CSL Limited

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A major contributor to this article appears to have a <u>close connection</u> with its subject. (December 2018)



<u>Type</u>	<u>Public</u>
<u>Traded as</u>	ASX: CSL
<u>ISIN</u>	AU00000CSL8 /
Industry	<u>Biotechnology</u>
Founded	1916 (Federal government department), 1994 (privatised)
Headquarters	Parkville, Melbourne, Victoria, Australia ^[1]
Key people	Paul Perreault (CEO)
Products	blood plasma, vaccines, antivenom, other laboratory and medical products
Revenue	▲ USD\$8.539 billion (2019) ^[1]
<u>Net income</u>	▲ USD\$1.919 billion (2019) ^[1]

Number of employees	25.000 person (2019) ^[1]
<u>Divisions</u>	CSL BehringSeqirus
Website	www.csl.com.au

CSL Limited

CSL Limited is a global specialty <u>biotechnology</u> company that researches, develops, manufactures, and markets products to treat and prevent serious human medical conditions. CSL's product areas include <u>blood plasma</u> derivatives, <u>vaccines</u>, <u>antivenom</u>, and cell culture reagents used in various medical and genetic research and manufacturing applications. [2]

History

CSL was founded in 1916 as the **Commonwealth Serum Laboratories**, an Australian government body focused on vaccine manufacture. Under the first director, William Penfold, CSL commenced operation in the vacant Walter and Eliza Hall Institute building at the Melbourne Hospital in 1918, before moving to its purpose-built Parkville premises in the following year. After ongoing disputes with the Commonwealth Department of Health and its director, (John) Howard Cumpston, Penfold resigned in 1927 and was replaced by Frederic Morgan. Soon after Morgan's appointment, CSL was drawn into a serious public health disaster when a batch of its diphtheria toxin-antitoxin was implicated in the deaths of twelve children in what became known as the 'Bundaberg tragedy' of 1928. Although CSL's manufacturing processes were absolved, its labelling procedures were seen to be in error, leading to an enduring focus on the highest standards across the facility's production. [4]

In 1928, CSL also became involved in antivenene (antivenom) manufacture in conjunction with the snake venom research undertaken by Charles Kellaway at the Hall Institute. This led to the successful clinical testing of antivenene against tiger snake Notechis scutatus bite in 1930, and its commercial release in 1931. In 1934, the research on snake venoms was transferred from the Hall Institute to CSL under the direction of former snake showman, Tom 'Pambo' Eades. This represented the initiation of research at the laboratories – an outcome its directors had been seeking for over a decade. The relationship with the Hall Institute continued until World War II, particularly via joint projects on viral diseases including polio and influenza coordinated by Frank Macfarlane Burnet and Esmond 'Bill' Keogh. Keogh played an important role in the establishment of penicillin production at CSL in 1944 – a critical wartime achievement. [5]

The operation commenced plasma fractionation in 1952. Thereafter the range of antivenoms increased, including those against other snake species such as death adder (*Acanthophis antarcticus*) and the taipan (*Oxyuranus scutellatus*), plus spiders including the redback (*Latrodectus hasselti*) and – after much difficulty – the Sydney funnel-web (*Atrax robustus*). Much of this work, including the introduction in 1962 of a polyvalent antivenom against all of the major terrestrial Australian snakes, occurred under the direction of <u>Saul Wiener</u>, while from 1966 until the mid-1990s, venom research was coordinated by the eccentric but dedicated <u>Struan Sutherland</u>, who in 1979 released new guidelines for snakebite first aid, ^[6] and a new test for snakebites that would identify which snake had envenomated the victim. ^[7]

Other major achievements of CSL include: [8]

- early production of insulin for treatment of Australian diabetics (1923)
- development of a <u>tetanus</u> vaccine (1938)
- development of a combined vaccine for <u>diphtheria</u>, tetanus and <u>whooping cough</u> (1953)
- rapid adoption and production of a <u>polio</u> vaccine (1956)
- development of a multi-purpose animal vaccine covering pulpy kidney (enterotoxemia), tetanus, <u>black disease</u>, <u>malignant oedema</u> and <u>blackleg</u> (1961)
- production of Rhesus (D) immunoglobulin to prevent haemolytic disease in newborns due to Rh factor incompatibility (1966–67)
- pioneering heat treatment to protect blood and plasma products from infection with <u>HIV</u> (1983)
- collaboration on development of the world's first <u>human papillomavirus</u> vaccine, <u>Gardasil</u>, building on the pioneering work by <u>Professor Ian Frazer</u> (1994-2005). [9]

In 1994, the Commonwealth facility was privatised as CSL Ltd. In 2000 CSL doubled its size through the purchase of a Swiss plasma company, the Bern-based ZLB Bioplasma AG. In 2004, during a period of plasma oversupply, the company expanded again with the purchase of the German medical company Aventis Behring. The company was the 2nd Australian public company to have reached a share price of over \$100 per share.

In 2011, the company received the Minister's Award for Outstanding Equal Employment Opportunities Initiative for their Thinking Kids Children's Centre. $^{[10]}$

In October 2014, Novartis announced its intention to sell its influenza vaccine business, including its development pipeline, to CSL for \$275 million. CSL merged it into its BioCSL operation. [11] In November 2015, BioCSL rebranded the combined business with Novartis Influenza Vaccines as *Seqirus* [Sek-eer-us] creating the world's second largest influenza vaccine company. [12] Completed in 2018, Seqirus's Holly Spring, NC, plant was funded with \$59 million from the U.S. government. [13]

Locations

The company's headquarters remain in <u>Parkville</u>, <u>Victoria</u>, an inner suburb of <u>Melbourne</u>. CSL Behring is headquartered in <u>King of Prussia</u>, <u>USA</u> and it has manufacturing operations and R&D laboratories in the Swiss city of <u>Bern</u>, in <u>Marburg</u> in Germany, and <u>Kankakee</u>, <u>USA</u>.

Seqirus has its headquarters in <u>Maidenhead</u> and has production facilities in <u>Holly Springs</u>, <u>USA</u>, <u>Liverpool</u>, <u>UK</u>, and <u>Parkville</u>, <u>Victoria</u>

Ownership

CSL is a public company and its stock is traded on the <u>Australian Securities Exchange</u> under the stock code CSL. The company completed an <u>Initial Public Offering</u> in June 1994 at A\$2.30 per share. CSL stock is part of the <u>S&P/ASX 20</u> Index.^[14]

Vaccine for A/H1N1 2009 Pandemic

Influenza (Flu)



CSL's vaccine for <u>Swine Flu</u>, the world's first, was approved in September 2009 for use by people aged 10 and over. The federal government ordered 21 million doses of vaccine for Australians. Further doses were made for customers in Singapore and USA. <u>2009</u> <u>A/H1N1</u>. The Australian government intended to use the CSL Vaccine in one of the largest national vaccine programs in the country's history.

Divisions

CSL Limited's products can be separated by company division. Some of the key products produced by each division, have included:

Seqirus (bioCSL)

Vaccines:[16]

- Afluria (influenza vaccine) -- Argentina, Peru, South Africa, Spain, US[16]
 - Enzira -- in various different markets [16]
 - Fluvax -- in various different markets[16]
 - Nilgrip -- in various different markets [16]
- Afluria Quadrivalent (influenza vaccine) -- Australia, Canada, New Zealand, US[16]
 - Afluria Quad -- in various different markets[16]
 - Afluria Tetra -- in various different markets [16]
- Agrippal (influenza vaccine) -- Argentina, Austria, Brazil, Canada, Chile, Colombia, Germany, Italy, Mexico, Spain, Thailand^[16]
 - Agriflu -- in various different markets [16]
 - Begripal -- in various different markets [16]
 - Chiroflu -- in various different markets [16]
 - Fluazur -- in various different markets[16]
 - Sandovac -- in various different markets[16]
- Audenz (influenza A (H5N1) vaccine) -- US^[16]
- Fluad (influenza vaccine) -- Argentina, Austria, Australia, Brazil, Canada, Denmark, Germany, Italy, Spain, Switzerland, UK, US^[16]

Chiromas -- Spain^[16]

- Fluad Pediatric (influenza vaccine) -- Canada[16]
- Flucelvax Quadrivalent (influenza vaccine) -- Germany, Italy, Spain, UK, US[16]
- Q-VAX (Coxiella burnetii vaccine) -- Australia[17]
- Rapivab (peramivir) -- Australia, US[16]

Antivenoms: (Australia)[17]

- Black snake
- Box jellyfish
- Brown snake
- Death adder
- Funnel web spider
- Polyvalent <u>snake antivenom</u>
- Redback spider
- Sea snake
- Stonefish
- <u>Taipan</u>
- Tiger snake
- Snake Venom Detection Kit

CSL Behring (Australia)^[18]

- Albumex (serum albumin)
- Biostate (Factor VIII)
- Carimune, which is <u>immunoglobulin</u> for <u>intravenous</u> administration (IGIV)
- CMV Immunoglobulin-VF (cytomegalovirus immunoglobulin)
- Helixate, which is <u>recombinant</u> Antihemophilic Factor, a blood-clotting factor for the treatment of <u>haemophilia</u>
- Hepatitis B immunoglobulin
- human immunoglobulin Intragam P, Normal, Rh(D) Immunoglobulin-VF, Sandoglobulin,
- MonoFIX-VF (Factor IX)
- Prothrombinex-HT (prothrombin complex)
- Rhophylac (Rh(D) immunoglobulin G)
- Tetanus Immunoglobulin-VF
- Thrombotrol-VF (antithrombin III)
- Vivaglobin, sub-cutaneous human immune globulin indicated for the treatment of <u>primary immunodeficiency</u>. This product gained FDA approval in January 2006.
- Von Willebrand factor
- Zoster Immunoglobulin-VF (<u>varicella zoster</u> immunoglobulin)

CSL Behring

Immunology:[19]

- Beriglobin P, human <u>hepatitis A immunoglobulin</u>, liquid 16% solution for <u>intramuscular</u> injection
- Berirab P, human <u>rabies immunoglobulin</u>, liquid 16% solution for <u>intramuscular</u> injection
- Carimune NF, Sandoglobulin, Sanglopor human normal <u>immunoglobulin</u>, freezedried formulations for <u>intravenous</u> administration
- Cytogam, human <u>cytomegalovirus immunoglobulin</u>. Liquid <u>immunoglobulin</u> containing a standardized amount of antibody to <u>cytomegalovirus</u>.
- Hepatitis B Immunoglobulin P Behring, human <u>hepatitis B immunoglobulin</u>, liquid 16% solution for <u>intramuscular</u> injection
- Hizentra, Human normal <u>immunoglobulin</u>. Liquid 20% immunoglobulin solution, ready-to-use for <u>subcutaneous</u> administration
- Privigen, human polyvalent <u>immunoglobulin</u>, liquid 10% solution for <u>intravenous</u> injection
- Rhesogamma P, human <u>anti-D immunoglobulin</u>. Prefilled syringes of highly purified anti-<u>Rhesus factor</u> D IgG for <u>intravenous</u> administration and <u>intramuscular</u> injection.
- Rhophylac human <u>anti-D immunoglobulin</u>. Prefilled syringes of highly purified anti-<u>Rhesus factor</u> D IgG for <u>intravenous</u> administration and <u>intramuscular</u> injection.

- Sandoglobulin NF Liquid, Redimune, Redimune NF Liquid, human normal <u>immunoglobulin</u>, liquid 12% solution for <u>intravenous</u> administration
- Tetagam P, human <u>tetanus immunoglobulin</u>, liquid 16% solution for <u>intramuscular</u> injection
- Varicellon P, human <u>varicella immunoglobulin</u>, liquid 16% solution for <u>intramuscular</u> injection
- Vivaglobin, human normal <u>immunoglobulin</u>, liquid 16% solution for <u>subcutaneous</u> administration

Coagulation/Bleeding Disorders:

- Beriate, freeze-dried human <u>coagulation factor VIII</u> concentrate
- Berinin P, freeze-dried human <u>coagulation factor IX</u> concentrate
- Factor X P Behring, a freeze-dried human <u>coagulation factor IX</u> and <u>factor X</u> concentrate
- Fibrogammin P, Cluvot and Corifact, freeze-dried human <u>coagulation factor XIII</u> concentrate
- Helixate FS and Helixate NexGen, freeze-dried recombinant coagulation factor VIII
- Humate-P and Haemate P, freeze-dried human <u>coagulation factor VIII</u>: C and <u>von Willebrand factor</u> concentrate
- Monoclate P, a freeze-dried <u>monoclonal antibody</u> purified human <u>coagulation</u> <u>factor VIII</u> concentrate
- Mononine, a freeze-dried human coagulation <u>factor IX</u> that has been purified using monoclonal antibodies
- Stimate, a synthetic <u>desmopressin</u> acetate nasal spray
- Octostim, a synthetic <u>desmopressin</u> acetate nasal spray

Pulmonary:

Zemaira, Respreeza freeze-dried Human Alpha₁-proteinase inhibitor (A₁-PI)

Critical Care:

- AlbuRx, Alburex, Albumeon, Human Albumin Behring, Albuminar 25, human <u>albumin</u> solution (5%, 20% or 25% human albumin solutions)
- Berinert P, freeze-dried human C₁-esterase inhibitor (C1-INH) concentrate
- Beriplex P/N, freeze-dried human <u>prothrombin complex concentrate</u>
- Haemocomplettan P, RiaSTAP, freeze-dried human <u>fibrinogen</u> (factor I) concentrate
- Kybernin P, freeze-dried human <u>antithrombin</u> III concentrate
- Streptase, freeze-dried <u>streptokinase</u>

Wound Healing:

- Beriplast P Combi-Set, <u>fibrin sealant</u> kit, freeze-dried fibrin sealant for topical application
- Fibrogammin P, freeze-dried human coagulation factor XIII concentrate

• TachoComb, <u>fibrin sealant</u> fleece-type, fleece-type collagen preparations coated with <u>fibrin glue</u> components

Product availability varies from country to country, depending on registration status.

See also

Australian Red Cross Blood Service

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