

# CSL

ILOW causaton loop from the  
purchaser perspective



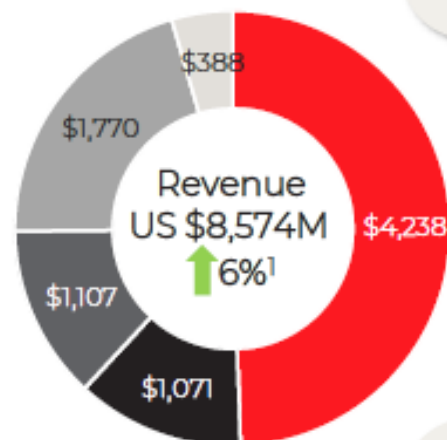


# Markets

# CSL Behring FY21 Commercial Highlights



- Ig
- Albumin
- Haemophilia
- Specialty
- Other<sup>2</sup>



## Performance

- Global revenue of \$8,574M/+6%<sup>1</sup>



## Immunology

- Underlying Ig demand remained strong through pandemic
- 15% Hizentra<sup>®</sup> revenue growth; continued success in CIDP



## Albumin

- Sales normalized in China under new GSP
- Significant contribution to FY21 YoY growth



## Haemophilia

- Maintained IDELVION<sup>®</sup> leadership in key markets<sup>3</sup>



## Specialty

- Strong growth from HAEGARDA<sup>®</sup> and KCENTRA<sup>®</sup>
- HAEGARDA<sup>®</sup> most patients since launch; 14% revenue growth
- KCENTRA<sup>®</sup> continued penetration vs FFP

Source:

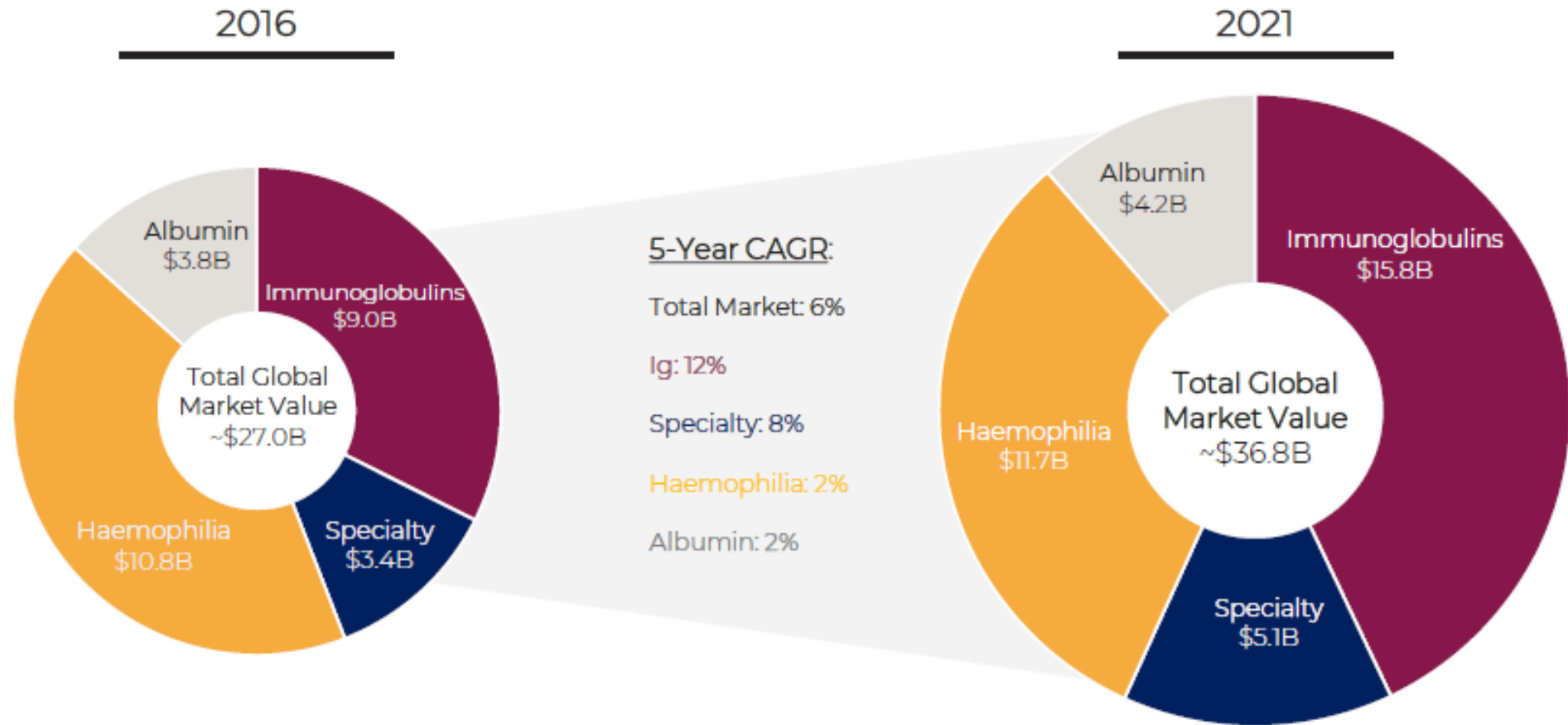
<sup>1</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.

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

<sup>3</sup> Data on file

Abbreviations: CIDP - Chronic inflammatory demyelinating polyneuropathy; FFP - Fresh Frozen Plasma; GSP - Good Supply Practices; YoY - Year on Year

# Targeted Protein Therapeutic Market Continues to Grow



Source: Company 3Q 2016 reports/financial schedule; MRB global Coagulation Factors Concentrate Market 2015 & 201; MRB WW Plasma Fractionation Market 2015 interim report; CSL Actuals FY16

Source: Analyst Reports; Company Annual Reports; Data on file; CSL Actuals FY21; Immunoglobulins market include Hyperimmunes; Haemophilia market include Factor XIII and non-factor; Specialty includes AAT, HAE, Fibrinogen, PCC, ATT markets

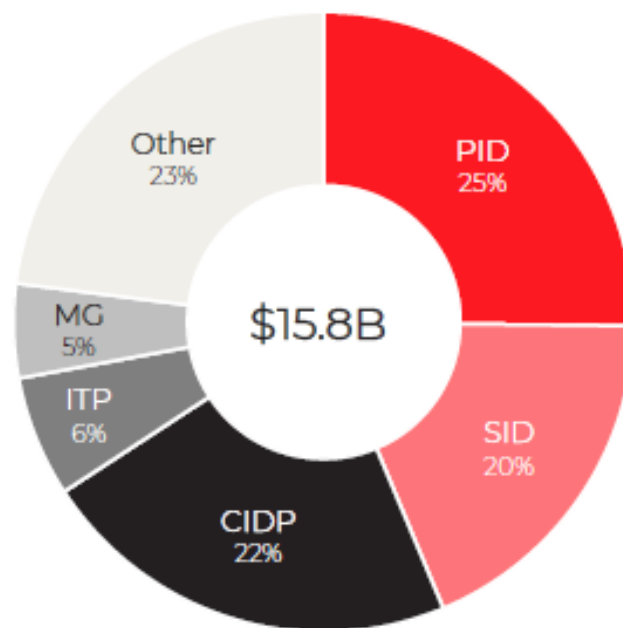


# Immunoglobulin Market

## Market Dynamics

- COVID-19: Industry-wide impact on plasma collection
- Underlying demand remains strong
  - Significant patient needs in PID & CIDP
  - Expanding usage for SID
- Shifting preference to SCIg and home administration

## Global Ig Volume by Indication



Source: Data on file for 2020

Abbreviations: CIDP - Chronic inflammatory demyelinating polyneuropathy; ITP - Idiopathic thrombocytopenic purpura; MG - Myasthenia Gravis; PID - Primary Immune Deficiency; SID - Secondary Immune Deficiency



## Immunoglobulins

FY21 Sales: \$4,238M<sup>1</sup>

Up 3%<sup>2</sup>

Christal: living with chronic inflammatory demyelinating polyneuropathy (CIDP)

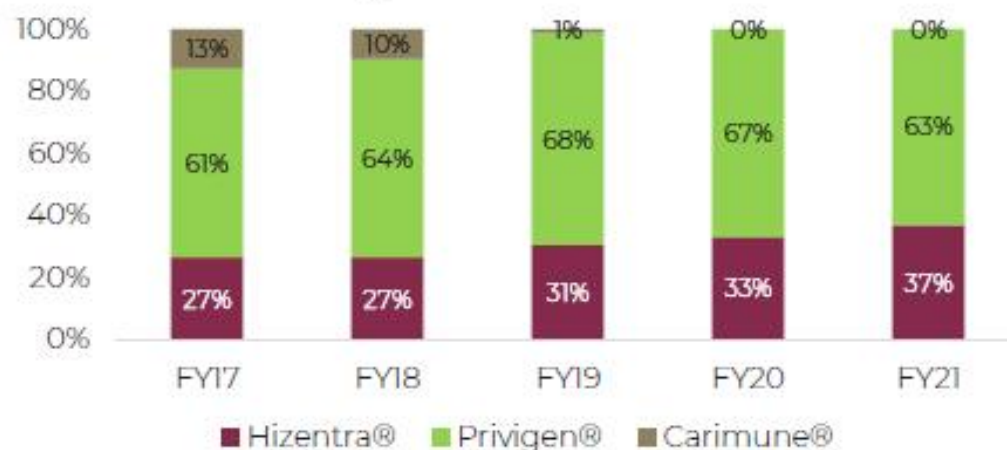
**Hizentra®**  
Immune Globulin Subcutaneous  
(Human) 20% Liquid

- Hizentra® +15% revenue growth<sup>2</sup>; remains the clear SCIg market leader
- Increased preference for at-home treatment
- Continued uptake in CIDP
- Recent Medicare Part B reimbursement approval

**privigen®**  
Immune Globulin Intravenous  
(Human), 10% Liquid  
IVIg therapy made simple

- Supply tightness intensified by COVID-19
- Privigen® volume impacted by shift to Hizentra®
- Global demand remains strong in core indications

US Ig Volume Mix Evolution<sup>3</sup>



<sup>1</sup> Excludes Ig hyperimmunes

<sup>2</sup> Growth percentages shown at constant currency to remove the impact of exchange rate movements, facilitating comparability of operational performance.

<sup>3</sup> CSL Internal Data





## Haemophilia

FY21 Sales: \$1,107M

Down 4%<sup>1</sup>

Logan: living with Haemophilia B.



### IDELVION®

- Standard of care for Haemophilia B
- Maintained leadership<sup>2</sup> in several key markets, including US, Germany, Italy, Switzerland & Japan
- Recent strong launches in France, Spain and Taiwan



### AFSTYLA®

- Impacted by competitive market & reduced doctor visits during COVID-19

### pdFVIII

- Maintained market leadership globally in vWD with 56% patient share<sup>2,3</sup>

### HUMATE®

- Strong revenue growth of 13%<sup>1</sup> in the US

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

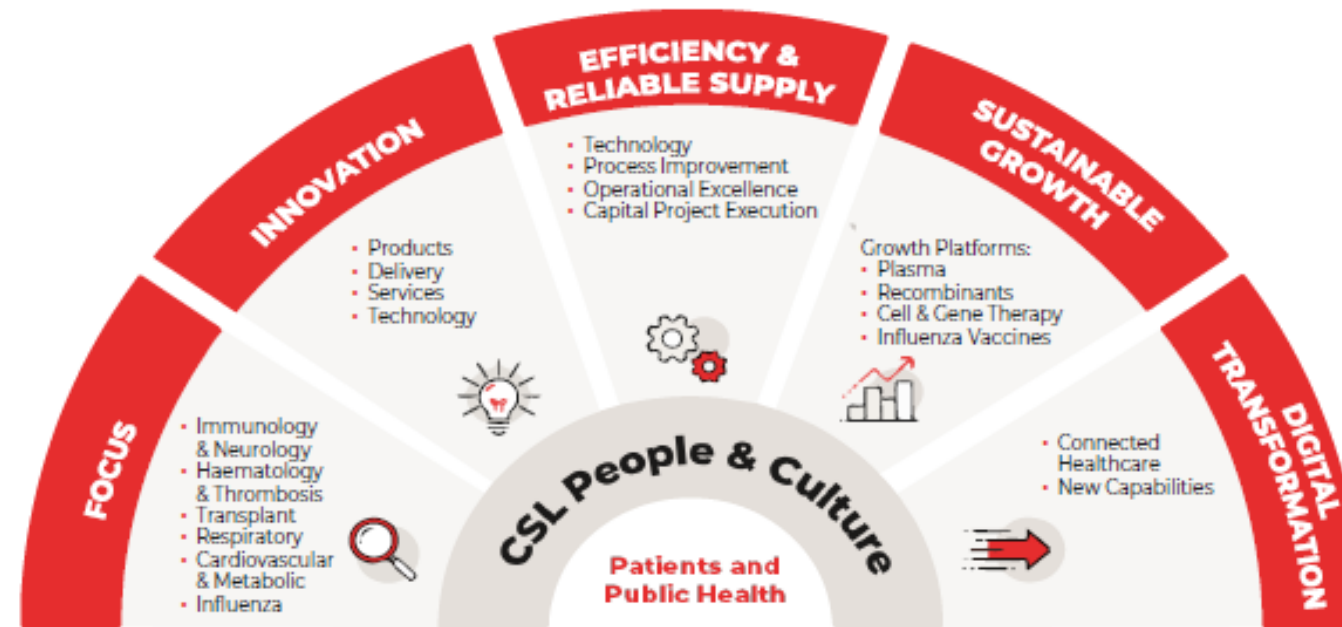
<sup>2</sup> Data on file

<sup>3</sup> Includes HUMATE®/HAEMATE® and VONCENTO®

Abbreviations: vWD – von Willebrand Disease

# Values and 2030 Strategy

## Strategic Overview



## Core Values



### Patient Focus

We deliver on our promise to patients



### Innovation

We turn innovative thinking into solutions



### Integrity

We walk the talk



### Collaboration

We are stronger together



### Superior Performance

We take pride in our results

Driven by **Our Promise™**

**CSL**





# Products



## Specialty Products

FY21 Sales: \$1,770M

Up 2%<sup>1</sup>

Cheryl: living with Hereditary Angioedema (HAE).

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

<sup>2</sup> Data on file

<sup>3</sup> In the clinical trial, 95% median reduction in number of attacks in patients receiving 60 IU/kg of HAEGARDA® vs placebo, and a >99% median reduction in rescue medication use in patients receiving 60 IU/kg of HAEGARDA® vs placebo.



### KCENTRA®

- Remains the gold standard for warfarin reversal in the US
- Substantial growth opportunities, with FFP still used in ~40% of patients<sup>2</sup> in the US
- Demand rebounded to pre-COVID levels in the US



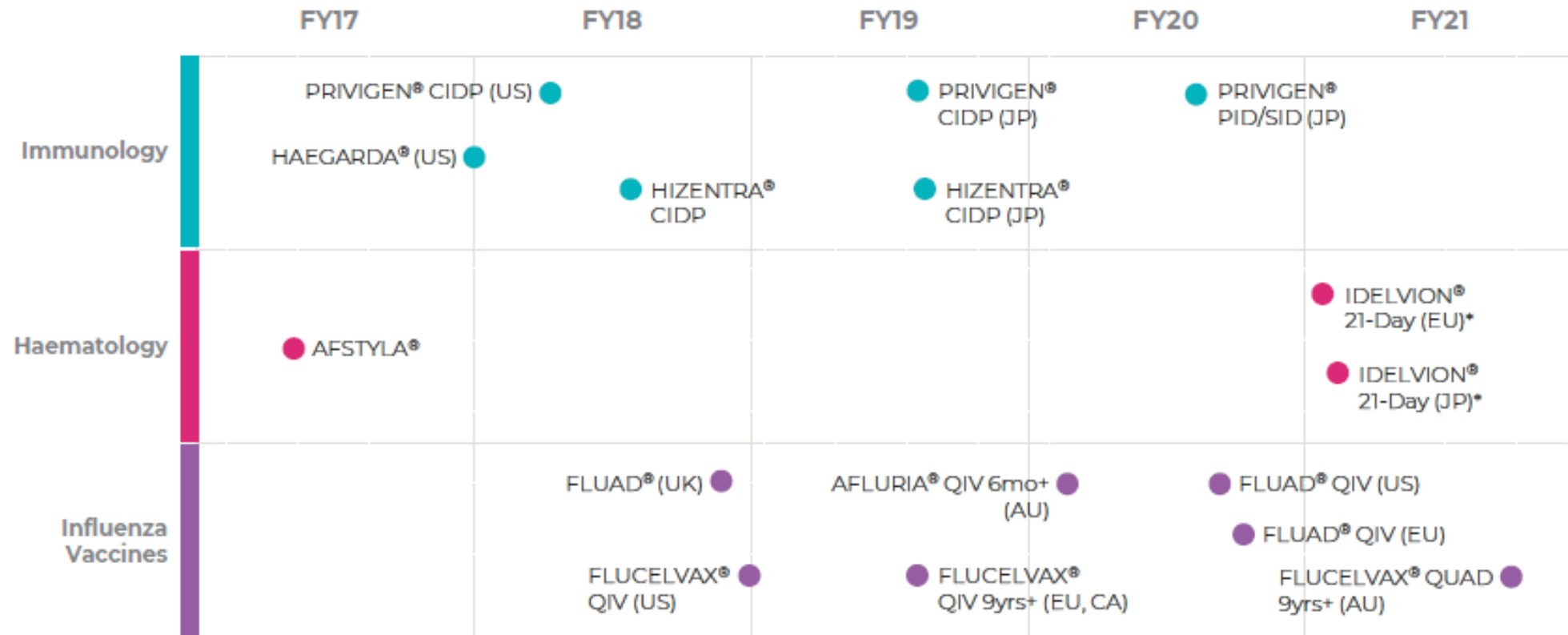
### HAEGARDA®/ Berinert SC®

- Offers best in class efficacy<sup>3</sup>
- US: Most patients since launch
- Treatment paradigm further shifts from on-demand to long-term prophylaxis

### Respreeza®/ Zemaira®

- Investing to enhance supply chain & ensure future supply

# Key Past Launches from R&D Portfolio



\* Expanded label for dosing every 21 days for patients ≥12 years in age, depending on individual patient and efficacy (and jurisdiction)

# R&D Highlights – FY21



## Immunology

- HIZENTRA® 5-, 10- & 20-mL pre-filled syringes launched in US
- **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



## Cardiovascular & Metabolic

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



## Haematology

- 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



## 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 **aQIVc** Phase II study
- Pre-clinical assessment of self-amplifying **mRNA** vaccine for seasonal & pandemic influenza

# Seqirus



## Operating Highlights

- Delivery of a record-setting >100 million doses for the Northern Hemisphere 20/21 influenza campaign
- Ongoing shift to differentiated products
- Real-world evidence continues to demonstrate the potential for improved effectiveness of FLUCELVAX® & FLUAD®

## Looking Forward

- Planning underway for construction of new cell-culture vaccine facility in Melbourne
- Fill & finish expansion:
  - Liverpool operational from Northern Hemisphere 21/22
  - Holly Springs operational from Northern Hemisphere 22/23





# Development of Garadacimab for PF-ILD/IPF

## Summary of Key Supportive Research Data

### Clinical Data

- FXII increased in IPF lung tissues and in blood from patients with progressive IPF

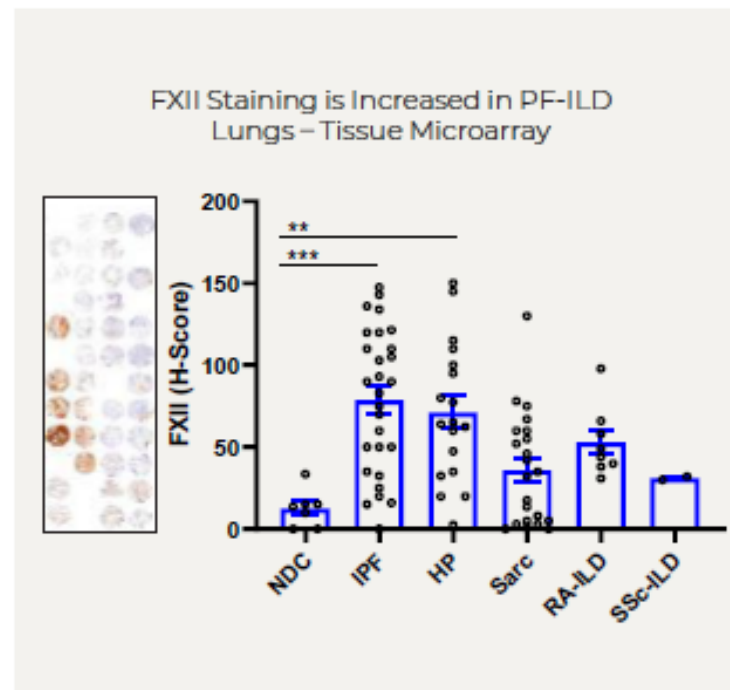
### Experimental Data

- Garadacimab inhibits FXIIa- $\beta$ -induced fibrotic function of primary human lung fibroblasts
- FXIIa- $\beta$  promotes fibrotic M2-type macrophages, reinforced by IL-6  $\rightarrow$  feedback loop
- Blocking FXIIa- $\beta$  with 3F7\* inhibits fibrosis in experimental mouse models:
  - Lung, liver and renal fibrosis models



Phase II – expected to commence H2 FY22

\* Parental Monoclonal Antibody (mAb) of Garadacimab





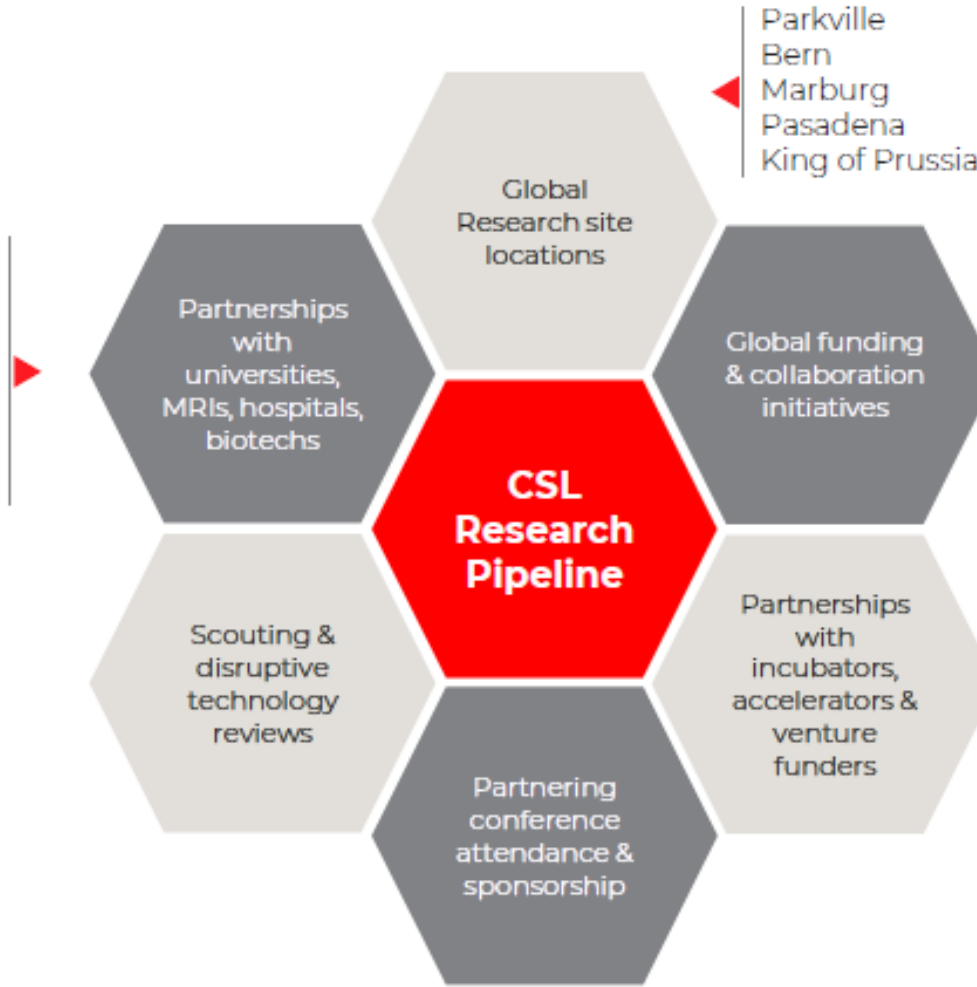


# Research External Innovation & Collaboration Strategy

## The Competition for Innovation



Seattle Children's  
Research Inst.  
ASLAN  
Kiniksa  
Lassen  
Denteric  
WEHI



Abbreviations: MRI – Medical Research Institute



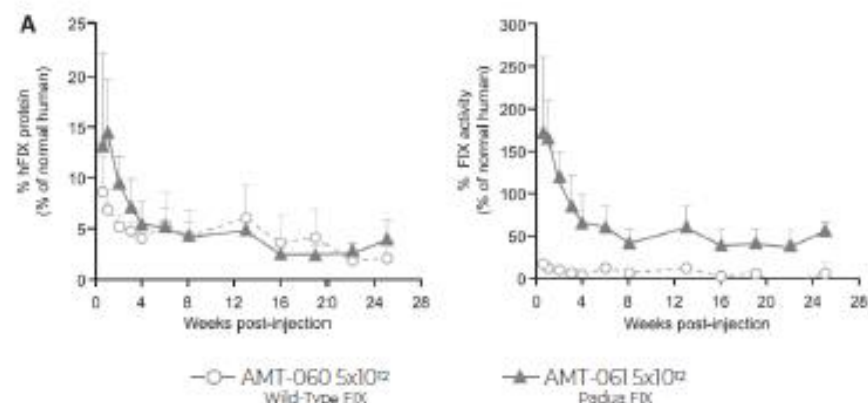
Seattle Children's®  
HOSPITAL • RESEARCH • FOUNDATION

Research Institute

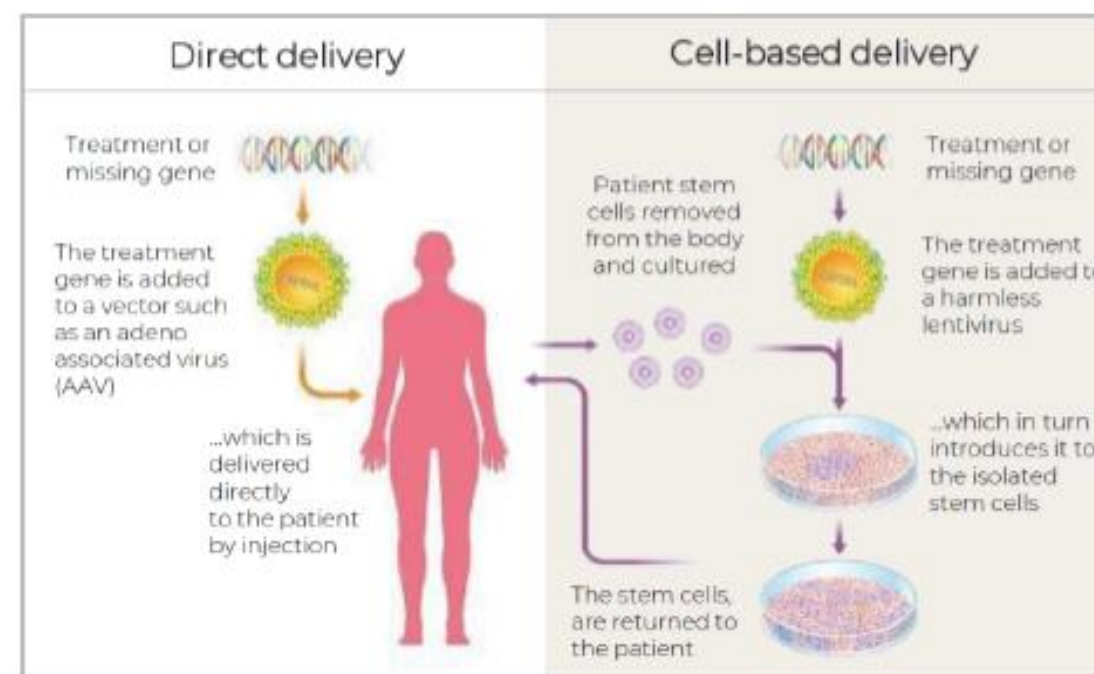
# Gene Therapy Technologies

## EtranaDez (Etranacogene dezaparvovec)

Enhanced Factor IX Activity following Administration of AAV5-R338L "Padua" Factor IX in NHPs



## Gene Therapies for Immune Deficiencies



Source: Spronck, E.A. et al., [2019] *Mol. Ther. Meth. Clin. Dev.* 13; P334-343.

# Gene Therapy for Immune Deficiencies

## WAS Gene Therapy Program

- Mutation in gene that produces WAS protein (WASp)
- Incidence one in 100,000 male births per year (100-300pts/yr)
- Bleeding, eczema, and recurrent infections

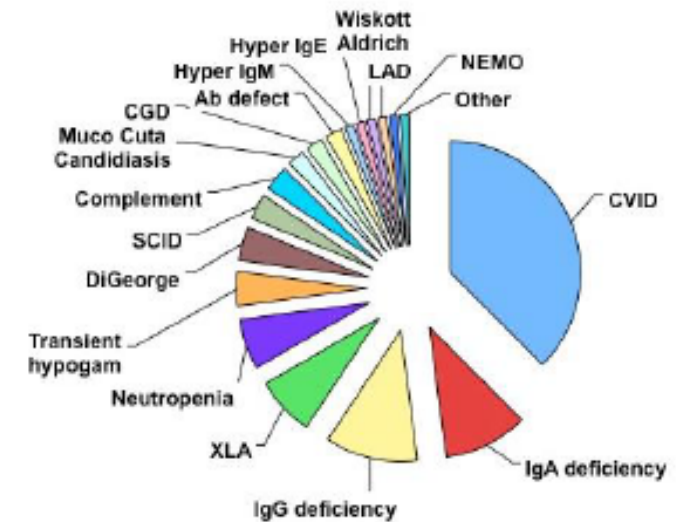


Phase I/II – expected to commence H1 FY23

Source: Icahn School of Medicine at Mt Sinai  
Abbreviations: WAS – Wiskott-Aldrich Syndrome

23 Driven by Our Promise™

## Primary Immune Deficiencies\*



# Gene Therapy for Immune Deficiencies

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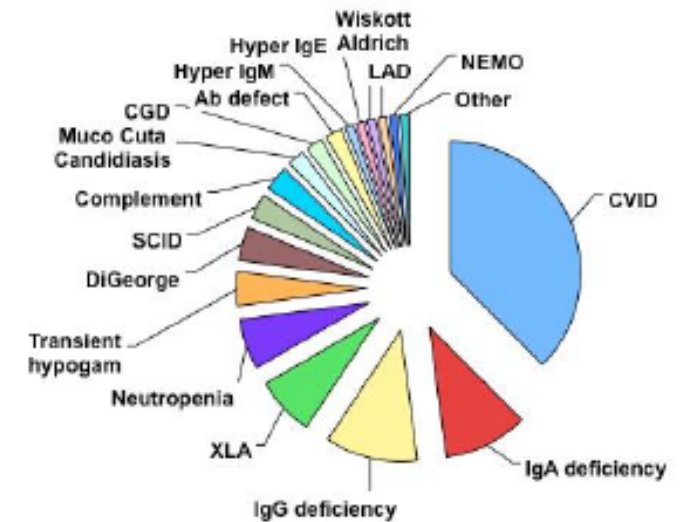


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23 Driven by Our Promise™

## Primary Immune Deficiencies\*





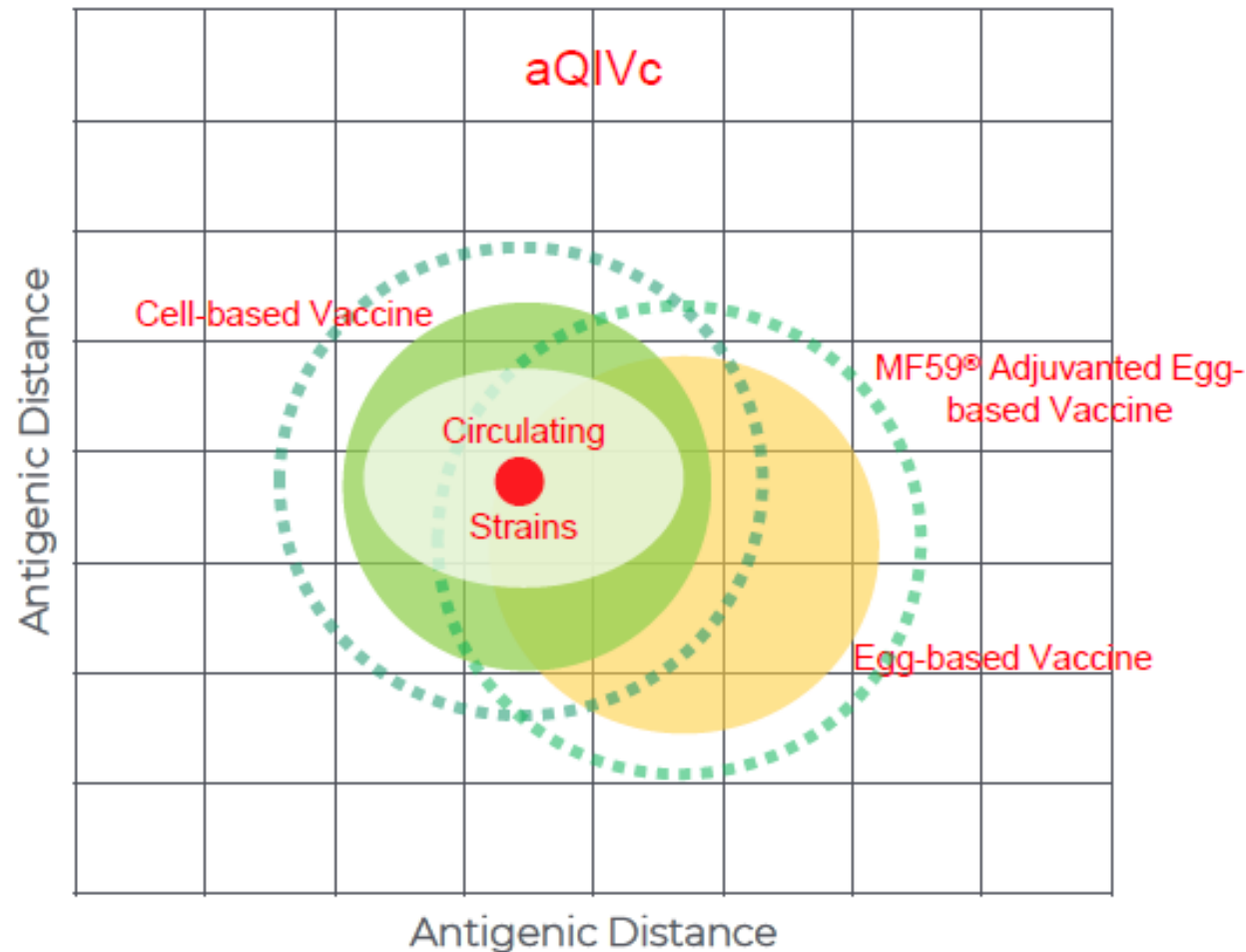
# Kiniksa - Giant Cell Arteritis (GCA) and COVID

- In Dec 2017, AstraZeneca / CSL granted Kiniksa full global rights to develop, manufacture and commercialise Mavrilimumab in all indications. CSL receives milestones and royalties
- Mavrilimumab targets GM-CSF receptor and inhibits action of GM-CSF, a key mediator in inflammation and autoimmune disease
- Positive data reported from Phase II trial of Mavrilimumab in GCA, a chronic inflammatory disease of medium-large arteries (75,000- 150,000 cases estimated in US)
- Reduced need for mechanical ventilation and improved survival reported for Mavrilimumab (compared to placebo) in Phase II portion of Phase II/III clinical trial in patients with COVID-19-related ARDS; enrolment ongoing<sup>1</sup>

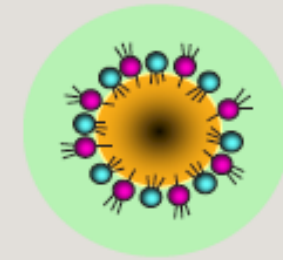
Program & Target	Preclinical	Phase I	Phase II	Phase III
Mavrilimumab Anti-GM-CSFR $\alpha$	COVID-19 Pneumonia & Hyperinflammation			
	Giant Cell Arteritis			

<sup>1</sup> Pupim, L. et al, (2021) *Ann. Rheum Dis* 80(1):198-199.  
Abbreviations: ARDS – Acute Respiratory Disease Syndrome

# Improving Influenza Vaccines by Combining Two Advanced Technologies



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MF59® Adjuvant

Increases “breadth”

Increases antibody response

Dose-sparing potential (pandemic)



Cell Culture

Closer match to circulating strain

More efficient manufacture than egg

Greater flexibility – faster in pandemic

CSL





# Projects

Most of the following slides are taken directly from Mcilvaine Pharma Prospect which is published twice per week



## **CSL's Illinois Operation Expansion**

CSL has announced that its full year results saw the company's net profit increase by 30%, in the same year that it announced plans for a 1.8m-square-foot expansion to its Illinois site.

CSL, an Australian-based biotech manufacturer, revealed in its full year results that it had achieved a post-tax net profit of \$1.7bn (\$2.34bn AUD).

The press release regarding its financials for the full year-to-date also suggested that it expects growth of 10-14% for the year to come.

The full details revealed that the company's US subsidiary, CSL Behring, was responsible for the lion's share of the sales generated by the company (\$6.6bn in sales against total sales of \$7.5bn). In addition, this part of the business grew by 11%.

CEO, Paul Perreault, also pointed towards the launch of several products, including Haegarda and Idelvion, as part of the reason the company has seen such growth.

In addition, he noted that it had opened 27 plasma collection centers in the US, as part of an expansion plan to bolster its CSL Plasma division – a subdivision of CSL Behring.

The success of its CSL Behring unit explains why the company felt secure in announcing a massive 1.8m-square-foot expansion to its campus in Kankakee, Illinois.

The plans for the site, announced earlier this year, could take as long as 12 years to complete.

How much the company is investing in the development was not released but it is currently completing construction of its 'CSL South' building, a space of 300,000-square-foot, which cost \$240m.

The company is also set to further invest in a 74-acre site in Bourbonnais Township, located next to its current campus, which has already been purchased but with no announcement made to the public regarding its plans for the site.

## **Seqirus' Influenza Vaccine Manufacturing Facility, Melbourne**

Seqirus, an influenza vaccine maker, is building a new cell-based influenza vaccine manufacturing facility in Melbourne, Australia.

The facility will be a significant addition to the company's global manufacturing and supply chain for the influenza vaccine, including the facilities in Holly Springs, North Carolina, US, Liverpool, UK, and Parkville, Australia.

The new plant will be utilized to manufacture influenza vaccines for both pandemics and seasonal vaccination programs, using advanced cell-based technology. It will produce products for the domestic market and export, help Victoria's 1,000+ STEM workers, and have an estimated supply chain of more than \$300m a year.

The development of the facility will cost approximately A\$800m (\$581.4m). Construction should begin in February 2021, while operations could commence by mid-2026.

It will create approximately 520 jobs during the construction phase and will employ several hundred people upon completion.

The Victorian Government will support the project to expand the globally active community of medical research and biotechnology in the state.

The influenza vaccine manufacturing facility will be in Tullamarine in the Melbourne Airport Business Park in Victoria, Australia.

It will utilize the airport's transportation facility to supply vaccines round-the-clock.

# New Cell Culture Facility in Australia

Tullamarine, Victoria

- Under construction – open in 2026
- A\$800m capital investment from Seqirus
- Commercial export manufacturing facility
- Next-generation, cell-based seasonal influenza vaccines
- A\$800m/10 year supply agreement with Commonwealth for antivenoms, Q-fever vaccines, pandemic influenza vaccines





## **GEA Builds Process Plant for the Production of Immunoglobulin**

The CSL Behring facility in Bern has improved on previous modules with a purely manual switchover panel that could be replaced by a complex valve combination in the cleanroom.

PROTINUS is the name of the project with which the biopharmaceutical company CSL Behring will significantly increase the production capacity of immunoglobulin at its site. GEA received the order for the process plant, the heart of the facility.

The two additional production lines will enable a further 90,000 patients per year to be supplied with life-saving drugs. Thanks to the good cooperation of all parties involved in the project, it was possible to continue the project on schedule despite the global corona pandemic.

Following the successful commissioning of the modules I and II also in Berne, Switzerland (2007 and 2009) and modules III and IV at CSL Behring's Melbourne, Australia site (2013 and 2017), this is now the third GEA process plant at CSL Behring to be commissioned with modules V and VI.

CSL Behring relied on GEA not only because of the good experience with the previous projects in Berne and Melbourne. As a supplier of sterile process plants with many years of experience, GEA can draw on the extensive theoretical knowledge and professional competence of its engineers to provide modern, customized and cost-efficient process lines for the production of new drugs in accordance with the current requirements of the global drug regulatory authorities.

The technological competence for the biotechnology industry includes cultivation, fermentation, separation, homogenization, crystallization, concentration, freeze drying and fractionation, complemented by a comprehensive range of bioreactors, fermenters, vessels and high-quality components. GEA plants are also characterized by high availability and economical operation.

## GEA CSL continued

This is backed up by a long history, combined with a great deal of competence and experience in this field. In fact, it is the first pharmaceutical built back in the 1970s. Since the 1980s the company has strategically focused on biopharmaceutical applications.

The PROTINUS project in Berne had other success factors. For example, GEA was able to build on the many years of experience gained with the running plants in Berne and Melbourne. This was another reason why GEA was involved in the engineering process from the very beginning. Together with CSL Behring, GEA continued to work on the degree of automation and took it to new levels.

Significant progress was made in the areas of "increased availability", "operability" and "safety". A concrete example: As an improvement on the previous modules, a purely manual switchover panel could be replaced by a complex valve combination in the cleanroom.

This allows CIP cleaning and product transfer without risk of contamination in parallel and without manual operator actions.

"Our greatest incentive in this project is that the additional production capacity will enable around 90,000 people per year to lead a normal life," said Pierre Caloz, Head of Manufacturing EU & APAC, CSL Behring. CSL Behring has therefore invested 250 million Swiss francs in the project, creating 50 new jobs.

Immunoglobulins are proteins of the globulin class. They are used to defend the human organism against foreign substances that have entered the body. They therefore play a central role in the immune defense. They are used in autoimmune diseases as well as in passive immunization against certain pathogens and in cancer therapy.



## CSL Covid Activities

- CSL is evaluating additional assets in its portfolio and partnerships with external researchers for potential use in the fight against COVID-19.
- CSL Behring co-founded the CoVlg-19 Plasma Alliance, an unprecedented industry of 11 plasma companies across 13+ countries and five continents, to develop a potential plasma-derived hyperimmune therapy for treating COVID-19. The one-year collaboration concluded in April 2021 after a Phase 3 clinical trial of the potential therapy did not meet its endpoints. More information is available [here](#). In addition, CSL's work on an Australian hyperimmune, which was dependent on positive data, has also been discontinued.
- In 2020, CSL worked with the University of Queensland in the early stages of its UQ-CSL v451 COVID-19 vaccine candidate. A Phase 1 clinical trial showed that the vaccine elicited a robust response towards the virus and has a strong safety profile. However, following consultation with the Australian Government, CSL did not progress the vaccine candidate to Phase 2/3 clinical trials. More information is available [here](#).
- Additionally, from the time the coronavirus was first identified in Wuhan, China – where CSL Behring has a manufacturing facility – the company has been assisting in the fight against COVID-19 in a number of ways including offering expertise, technologies, equipment and materials on a humanitarian basis.

## **CSL teams with Thermo Fisher to expand biologics manufacturing in Switzerland**

Thermo Fisher has inked a long-term tie-up at CSL Behring's Lengnau, Switzerland, facility to boost its biologics manufacturing capacity, the companies said.

As part of the deal, Thermo Fisher will take over operations of CSL's "state-of-the-art" biologics facility once it comes online in mid-2021. In return, Thermo Fisher will streamline discovery and manufacturing for CSL's drug portfolio, including producing hemophilia B therapy Idelvion at the Lengnau site.

According to CSL's website, the drugmaker broke ground on the \$413 million Lengnau plant in June 2015. The company planned the site to employ 300 once it was fully operational.

Thermo Fisher intends to continue to expand the Lengnau site to "support additional biopharma customers," the company said.

"We continue to invest to meet the growing need for flexible biologics capacity, and Lengnau will significantly expand our pharma services capacity and capabilities," Thermo Fisher Executive Vice President Michel Lagarde said in a release.

Thermo Fisher's newest lease agreement follows a rich year for the Massachusetts-based CDMO, which has been aggressively expanding its global capacity.

*Note: CSL as well as many other manufacturers are relying on CDMOs for some of their product manufacturing*



## CSL Acquiring Vifor

CSL which will acquire Vifor Pharma Ltd, a global specialty pharmaceutical company with leadership in Iron Deficiency, Nephrology & Cardio-Renal Therapies, today announced that they have entered into a definitive agreement for CSL to launch an all-cash public tender offer to acquire all publicly held Vifor Pharma shares for US\$179.25 per Vifor Pharma share, for an aggregate equity value for Vifor Pharma of US\$11.7 / A\$16.4 billion.

The transaction, which has been unanimously approved by both companies' Boards of Directors, further advances CSL's 2030 strategy to create value by adding a high-growth, cash generative and sustainable business which complements and expands the global leadership positions of CSL's two business units, CSL Behring and Seqirus. "Vifor Pharma enhances CSL's patient focus and ability to protect the health of those facing a range of rare and serious medical conditions. It brings an outstanding team and a leading portfolio of products across Nephrology, Dialysis and Iron Deficiency therapies and a proven partnering, business development and licensing strategy. Vifor Pharma will also expand our presence in the rapidly growing nephrology market, while giving us the opportunity to leverage our complementary scientific expertise" said Paul Perreault, Chief Executive Officer and Managing Director of CSL.

[In 2019 Haemonetics](#) (NYSE:[HAE](#)) sold a plant in South Carolina to CSL Plasma for \$10 million.

The Union, S.C., facility makes the liquid saline and sodium citrate solutions used in plasma collection. CSL Plasma, the supplier for CSL Behring, “This facility transfer is an important step in our asset optimization strategy, allowing us to improve our operating performance and focus on our core competencies. We will continue to redeploy our resources to invest in areas that hold the greatest potential for growth as we develop medical technology products and services that improve the quality, effectiveness and efficiency of patient care,” president & CEO Chris Simon said in prepared remarks.

“This transaction is an additional step to vertically integrate our supply chain, but more importantly, it provides CSL Plasma the ability to continue to deliver on its promise to patients who depend on life-saving therapy derived from plasma,” [added](#) CSL Plasma SVP & GM Mike Deem



# Manufacturing

## Cleanroom in CSL Bern

Urim Ibrahimi methodically uses a sterilized tool to remove sticky stoppers from the stopper bowl in a clean room at a filling line in CSL Behring's leading-edge manufacturing facility in Bern, Switzerland. A clean room is a highly filtered environment that aims to protect personnel, equipment and products from microbial contamination -- meaning the area is germ-free.





**Chromatography  
Columns  
and Valves  
in Melbourne,  
Australia**



# Manufacturing Sites

## Australia

- R&D and Manufacturing Locations

- **Parkville, VIC**

CSL Limited  
Global Corporate HQ  
R&D and Manufacturing  
phone: +61 3 9389 1911  
fax: +61 3 9389 1434  
45 Poplar Road,  
Parkville, VIC 3052

**Broadmeadows, VIC**

CSL Behring  
R&D and Manufacturing  
phone: +61 3 9246 5200  
fax: +61 3 9246 5299  
189-209 Camp Road,  
Broadmeadows, VIC 3047

**North Melbourne, VIC**

Bio21 Global Research and Translational Medicine  
Hub  
phone: +61 3 8344 2220  
Unit 400/30 Flemington Rd,  
Parkville  
VIC 3052

## United States

- **King of Prussia, PA**

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Head Office and R&D  
phone: +1 610-878-4000  
fax: +1 610-878-4009 1020  
First Avenue PO Box 61501  
King of Prussia, PA 19406-0901

- **Kankakee, IL**

CSL Behring  
R&D and Manufacturing  
phone: +1-815-932-6771  
fax: +1-815-802-3333  
P.O. Box 511  
Kankakee, IL 60901

- **Pasadena, CA**

CSL Behring

- R&D  
Suite 650, 35 N. Lake Avenue  
Pasadena, California 9110



# Manufacturing continued

## Germany, Switzerland

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R&D and Manufacturing  
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fax: +49-6421-39-3985  
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CH-3014 Bern  
Switzerland  
[info@cslbehring.ch](mailto:info@cslbehring.ch)  
Phone: +41 (0)31 344 44 44  
VAT number (UID): CHE-105.544.325

## China , Japan

- Ruide  
R&D and Manufacturing  
phone: +8627 86698337  
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Donghu New Technology Development Zone  
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Hubei Province 430206
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