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# **ASX Announcement**

For immediate release

12 October 2021

## **CSL LIMITED 2021 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 & Managing Director at CSL Limited's Annual General Meeting today.

The meeting will be webcast at https://web.lumiagm.com/391802826.

Authorised for release by

Fiona Mead

Company Secretary

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## **CSL 2021 Annual General Meeting: Chair address**

It is my pleasure to welcome our shareholders to CSL Limited's 2021 Annual General Meeting.

Once again, circumstances have forced us to conduct this meeting virtually. While I am thankful that technology allows your Board to connect with shareholders far and wide, I am looking forward to being able to speak to you once again in person as soon as possible.

There is a quorum present and I am delighted to open the meeting.Let me commence our business for today with some introductions. Joining us online are our directors.

Our Chief Executive Officer and Managing Director:

Mr Paul Perreault

### Our Non-Executive Directors:

- Mr Bruce Brook
- Dr Megan Clark
- Professor Andrew Cuthbertson
- Ms Carolyn Hewson
- Professor Duncan Maskell
- Ms Marie McDonald
- Ms Alison Watkins

We also have with us our auditor partners from EY and a number of our senior executives including Joy Linton our Chief Financial Officer.

I am stating the obvious when I say the pandemic has been persistent in the challenge it has presented to us all.

At this time last year, we could not foresee the significant impact the Delta variant would have on the endurance of the virus, and the subsequent ongoing impact to our lives.

Most of us are looking forward to a time when we don't need to talk about the pandemic anymore. But for today it is here at which I'd like to start because the pandemic has shone a light on your company's purpose, and the role we play in protecting the health of communities around the world.

The pandemic is a prime example of how a company like CSL adds value to society. To simplify the story: we identify serious and life-threatening conditions, and we try and solve them through scientific research and innovation, finishing with safe and reliable products.

In the case of COVID-19, we knew we had to use our expertise in medical science, and particularly vaccine development and manufacture, to help the world confront this extraordinary challenge.

This is where your company operates: the point at which the commercial imperative for our shareholders coincides with social license for broader society.

While this equation is simple to say, in reality it was more nuanced. We had to decide – quite quickly – where we would redirect our resources.

Early in 2020, CSL worked with the University of Queensland on its COVID-19 vaccine candidate, a unique and innovative platform that had all the makings of a breakthrough vaccine.

As we accelerated preparations to take this candidate into a Phase 2/3 clinical trial, the Phase I clinical trial showed that the vaccine elicited a robust response towards the virus. Disappointingly though, the decision was taken not to progress the vaccine candidate due to the partial immune response causing an unexpected interference with certain HIV tests.

As many of you will be aware, we redeployed dedicated COVID-19 vaccine teams across our business units and transitioned elements of our Australian manufacturing capacity to manufacture AstraZeneca's COVID-19 vaccine for local use.

We are pleased to say that the Australian Government and AstraZeneca trusted us as their partners to help the country respond to the emerging crisis through the most effective solution available: vaccination.

Notwithstanding the perhaps disproportionate criticism that this vaccine's reputation has experienced, we couldn't be prouder that the AstraZeneca vaccine has given protection to many millions of Australians, and even more will be sent to support our neighbours in the region.

I would like to re-emphasise how delighted I am with the role CSL has played in the pandemic, and I extend my gratitude to those whose priorities were shifted throughout the year to work on initiatives aimed at fighting the virus.

Shortly, our CEO and Managing Director Paul Perreault will review the financial and operational highlights for the year. Once again, our businesses delivered a strong result, which was particularly impressive given the difficult environment across the nearly 40 countries where we have operations around the world and more than 100 countries where our medicines are used. Our people have done an exceptional job navigating the different jurisdictions and shifting environmental conditions to not only remain operational, but to grow and excel. I thank Paul and his leadership team for their leadership and guidance during this time.

I'd also like to reference our strategy in this performance. Our 2030 strategy was devised prior to the pandemic, with the aim of maximising our capabilities and advantages in a competitive and changing world. Those last two words 'changing world' turned out to be very relevant over the last 18 months.

Our performance during this period has given us even more reasons to believe that our 2030 strategy is right - and it has proven resilient in the face of these challenges which none of us have ever seen before in our lifetime.

Our efforts over the last year have focused on maintaining our leadership position and preparing for strong growth when market conditions normalise. Paul will talk to some of those efforts, but your Board is confident that our 2030 Strategy will continue to deliver sustainable growth for our shareholders well into the future.

As we look to this future, one of my focus points is to ensure we have the right skills and expertise on the Board, which flows through to our management teams and operations.

When we look at this, we look at multiple parameters including deep but complementary and diverse domain expertise, as well as global and market experience. These considerations are not static and evolve in line with the markets in which we operate and the nature of our business. The Board is acutely aware of the importance of talent management and succession planning in good Governance.

This year, the Board regretfully accepted the resignations of Mr Abbas Hussain and Mr Pascal Soriot. CSL has benefited from their immense experience and we wish them the best in their future endeavours.

We are pleased that Ms Alison Watkins and Professor Duncan Maskell joined the Board on 18 August 2021 as Non-Executive Directors. Both Directors bring great experience to CSL, gained through senior and diverse roles across manufacturing, science, commerce, and entrepreneurship. They will be valuable assets to our Board as we aim to grow shareholder value over the long term.

Professor Andrew Cuthbertson retired as an employee of CSL earlier this month. Andrew has acted as a strategic counsellor on various projects since handing over the reins as Chief Scientific Officer and Head of R&D in 2019, including shepherding the company's efforts in the University of Queensland and AstraZeneca COVID-19 vaccine projects.

Andrew's skills throughout the pandemic have been invaluable in facilitating the complex passage of our efforts with many partners, and his sound advice and direction were paramount in the successful production of the two very different vaccines we were able to produce in a remarkably short period of time. I am grateful that CSL and its shareholders will continue to benefit from Professor Cuthbertson's expertise on our Board of Directors.

Earlier I spoke of the social imperative that is built into our business model through our promise. In today's evolving context however, caring for a healthier world also requires delivering sustainable value beyond our stakeholders. To that end, the Board recently signed-off on a new sustainability strategy for CSL.

Our new sustainability vision captures our commitment to a healthier world. To deliver on this vision and further support the execution of our 2030 strategy, we have identified 3 key sustainability strategic pillars: Environment, Social and Sustainable Workforce.

We have identified a number of focus areas for each of these pillars and a series of actions across these focus areas to deliver over the medium term. I look forward to keeping you updated on our progress.

Now to our outlook.

The Board has every confidence that CSL's strong foundations and disciplined execution of strategy will, in the next 24 months, allow us to return to sustainable growth. Earlier this year, we increased the total full year dividend to US\$2.22 per share as a reflection of this confidence. The dividend was also partially franked for the first time in many years.

This confidence has also underpinned our continued investment in the business. We have several major expansion projects underway that will be vital to the continued sustainable growth of CSL.

In addition to these capital projects we continue to develop our world-class R&D pipeline. Paul will speak to this, but I encourage you to follow our R&D Investor day being held on 19 October.

At a macro level, a full economic recovery is dependent on vaccine uptake. This has been widely recognised: less than a fortnight ago, the Victorian Government issued a directive that all authorised workers must be vaccinated.

In line with our responsibility to ensure the safety of people in our workplace, we have extended this mandate to all those at our Australian sites, and we intend to do the same at our US operations in keeping with requirements set by the U.S. government.

These policies – and the net effect of a healthier population – are important in allowing the world to return to prosperity. I encourage all to continue to reflect the spirit that we have seen come to the fore throughout the pandemic so far; a spirit of working for the collective community for the greater good of society.

Finally, I would like to extend my gratitude once again to our people for adapting to the everchanging environment that has resulted from the pandemic. I would also like to thank our shareholders for your continued support. Our industry has well and truly been under the microscope over the last two years.

Our community has risen to the challenge and showed what the power of science and collaboration can do. The Board and I are confident in the company's people, our strategy, and the long-term fundamental outlook for the vital products we supply.

I look forward to taking your questions later, but now I will hand over to Paul.

# **CSL 2021 Annual General Meeting: Chief Executive Officer and Managing Director address**

Thank you, Brian, and good morning to everyone. Thank you for joining us today for CSL's 2021 AGM. I agree with the Chair's sentiment about connecting with shareholders. While I am thankful that technology has allowed us to run our usual program with our investors, I miss interacting with many of our stakeholders around the world.

Covid has been a tremendous burden on the world, and the world of CSL and our employees have also seen disruption and a loss of social capital as we have been subject to lockdowns and unable to travel to many parts of this business.

However, across all the countries where we operate, we have maintained a strong connection and a spirit of collaboration that our business requires.

Personally, I can't wait to come back to Melbourne to be with our teams. I'm also looking forward to inspecting the progress of our new Global Headquarters and R&D Facility at Elizabeth Street North, and the new Seqirus facility at Tullamarine.

I would like to take this opportunity to thank our people all over the world who have worked tirelessly to maintain our operations against the difficult backdrop of the pandemic. The products that CSL produces are not discretionary. They are essential to keeping patients healthy, and in some instances, alive. This is the basis of 'our promise' and I am proud that we have been able to keep it throughout the last 18 months.

Now I will take you through both the financial and operational highlights of what we have achieved over the 2021 financial year and provide an outlook for 2022.

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

### 1. Highlights

I am pleased to report that CSL delivered a strong result for fiscal 2021, with:

- revenue was up 10% at constant currency; and
- net profit after tax was also up 10% at constant currency.

This is an excellent performance given the very challenging conditions and the uncertain environment we have faced through the global pandemic.

Despite all the complexities, our CSL Behring and Seqirus businesses maintained all critical operations, demonstrating resilience and agility across the company. This is a testament to the CSL values and to our dedicated employees who have remained focused on delivering on our promise to patients and to public health around the world.

In terms of highlights:

For CSL Behring:

- we achieved strong growth in many of our core products;
- this included another strong performance from Hizentra, our market leading subcutaneous lg product, which was up 15%;
- two of our leading specialty products also showed solid growth:
  - Haegarda was up 14%; and
  - o Kcentra up 7%,
- albumin sales grew 61% as our sales in China normalized;
- in the CSL Behring business, we implemented several digital transformation initiatives which has expanded our flexibility and enhanced our customer facing interactions;
- our influenza vaccines business, Seqirus, delivered an exceptional performance;
- sales of seasonal influenza vaccines were up a very strong 41%;
- Seqirus distributed a record number of doses globally of some 130 million; and
- we announced a new world class biotech manufacturing facility to be constructed in Melbourne, Australia.

Since COVID-19 hit in early 2020, it has had an impact on many aspects of our operations. In our CSL Behring business, plasma collections have been challenging, however, we put a number of initiatives in place and are starting to see improvements. I will go into more detail on this later in my presentation. And for Seqirus, COVID has provided a tailwind as demand for influenza vaccines has increased.

Despite the challenging environment, we have continued to invest in the business and remained focused on executing our long-term strategy. I am confident that CSL is well positioned to emerge stronger than ever.

### 2. CSL Behring

Turning to CSL Behring's sales by therapeutic area. Overall, the Behring portfolio recorded revenue growth of 6% at constant currency.

### Immunoglobulins:

- our core franchise, was up 3% with Hizentra growing an impressive 15%; and
- underlying demand for Ig continues to be strong. This is due to significant patient needs in core indications – namely Primary Immune Deficiency, Secondary Immune Deficiency and CIDP.

## Albumin:

- was up 61%;
- our new distribution model in China has been operational now for 12 months with sales for FY21 now reflecting a more normalised level; and
- the new model is working well and gives us direct management of over 180 distributors in China, expanded our geographic coverage and given us increased penetration into retail pharmacy and lower tier cities and hospitals.

## Haemophilia:

- was down 4%;
- this portfolio was impacted by reduced doctor visits and patient consultations during COVID-19; and
- against this backdrop however, Idelvion, our long-acting recombinant factor 9 product, achieved modest growth and remains the clear market leader for haemophilia B patients.

### Specialty products:

- was up 2% all at constant currency;
- the standout performer continues to be Haegarda, our transformational therapy for treating patients with hereditary angioedema or HAE which grew strongly by 14% due to strong patient demand; and
- the other main specialty product to record solid growth was KCENTRA which was up 7%. This is a very strong result given sales have been tempered by the reduction in elective procedures and incidents of trauma during the pandemic.

In terms of the geographic split of CSL Behring revenue:

- North America continues to be our largest market where revenue grew 5%;
- our next biggest market is Europe which was down 6% in revenue this is where we felt the supply tightness in IVIG; and
- Asia Pacific was up 44% as a result of the strong growth in albumin in China.

### 3. Plasma Collections

Turning to plasma collections.

COVID-19 has presented the industry with many challenges and plasma collections is one such area of our business that has been adversely impacted by the pandemic over the past 18 months. Not only were we impacted by quarantines, stay-at-home orders, restricted movement of donors and fear of disease but also the unprecedented government stimulus programs provided by the US government.

As a result, our plasma collection volumes for FY21 were down around 20% on the previous year and these litres were collected at a higher cost per litre. This included:

- additional PPE and cleaning requirements, social distancing and labour costs; and
- higher compensation paid to donors, particularly in the last quarter of the year.

In response to these challenging conditions, CSL Plasma implemented several targeted initiatives to focus on growing plasma collections.

As a result of our efforts, I am pleased to say we have seen sustainable improvement in our collections over the course of the past year and the following slide will show how we've been tracking.

First, I would like to share some of the initiatives that CSL Plasma has undertaken:

- We've enhanced our operating and marketing efforts to attract not only lapsed donors but also new donors which are an important source of future donations.
- We've seen a strong adoption of new technologies introduced to improve the donor experience, such as a donor app, self-serve kiosks and the ability for donors to register online. At last count we had over 800 thousand downloads of the donor app.
- We continue to lead the industry in the opening of new plasma collection centres we opened 25 new centres in FY21 and plan to open to another 40 in FY22.
- We now have a network of over 300 collection centres globally, which we believe to be the most efficient in the industry.
- We continue to manage our supply chain carefully and optimise finished goods inventory in order to take care of patients.
- Finally, we have entered a collaboration with Terumo to deliver a new plasmapheresis platform. Trials are progressing and we anticipate regulatory clearance in early 2022.

### 4. Plasma Collections

This next graph shows our donor numbers in the US on a weekly basis. The red line is calendar year 2021 to June 30, black is 2020 and grey 2019. If we go back to the start of our fiscal year 2021 which is July 2020, this is when we launched our first series of initiatives and we saw collections start to improve over the 6 months to December. Then, if we turn to Jan 2021 and the most recent 6 months (the red line), you will see that collections declined in March/April as a result of another round of US stimulus and some damaging weather events in the US.

From this point in mid-April up to today, we have seen a promising rebound. After introducing additional initiatives which included higher donor fees combined with the stimulus effect beginning to wear off and the rapid rollout of COVID vaccines in the US, we have seen increased movement and more donors coming into our centres.

You will note a slight reduction in late June and then the resumption of growth. This was the effect of the US-Mexican border closure for the purposes of plasma donation. Despite this, growth has resumed and continues into the new financial year. Whilst we are still not back to pre-COVID levels, we are encouraged by the continued upward trend.

## 5. Segirus Revenue

Moving on to our influenza vaccines business, Seqirus. Seqirus delivered an exceptionally strong performance in FY21.

Total revenue was over \$1.7 billion, up 30% at constant currency. This was driven by the very strong sales growth in seasonal influenza vaccines of some 41%. The increase reflects an

ongoing shift to Seqirus' differentiated products, such as FLUAD which was up 60%, and increased demand due to COVID-19.

The northern hemisphere continues to be the dominant market for Seqirus with the US and Europe accounting for approximately 80% of Seqirus' revenue for the full year with both regions delivering strong growth.

You will note that Asia Pacific was down 6% or \$15 million. This is due to the lower in-licence vaccine sales, following the completion of the Zostavax catch-up program in Australia.

## 6. R&D Highlights

Moving over to Research and Development. There's been a lot of activity and achievements in R&D over the past year. Whilst some programs were disrupted by COVID-19 in the first half of the year, everything is now back up and running at full pace.

We have a number of exciting programs underway in each of the six therapeutic areas and in the interest of time I will highlight just a few.

## Beginning with Immunology:

- Privigen for the treatment of CIDP was launched in Japan.
- The first patient was enrolled for our Phase 3 study for Garadacimab for the treatment of HAE.

## In Hematology:

We closed the uniQure transaction to commercialise the gene therapy product EtranaDez.
 The BLA is being prepared for submission to the FDA following completion of the Phase 3 trial.

### In Cardiovascular and Metabolic:

• The phase 3 trial for CSL 112 continues to progress well with over 13,000 patients now enrolled and successfully completed the first and second futility analysis.

### In Influenza Vaccines:

 We commenced a Phase 2 study for our adjuvanted QIV cell vaccine, and we have undertaken pre-clinical assessment of self-amplifying mRNA technology for influenza and are expected to commence a Phase 1 study in 2022.

## 7. CSL Strategy & Values

Before I move to the FY22 outlook, I would like to touch on our strategy. This is our 2030 strategy that we put in place a few years ago - before COVID came along. Despite the challenges we have faced with the pandemic, our long-term strategy remains intact – nothing has changed.

Our purpose on serving our patients and delivering innovative products still holds true. Our employees and purpose-driven culture are at the heart of our strategy and our values will always guide us in everything we do.

Throughout the challenges of the pandemic, our people and our business model have shown great resilience and agility. I have been incredibly proud of their performance.

The fundamentals of our business have never been stronger, and the diversity of our pipeline is robust. This sets up CSL to build on our track record of sustainable growth for many years to come.

#### 8. Outlook

Turning to the outlook for FY22.

Looking specifically at CSL Behring:

- Underlying demand for our core product IG is expected to remain strong.
- IG and albumin sales are reliant on our current plasma collections and the manufacturing cycle times.
- Plasma collections are expected to continue improving with the initiatives we have implemented and with the roll out of COVID vaccines.

### For Segirus:

 Product differentiation and COVID-19 are expected to continue driving strong demand for influenza vaccines.

At a CSL group level, gross margin is expected to come under pressure following the increased costs of plasma collections offset by some modest margin expansion arising from the growth in Segirus differentiated influenza vaccines.

In terms of guidance for FY22:

- we expect revenue growth to be in the range of 2 to 5% over FY21 at constant currency;
  and
- with net profit after tax expected to be approximately \$2.15 to \$2.25 billion at constant currency.

Of course, our forward-looking statements are subject to the usual disclaimers as mentioned at the start of this presentation.

I'd just like to finish by saying COVID-19 is a once in a lifetime event. I'm very proud of CSL's response. CSL is a growth company. Although the impact of COVID on plasma collections puts FY22 behind this year's profit number, we will continue to invest in the business and look forward to returning to the growth all of you expect from CSL.

I'll now pass you back to Fiona to take you through the meeting protocol.

# Address from the CEO and Managing Director

Mr Paul Perreault



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# Highlights<sup>1</sup>

Revenue up 10% with net profit after tax up 10%

# **CSL Behring**

- HIZENTRA® +15%
- HAEGARDA® +14%

# Segirus

- Seasonal influenza vaccines +4]%
- Record volume ~130 million doses distributed globally
- Next generation influenza vaccine manufacturing facility to be constructed

Critical operations maintained during COVID-19 pandemic demonstrating CSL's resilience and agility

- COVID-19 has produced a headwind for Behring and a tailwind for Segirus
- Plasma collections have been challenging however multiple initiatives are driving solid growth
- Continued capital expenditure and R&D investment places CSL in a position to emerge strongly post COVID-19

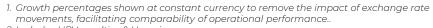


KCENTRA® +7% AI BUMIN +61% Digital transformation initiatives

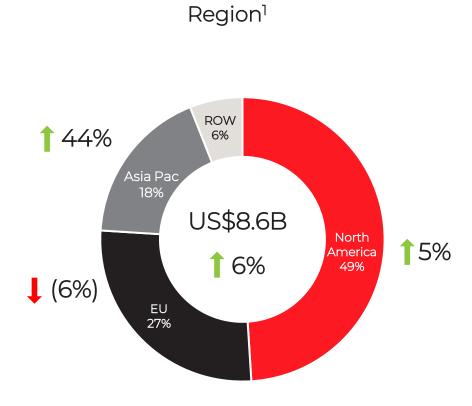
<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational

# CSL Behring Revenue up 6%<sup>1</sup>

Therapy	Sales \$m	Change <sup>1</sup> %
Immunoglobulins	4,238	3%
- IVIG	2,696	(3%)
- SCIG	1,542	15%
Albumin	1,071	61%
Haemophilia	1,107	(4%)
- Recombinants	674	0%
- Plasma	433	(9%)
Specialty	1,770	2%
- Peri-Operative Bleeding	847	5%
- Other Specialty	923	(1%)
Other <sup>2</sup>	388	(7%)
Total	8,574	6%



<sup>2.</sup> Includes HPV royalties & Hyperimmunes







25 new centres opened in FY21

up to **40** 

new centres planned to open in FY22

# Plasma Collections

# Challenges

- Plasma collections adversely impacted by:
  - US stimulus, stayat-home orders, extended lockdowns
- FY21 plasma collection volume down ~20% v FY20
- Increased collection costs

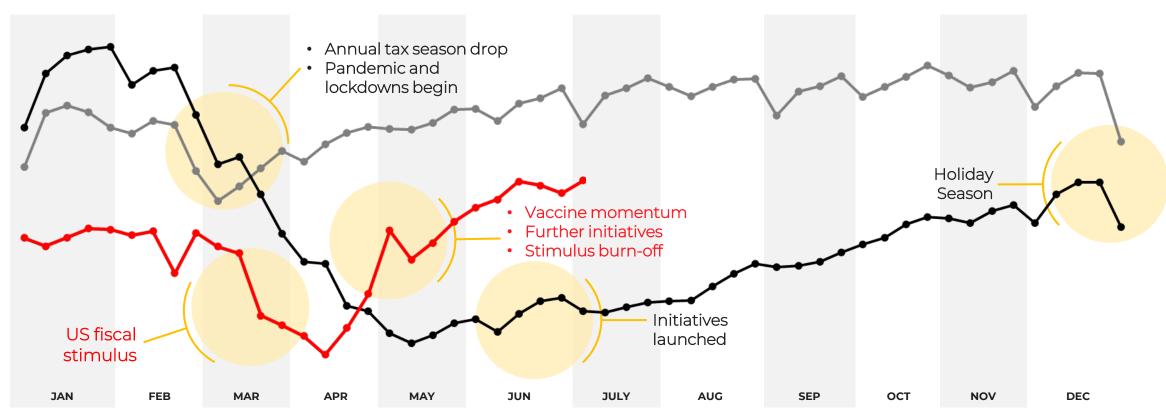
## **Initiatives**

- Enhanced operating & marketing initiatives to attract lapsed and new donors
- Strong adoption of new technology (donor app, kiosks, online)
- Industry leadership in new collection centres
- Plasma hold period reduced from 60 to 45 days
- Use of available finished goods inventory
- Collaboration with Terumo to deliver a new plasmapheresis platform



# Plasma Collections Initiatives driving donor growth





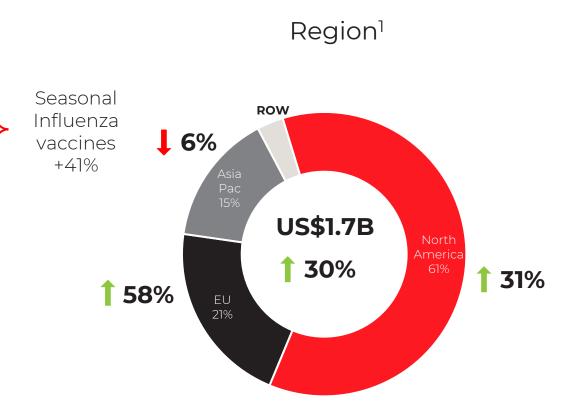
Not to scale



2019 2020 2021

# Seqirus Revenue up 30%<sup>1</sup>

Therapy	Sales \$m	Change <sup>1</sup> %
QIV	702	28%
Adjuvanted	629	60%
TIV	45	49%
Other / In-licence	176	(11%)
Total Product Sales	1,552	33%
Pandemic	160	5%
Other Income	24	35%
Total Revenue	1,736	30%





<sup>1.</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.

# R&D Highlights













# **Immunology**

- PRIVIGEN® for CIDP launched in Japan
- HAEGARDA® approval for paediatric patients (US, AU & CA)
- HAEGARDA® ODD approved in Japan
- First patients enrolled in Garadacimab Phase III studies

# Hematology

- uniQure announced positive data from Phase III trial of EtranaDez
- Anti-trust clearance received; licence agreement with uniQure completed for EtranaDez
- CSL889 Hemopexin ODD approved in EU & US
- CSL889 Hemopexin fast track designation for SCD approved by US FDA; first patient enrolled in Phase I study
- IDELVION® 21 day extended dosing option approved in Japan
- Recombinant FIX approved in Mexico as IDELVIAN
- AFSTLYA® approved in Great Britain, Russia & Mexico

# Cardiovascular and Metabolic

- CSL112 (ApoA-1) Phase III study (AEGIS-II) >13,000 patients enrolled, successful completion of 1st & 2nd futility analyses
- First patient enrolled in CSL346 Anti-VEG-B DKD Phase II study

# Respiratory

• First patient enrolled in CSL787 Nebulised Ig Phase I study

# **Transplant**

• Last patient dosed in Part 1 of CSL964 for prevention of **GvHD** study

## Influenza Vaccines

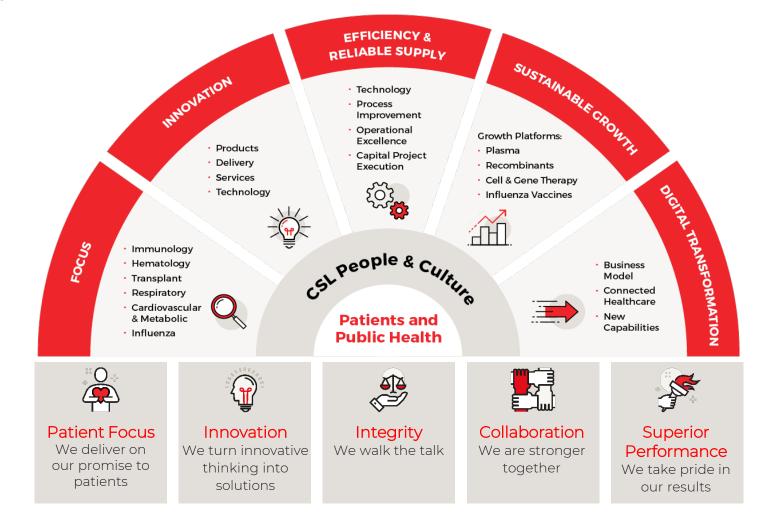
- Commencement of aOIVc Phase II study
- Pre-clinical assessment of self-amplifying mRNA vaccine for seasonal & pandemic influenza



# CSL Strategy and Values

**Strategic Overview** 

> Core **Values**



CSL is committed to a *healthier world*. Our vision is a *sustainable future* for our employees, communities, patients and donors, inspired by *innovative science* and a values-driven culture





# Outlook for FY22<sup>1</sup> Guidance Reaffirmed

## **CSL Behring**

- Underlying IG demand expected to remain strong
- IG & albumin sales reliant on current plasma collections and cycle times
- Plasma collections expected to improve with CSL plasma initiatives and COVID-19 vaccine rollout

# Segirus

Segirus' product differentiation and COVID-19 expected to drive strong demand for influenza vaccines

# **CSL Group Margin**

Gross margin easing expected following increased plasma collection costs, partially offset by modest margin expansion arising from growth in differentiated influenza vaccines

COVID-19 is a once in a lifetime event. I'm proud of our company's response and confident of a return to strong growth



FY22<sup>1</sup> Outlook **Revenue Growth** c. 2 - 5% @CC<sup>2</sup> **NPAT** c. \$2,150 - \$2,250m @CC<sup>2</sup>

- For forward looking statements, refer to Legal Notice
- Constant Currency (CC) removes the impact of exchange rates movements to facilitate comparability.
- Full year FX impact expected to be immaterial if current rates remain steady for the remainder of the financial year

