. Christine has been a highly respected and trusted member of the Board, and has made a strong contribution to CSL in Board discussions, in strategic discussions and in Remuneration Committee and Audit & Risk Management Committee meetings. She was the founding Chair of our Corporate Governance & Nomination Committee, which now forms a key plank in CSL's governance framework.

In a few minutes, Paul Perreault, our CEO and Managing Director, will share with you some detail on the performance of our individual business units for the year past. While we were pleased to be able deliver to our shareholders another strong year, including the payment of a dividend of US\$2.02 per share, I want to acknowledge the impact that COVID-19 has had on the communities and economies in which we live and work around the world. There is not one of us who hasn't experienced its effects in some way.

While this deeply challenging circumstance has added complexity to our business and operating environment, it has also demonstrated to us just how critical having a Values-based culture as the bedrock of the organisation is to sustain us through tough situations like this. I have been very pleased to see the steadfast commitment of our people to patients and protecting public health throughout this time.

For this, I'd like to recognise and thank Paul and his Management team for their strong leadership over the year. I'd also like to thank my fellow Directors for their guidance and commitment to excellence.

Despite the challenges, we have continued to effectively cultivate our strategy and drive a culture of innovation, not only across our Research and Development (R&D) organisation, but across the enterprise.

One of the ways the Company continues to stay focused is by using CSL's 2030 Strategy as our compass. With a global workforce in more than 35 countries and a strong baseline culture, we are committed to executing our Company strategy -- an approach that has held our company in good stead over time.

The pandemic will have some shorter-term impacts to our plasma collection capabilities – and Paul will speak further to this. However, we see potential in the years ahead to create enhanced value and to better serve our patients through the use of data, connectivity and technologies that can improve our operations and increase our understanding of the patient experience. Today, we are taking the necessary steps to enable digital transformation throughout the business.

The sustainable growth of our business requires that the patients who will benefit most from our therapies have access, and that we also capture the value that our products brings to patients. Global demand for our products is increasing and we strive to maximise the value of our franchises. For our core therapeutic areas, we will continually tailor our portfolio of products to deliver unmet need to patients and value to stakeholders. We also continue to make significant investments in expanding infrastructure around the world to support future growth. Just this year, around \$1.3 billion has been allocated to capital projects and we expect to spend \$1.6 billion in the coming year. These long-term investments are critical to sustaining future demand for our products.

Some of our significant expansion activities include the construction of new base fractionation plants at our sites in Kankakee, U.S., Broadmeadows, Australia and Marburg, Germany as well as the extension of our Immunoglobulin finishing capabilities in Bern, Switzerland. We're also expanding our R&D footprint with the development of a new R&D campus in Marburg, and this year we opened our first laboratory in Philadelphia, not too far from our U.S. CSL Behring headquarters.

The construction of our new 16-storey global R&D hub facility and corporate headquarters in the heart of Melbourne's biomedical precinct is tracking along well, scheduled to open in 2023. Supporting this physical network are upgrades to the digitization of our platforms and systems, strengthening efficiency across the global network.

CSL has long been a trusted partner in protecting public health, and through our unique capabilities and expertise, take this responsibility seriously. Along with our expertise in fighting influenza – both seasonally and through influenza pandemics - our response to COVID-19 has

demonstrated how CSL can respond with flexibility and purpose to events that impact global health.

As a business, we've needed to adapt to the evolving environment that is COVID-19.

Very deliberately, we have focused our energies on matching our science with our technical capabilities and facilities around the world. We are currently working on a number of programs to both prevent and treat COVID-19, and you will hear more about in a few minutes.

Before I turn it over to Paul, I'd like to offer my deep gratitude to all of our 27,000 employees for their steadfast commitment during this unprecedented year. Whether they are among our workforce supporting our manufacturing sites or plasma collection centers or are working remotely because of stay-at-home orders – the contributions of our people have been invaluable to ensuring our business continues to operate and that we've been able to continue delivering on our promise for helping patients and protecting public health.

And to our shareholders, thank you for your continued support of our company.

With that, I now call on Paul to present a more detailed review of the Company's operations.

Thank you all and I look forward to taking your questions later in the meeting.

### 2020 CSL Annual General Meeting: CEO and Managing Director Address

Good morning and thank you for joining us today for CSL's 2020 AGM.

I would like to take you through both the financial and operational highlights of what we have achieved over the 2020 financial year.

Additionally, I will provide an overview of our expectations for 2021.

Just before I go into the results, I would like to take this opportunity to reflect on the devastating impact of COVID-19 globally. As the pandemic continues to spread across the globe, all of us are experiencing its impact both at work and at home.

Without question, our daily life routines and those of our loved ones have been altered, and we are all adjusting rapidly. Whilst the pandemic is still an evolving situation, I want to assure you that the health and safety of our employees, patients and donors remain our top priority.

As a business, we understand the need to be agile and adapt to the evolving environment that is COVID.

Before moving to the highlights, I draw your attention to the legal statement in relation to forward looking statements in my presentation.

### A strong year for CSL

I am pleased to report that CSL delivered another strong year

- Revenue was up 9% at constant currency and
- Net profit after tax was up 17% at constant currency

This is an excellent performance given the strong result we achieved in the previous financial year.

The result is a reflection of our focus on strategy execution and delivering on our promise to provide innovative medicines for patients and public health around the world.

Now, more than ever, our patients and at-risk populations need a continuous, reliable supply of medicines and we will continue to work to support them in every way we can.

Some of the year's highlights include:

- Our largest franchise, immunoglobulins, has performed exceptionally well with PRIVIGEN® up 20% and HIZENTRA® up 34%. This is testament to our ability to consistently deliver our therapies to meet the growing demand
- The successful evolution of our haemophilia portfolio continues on track with IDELVION® up 25% and AFSTYLA® sales up 21%
- We transitioned to our own distribution model in China
- Seqirus delivered on its product differentiation strategy with strong profit growth, driven by influenza sales which were up 21%

### **CSL Behring Sales FY20**

CSL Behring recorded overall sales growth of 8% for FY20 at constant currency.

### Immunoglobulins

- Our immunoglobulin portfolio continues as the standout performer and our largest franchise with over \$4 billion in sales.
- Despite the challenges associated with COVID-19, demand remains strong and we have achieved above-market growth for our Ig portfolio.

#### Albumin

- Sales grew in all our key markets with the exception of China, where we transitioned to our own distribution model
- That transition is now complete, I'm proud to say there was no impact on supply to patients

### Haemophilia

 Our haemophilia portfolio has continued to evolve with strong growth in the recombinant haemophilia products, which saw total sales up 8%.

### Specialty

- Overall specialty products sales grew 10%
- Peri-operative bleeding was up 10%, primarily driven by strong demand in KCENTRA® and our fibrinogen concentrate products used for the treatment of acute bleeding
- Other Specialty products category grew 9% with HAEGARDA® and BERINERT® driving sales, moderated by a decline in our wound healing portfolio

In terms of geographic split, the pie chart on the right shows the broad global reach of CSL Behring's sales with our two key markets -- North America and Europe.

All regions recorded strong double-digit growth, the exception being Asia Pacific which was impacted by the change in our distribution model.

I want to take this opportunity to announce that we recently received US Food and Drug Administration approval for an expanded label indication for HAEGARDA, to now include patients 6 years of age and older. This label expansion makes HAEGARDA the first and only subcutaneous treatment option for prevention of hereditary angioedema attacks in this younger patient population.

### **Plasma Collections**

At CSL, we operate one of the world's largest and most efficient plasma collection networks.

In FY20, we opened another 40 centres in the US – with US centres now totalling 261 centres as of June 2020. We have 8 in Germany, 3 in Hungary and 5 in China, giving a grand total of 277 globally.

As well as opening new centres, we continually look at ways to do things better and more efficiently throughout our network.

#### **Segirus Revenue FY20**

When we founded this business in 2015, we outlined the strategy of how we intended to turn this loss-making business around and set long-range financial goals.

We targeted \$1 billion in revenue, with an accompanying EBIT margin of 20%. These objectives were largely underpinned by manufacturing efficiencies and a suite of differentiated products by FY20.

I am pleased to announce that Seqirus has exceeded these goals and performed exceptionally well with yet another impressive year.

This year Seqirus reported revenue in excess of \$1.3 billion -- which is 11% revenue growth on EBIT of over \$260 million, with a 20% margin. This reflects a 74% increase on FY19.

Breaking it down further, seasonal influenza vaccines grew 21% with the continued shift towards higher value and differentiated products – like our quadriavalent vaccines and FLUAD – the adjuvanted vaccine for the elderly market.

Whilst the US is our major market accounting for 62% of total revenue, there has been strong growth in other key geographic markets with governments seeking to secure manufacturing capacity to protect their populations against influenza in the midst of a COVID pandemic.

Pandemic sales continue to perform well with reservation fees up 11%, largely attributable to new contracts in EU and Canada.

### Research & Development (R&D) Highlights

Innovation is a hallmark of CSL strategy. During the past 12 months, we have been extremely active in undertaking a range of Research and Development initiatives to bolster and deepen our pipeline underpinning the Company's future growth.

There is an abundance of milestones to discuss, but in the interests of time I'll only talk to a few of the highlights.

### Beginning with **Immunology**

- In June, we announced positive results for the phase 2 trial for Garadacimab
- Data released showed that the study met its primary end-point, demonstrating reduced number of attacks compared to placebo in patients with HAE

### Cardiovascular and Metabolic and CSL112:

- First futility analysis completed recently by The Independent Data Monitoring Committee recommended the trial should continue as planned, now this does not mean the trial will necessarily be successful, only that it is worthwhile to continue the trial.
- For context, there are currently just under 10,000 patients enrolled to date, and we are slightly ahead of the projected recruitment rate since restart, following the COVID related trial pause

#### Haematology

- We acquired a late stage gene therapy candidate for the treatment of haemophilia B from uniQure.
- The program is currently in Phase 3 and could be one of the first gene therapies to provide long-term benefits to patients with haemophilia B with a potential launch in 2022

### **Transplant**

- We acquired from Vitaeris, Clazakizumab an anti-interleukin-6 monoclonal antibody for the treatment of chronic antibody-mediation rejection (or AMR) in kidney transplant recipients
- Clazakizumab joins our portfolio of other products in late-stage development to address significant unmet needs in the transplant area

### **Influenza Vaccines**

• The adjuvanted quadrivalent cell program in 2021, with phase II studies to commence at the end of 2021.

As you can see from the slide, I've only touched on a few of the highlights but we will be providing more details of the other programs at our annual R&D briefing next week – details of which can be found on our website.

### COVID-19

Whilst the pandemic is still an evolving situation, as a business we understand the need to be agile and adapt to the changing environment

#### Our People

- Safeguarding the health of our people continues to be our top priority
- We need to keep our 27,000 staff working in more than 40 countries that we operate in
- Wherever possible, employees who have been able to perform their work remotely, have been doing so

### Innovation

- Many trials were paused as we needed to prioritise patient safety during the pandemic, however, given the multi-year nature of these trials, we expect an opportunity to make up for lost time as the COVID pandemic recedes
- When it comes to COVID-19, whether its preventative with a vaccine, or preventing progression with a hyperimmune or using a mab like Garadacimab, we have taken on projects we think makes sense both scientifically and that fit our capabilities
- I recognise there is a great deal of community interest in the development of a vaccine.
   CSL is working closely, and at pace, with the Commonwealth Government of Australia, the University of Queensland and AstraZeneca to manufacture candidate vaccines should clinical trials prove successful.

### Demand

- Remains strong right across our portfolio, especially for IG and influenza
- Despite the COVID challenges, there has been no interruption in our supply chain
- Our logistics team have done a terrific job in getting product to where it needs to go

### Supply

- Plasma collections have been adversely impacted, however, the business is doing everything it possibly can to ensure patient access to these important medicines
- We are still some way from the volume of plasma collected this time last year, however, over the first quarter of this financial year, as each week passes our plasma collections have been growing.

Financial Position (Balance sheet)

- Our liquidity levels, leverage ratios, credit ratings remain strong
- Our prudent balance sheet management affords us flexibility, irrespective of the state of global economy and earlier this year we bolstered our capital position with a \$750 million private placement

### **Outlook for FY21**

As I mentioned at the beginning, I'd now like to make a few comments on the outlook for FY21

- We expect strong demand for our plasma and recombinant therapies to continue
- Segirus:
  - Is expected to continue to benefit from its differentiated products and strong demand for influenza vaccines, driven in part by Governments wanting to protect their populations from contracting two viruses – that is COVID and influenza.
- Sales of Albumin expected to normalise following the successful transition to the new business model in China
- In relation to plasma COVID restrictions are expected to restrain our ability to collect plasma and add to the overall cost of collection. However, we do have multiple initiatives underway to mitigate the impact.
- Our R&D response to COVID, as well as new R&D initiatives, will put upward pressure on R&D expense, but still within the 10-11% of revenue envelope as previously guided to.

In terms of guidance for FY21, we expect revenue growth in the range of 6 to 10% over fiscal 20. Net profit after tax is expected to be approximately \$2.170 to \$2.265 billion at constant currency, implying a growth of 3 to 8%, which is a slight tightening of the range advised at the Company's results announcement in August – the low end was zero, which we've now raised to 3%

All of what I have spoken about today is aligned with the key pillars of our Company's strategy and core values. Having the right people on the journey is an incredibly important element of success. So with that in mind, I would like to take this opportunity to announce some key leadership movements:

- Joy Linton Chief Financial Officer
- Dr Paul McKenzie Chief Operating Officer CSL Group
- Stephen Marlow General Manager, Seqirus, reporting to Dr. McKenzie
- Andrew Nash Chief Scientific Officer
- Karen Neave Chief Risk Officer
- Mark Hill Chief Digital Officer

David Lamont, our outgoing CFO will finish up with the Company at the end of this month. I'd like to thank David for his valuable contribution and wish him every success in his new role.

And to close, a thank you to all CSL shareholders. There are many who have been long standing owners and we thank you for your loyalty.

I'll now pass you back to the Chairman

# Address from the CEO and Managing Director





# Legal Notice

#### Forward looking statements

The materials in this presentation speak only as of the date of these materials, and include forward looking statements about CSL Limited and its related bodies corporate (CSL) financial results and estimates, business prospects and products in research, all of which involve substantial risks and uncertainties, many of which are outside the control of, and are unknown to, CSL. You can identify these forward looking 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. Factors that could cause actual results to differ materially include: the success 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; 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 or divestitures; research collaborations; litigation or government investigations, and CSL's ability to protect its patents and other intellectual property. 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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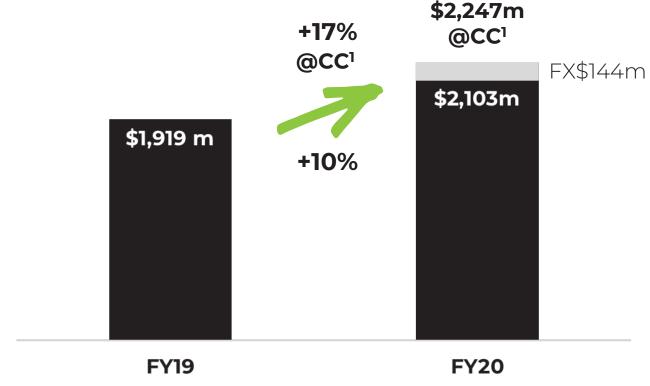


# A strong year for CSL with revenue up 9%<sup>1</sup> and profit after tax up 17%<sup>1</sup> reflecting:

- Strong growth in immunoglobulin portfolio
- Successful evolution of Haemophilia portfolio, driven by IDELVION<sup>®</sup>
- Transitioned to own distribution model in China
- Seqirus delivers on product differentiation strategy with strong profit growth

# A strong year for CSL

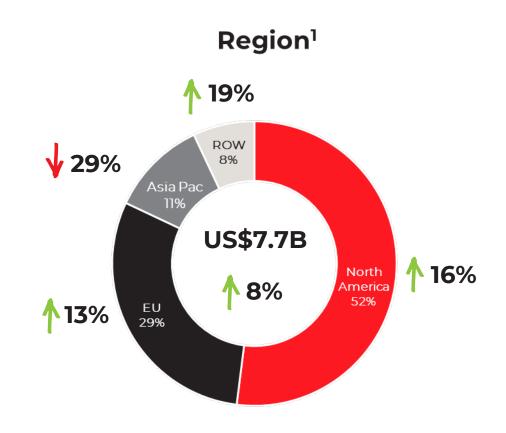
FY20 Net Profit After Tax





# CSL Behring Sales FY20

Therapy	Sales \$m	Change <sup>1</sup> %
Immunoglobulins	4,014	22%
- IVIG	2,699	16%
- SCIG	1,315	34%
Albumin	640	(36%)
Haemophilia	1,122	8%
- Recombinants	659	18%
- Plasma	463	(3%)
Specialty	1,697	10%
- Peri-Operative Bleeding	788	10%
- Other Specialty	909	9%
Other <sup>2</sup>	188	(1%)
Total	7,661	8%



Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.



<sup>2.</sup> Includes Hyperimmunes

### Plasma Collections

# Continue to grow plasma collection network



**40** new centres opened in the United States



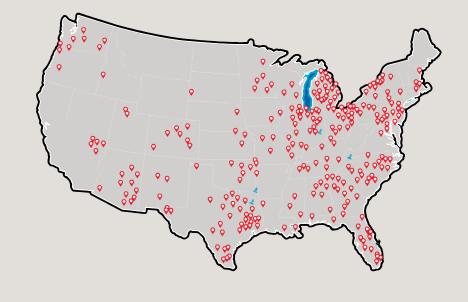


277 centres:

- ✓ 261 United States
  - ✓ 8 Germany
  - √ 3 Hungary
    - √ 5 China



Plan to open 20 - 30 new centres in FY21

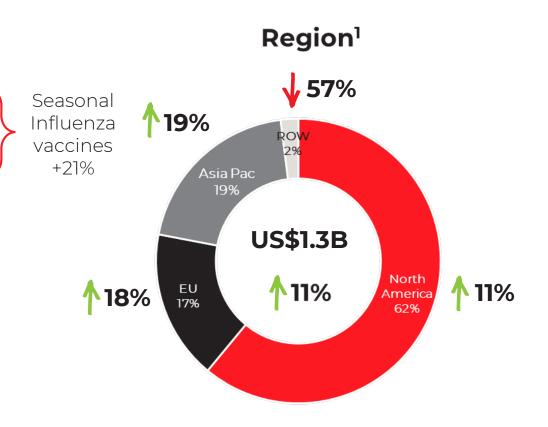




# Seqirus Revenue FY20

Revenue up 11%<sup>1</sup>

Therapy	Sales \$m	Change <sup>1</sup> %
QIV	542	27%
TIV	31	(53%)
Adjuvanted	379	30%
Other / In-licence	184	(11%)
Total Product Sales	1,136	14%
Pandemic	145	11%
Other Income	16	(64%)
Total Revenue	1,297	11%



Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.



# R&D Highlights



### Immunology

- HIZENTRA® Phase III DM study initiated
- PRIVIGEN® Phase II SSc study initiated
- HAEGARDA® Phase III HAE study in Japan initiated
- PRIVIGEN® approved for PID & SID in Japan
- Garadacimab Phase II HAE study results presented at EAACI Congress
- FDA granted HIZENTRA® orphan drug exclusivity for CIDP; PRIVIGEN® ODD and fast track designation for SSc
- Alliance with Seattle Children's Research Institute to develop stem cell gene therapies for PID – WAS and XLA



### Respiratory

• CSL311 (Anti-Beta Common) Phase I study in mild asthmatic patients initiated



### Haematology

- CSL200 in SCD Phase I study initiated
- CSL889 Hemopexin Phase I SCD study initiated
- FDA granted CSL200 fast track designation
- CSL889 Hemopexin ODD approved in EU for SCD
- CSL agreed to acquire exclusive global license rights to adeno-associated virus gene therapy program, AMT-061 EtranaDez for hemophilia B\*

\*The transaction with uniQure is subject to customary regulatory clearances before closing



# Cardiovascular & Metabolic

- CSL112 (ApoA-1) Phase III study (AEGIS-II) >9500 patients recruited
- CSL112 AEGIS-II first futility analysis conducted; trial to continue as planned



### Transplant

- AAT for prevention of GvHD Phase III study enrolment into Cohort 2 completed
- CSL acquired Vitaeris Inc. and Clazakizumab
- Clazakizumab AMR study initiated
- FDA granted Clazakizumab ODD and fast track designation



### Influenza Vaccines

- First cell-based quadrivalent seasonal influenza vaccine, FLUCELVAX® TETRA, approval in Europe
- US FDA approval of AUDENZTM adjuvanted, cell-based influenza A (H5N1) pandemic vaccine
- aQIVc (cell antigen + MF59) new product development commenced



### COVID-19

COVID-19 presents some challenges however we remained focussed on strategy execution and continue to invest for growth.

### **PEOPLE**



- Employees encouraged and supported to work remotely
- Flexible and robust IT systems facilitate ongoing productivity
- Development of strict protocols to ensure the safety of our employees and donors

### INNOVATION



- Focussed response leveraging the Company capabilities:
- Prevention vaccine collaboration

- Hyperimmune Global, Australia and SAB
  Pivoting Mabs and plasma products into ARDS patients
- Paused clinical trials to recommence in FY21

### **DEMAND**



- Products are used to treat serious rare diseases and often used chronically
- Demand remains strong across the portfolio
   Especially strong for IG & influenza vaccines
- Increased preference for home treatment driving HIZENTRA® demand

### **SUPPLY**



- Recognised as an 'essential' business
- All plasma centres remain open
- CSL Behring & Seqirus manufacturing facilities operational
- Plasma collections adversely impacted by COVID-19 pandemic
- Multiple initiatives underway to ensure patient supply of therapies

### **BALANCE SHEET**



- Ongoing conservative approach to liquidity and leverage
- Raised US\$750 million via private placement, bolstering existing strong capital position
- Net debt to EBITDA 1.5x. Available liquidity \$3.1 billion
- Credit ratings S&P A-, Moody's A3



### Outlook for FY211

### Demand

- Continued strong demand for plasma and recombinant products
- Seqirus' product differentiation and COVID-19 expected to drive strong demand for influenza vaccines
- Albumin sales to normalize following GSP transition

### Plasma Collections

- COVID-19 restrictions expected to restrain plasma collections
- Additional plasma collection costs
- Multiple initiatives underway to mitigate impact

### R&D

 COVID-19 response and new growth initiatives to drive uplift in investment towards the top end of prior guidance range<sup>3</sup>

### **COVID Vaccine**

 Agreement with Australian government to manufacture COVID-19 vaccine if approved



### FY21 Outlook

Revenue Growth ~6 - 10% @CC<sup>2</sup>

NPAT ~\$2,170 - \$2,265m @CC<sup>2</sup>



<sup>&</sup>lt;sup>1</sup> For forward looking statements, refer to Legal Notice on page 2

<sup>&</sup>lt;sup>2</sup> Growth shown at Constant Currency (CC) to remove the impact of exchange rates movements and facilitate comparability

<sup>&</sup>lt;sup>3</sup> Previously provided R&D investment auidance of ~10-11% of revenue

<sup>&</sup>lt;sup>4</sup> Full year FX impact expected to be immaterial if current rates remain steady for the remainder of the financial year



