



# Biotech Daily

Friday February 14, 2025

*Daily news on ASX-listed biotechnology companies*

## Dr Boreham's Crucible: C S L

By **TIM BOREHAM**

**ASX code:** CSL; **US (over-the-counter):** CSLLY

**Share price:** \$256.90; **Shares on issue:** 484,206,716; **Market cap:** \$124.4 billion

**Financials (first half to December 2024):** revenue \$US8,483 million (up 5%), net profit \$US2,056 million (up 7%), earnings before interest and tax \$US2,795 million (up 4%), dividend per share \$US1.30 (\$A2.08, up 16%), cash of \$US1,524 million (up 50%), total debt \$US11,964 million (down 2%).

**Chief executive officer:** Dr Paul McKenzie

**Board:** Dr Brian McNamee (chair), Dr McKenzie, Prof Andrew Cuthbertson, Dr Megan Clark, Caroline Hewson, Marie McDonald, Alison Watkins, Samantha Lewis, Elaine Sorg, Dr Brian Daniels.

**Identifiable major shareholders:** State Street 7.1%, Blackrock Group 5.6% Vanguard Group 5%.

If the newly-minted US Health and Human Services Secretary and anti-vaxxer Robert F Kennedy Junior really wants vaccination rates to fall, he won't have to try too hard because the American populace is doing his work for him.

While otherwise robust, CSL half-year results on Wednesday revealed the impact of an "alarming" fall off in influenza vaccination rates, especially in the US.

CEO Paul McKenzie attributes the drop-off to post-pandemic apathy and shrinking availability as fewer medical centres offer the jab.

The trend – which has resulted in a spike in deaths and hospital admissions – resulted in revenue from CSL’s flu arm Seqirus plunging nine percent.

Luckily for investors, CSL’s core plasma business Behring came to the rescue with a stellar showing.

The acquired, oft-maligned Vifor Pharmaceuticals iron/kidney health business also took up the slack - unexpectedly.

The bottom line is that management has maintained full-year revenue and earnings guidance.

“The fundamentals of CSL’s underlying business are robust and we are in a strong position to deliver annualized, double-digit earnings growth over the medium term,” Dr McKenzie declared.

Unconvinced, investors carved five percent from the stock price, on the back of what Wilsons analyst Dr Shane Storey dubbed a “compositionally wild” result.

## **Complex, but simple**

CSL is the biggest plasma-derived therapeutics house, vying with Takeda, Grifols, Octapharma and Baxter.

The country’s biggest biotech and the third biggest ASX-listed company overall, CSL seems complex but at its heart is a simple story.

The company’s core Behring division takes blood (plasma) from donors and turns it into dozens of life-saving therapies for conditions pertaining to immunology, haematology, cardiovascular, neurology, respiratory and transplants.

Complementing this, the Seqirus arm markets ‘flu vaccines and a few other bits and bobs.

The song has remained the same over the years, but the \$US12 billion (\$A17 billion) acquisition of Vifor in 2021 added a different - and at times discordant - tone.

Vifor specializes in the renal (kidney) market, notably dialysis and iron deficiency.

## **A century of achievement**

Believe it or not, CSL was once a sleepy government-owned entity called the Commonwealth Serum Laboratories.

CSL was founded in 1916 to supply vaccines to a country stranded during the war, later moving into penicillin and insulin production.

Along the way the company developed snake antivenom, launched plasma fractionation, produced insulin for diabetes, the tetanus vaccine and co-developed Gardasil for human papillomavirus.

In 1994, the then Keating Government privatized the company at a bargain-basement \$2.30 a share.

This means each of those shares is now worth circa \$770 when a three-for-one share split (carried out in 2007) is considered.

In 2004, CSL acquired German plasma rival Aventis Behring, which shaped the company we know today.

In 2009, CSL also tried to take over another plasma outfit, Talecris Biotherapeutics, but was stymied by US competition rules.

If that one had come off, CSL would have been the Bunnings of the plasma world: omnipotent.

Formerly known as CSL Bio, the UK-based Seqirus is a leader in the \$US4 billion a year seasonal 'flu vaccine market.

The Seqirus business was engorged by the 2015 purchase of Novartis's influenza drug business.

CSL was steered by the legendary CEO Dr Brian McNamee, who ceded to Paul Perreault in August 2013. Dr McNamee then returned as chair.

To the surprise of many investors, Mr Perreault pulled-up stumps in March 2023, in favor of anointed internal candidate Dr Paul McKenzie (only the third CEO at CSL in three decades).

## **CSL's greatest hits**

Of CSL's plasma products, the immunoglobulin franchise is the biggest component of revenue.

These include the subcutaneously-delivered Hizentra and the intravenously dispensed Privigen, for primary immune-deficiencies (PIDs) and the rare neurological disorder chronic inflammatory demyelinating polyneuropathy (CIDP).

Idelvion is an albumin fusion protein cited as the new standard-of-care for haemophilia B. Also albumin-derived, Alburx and Albuminar are used to replace blood loss after trauma and surgery.

Albumin is a protein derived from blood (and found in egg whites).

Specialty products include Haegarda, an esterase inhibitor for hereditary angioedema (severe swelling of the face and throat).

Then there's Kcentra for urgent warfarin reversal (that is, when a patient on the blood thinning medication is bleeding to death).

Hemgenix treats haemophilia B bleeding with a single one-time infusion.

That's a game changer given the standard-of-care - including CSL's own Idelvion - requires a dose as frequent as every 48 hours to 72 hours.

### **Regulatory wins ...**

In December 2024, the local Therapeutics Goods Administration approved CSL's Andembry (garadacimab) for treating hereditary angioedema (HA) attacks.

The UK's MHRA followed suit, while the FDA, and European and Japanese authorities, are mulling approval.

The approvals follow a phase III trial, Vanguard, which met its primary endpoint of reducing HA attacks (61 percent of trial patients were free of them).

The company expects FDA approval by June 2025.

This consent should reverse CSL's loss of HA market share over the last five years, owing to the launch of two rival products, Takhzyro and Orladeyo.

Andembry offers a more convenient monthly subcutaneous dosing.

### **And trial misses ...**

The benefit of being a jolly large company is that even humungous failures are not material.

In February 2024, CSL declared the failure of its clinical trial for CSL112, a short-term plasma derived infusion therapy for patients who have suffered a recent heart attack and are at risk of another.

Sadly, CSL112 proved no better than placebo in avoiding secondary heart attacks.

The \$1 billion heart trial - the biggest in CSL's history - enrolled 18,200 patients across 850 sites in 49 countries.

On broker estimates CSL112 could have added \$50 to CSL's share price.

Bugger! – but that's the high-stakes world of drug development.

## **Finances and performance**

CSL posted a five percent revenue surge to \$US8,483 million - another record result. Reported net profit climbed seven percent to \$US2,056 million, reflecting margin expansion in the Behring business.

Behring sales rose 10 percent to \$US5,743 million. Immunoglobulin product sales spiked 15 percent, to \$US3,174 million.

Sales of Hizentra, gained 16 percent on uptake of a new 50 millilitre pre-filled syringe.

Idelvion sales gained six percent.

Spurred by Chinese demand, albumin sales grew nine percent.

However, revenue from specialty products declined 20 percent to \$US920 million, the main culprit being a lost US contract to supply Kcentra.

Plasma collections “continued to grow”, with the cost of squeezing out the claret decreasing. This reflected the early benefits from ‘Rika’, a collection system that increases yields by 10 percent and reduces the time the donors need to be hooked up.

Seqirus revenue retracted nine percent to \$US1,661 million and operating profit shrank 17 percent \$US937 million.

The oft-maligned Vifor boosted revenue by six percent to \$1,079 million, on the back of strong European sales of its iron deficiency treatments (such as lead product, Ferinject).

Group research and development expenditure fell 3.6 percent to \$US646 million, equating to 7.6 percent of revenue. Management expects to ramp R&D costs to 10 percent of revenue for the full year.

Dr McKenzie points “confidently” to previously proffered full year earnings guidance (adjusted net profit) of \$US3.2 billion to \$US3.3 billion, up 10 to 13 percent.

Revenue should increase by five to seven percent.

Over the last year, CSL shares have oozed between \$317 in mid-July last year and the current nadir. The stock peaked at \$336 a share during the Covid-19 pandemic in mid-February 2020.

## **Threats ...**

Tuesday’s investor jamboree focused on CSL’s ability to maintain gross margins in the face of currency headwinds (a low US dollar - especially relative to the Euro - is not favorable).

But - hey! - currency is currency and CSL faces other growth challenges in the mid-term.

The Vifor purchase dealt CSL into the on-going debate about the anti-obesity class of drugs known as semiglutides, the thesis being that a bout of thinness improves kidney health.

Then there's the 'T' issue - as in Trump and tariffs.

The tariff issue is impossible to quantify, given Trump's position varies from hour to hour.

But on the question of migration, one danger is Mexican day visitors - a major source of CSL's paid blood donations - being denied access to its southern US centres.

The issue wasn't mentioned by the company - or raised by analysts - but debt watcher S&P Global Ratings had this to say about tariffs: "Given the company specializes in products and therapies that treat rare and serious diseases, we expect CSL to be less affected by potential tariffs than other major global pharmaceutical companies.

"However, we note there is a degree of unpredictability around policy implementation by the US Administration in relation to tariffs and their potential effects."

You can say that again.

### **... and opportunities**

Can the influenza business recuperate with a bit of chicken soup and TLC?

Dr McKenzie says the spike in hospitalizations - not to mention 50 paediatric deaths in the US - should shock everyone out of their complacency.

"These [fatalities] are a really sober reminder of the importance of immunization and hopefully that will re-energize healthcare providers in the coming season."

He adds that the company has maintained premium pricing for what it regards as its top-shelf products.

CSL has also won mandates to provide vaccines for the H5 zoonotic bird 'flu - a disease we probably should be more of a flap about than we are.

Still on Seqirus, a new treatment for certain types of vasculitis called Tavneos is on track to be launched in 30 countries this year. Seqirus will also launch its Fluad vax in Germany this year.

### **Dr Boreham's diagnosis:**

CSL derives the lion's share of revenue from the US, with dependencies on reimbursement procedures, FDA approval policies and official attitudes towards vaccinations.

So, it's interesting times ahead.

As acting chief finance officer John Levy quipped in relation to choppy foreign exchange rates: "We see unprecedented volatility in markets and a lot of it is coming out of 1600 Pennsylvania Avenue [the White House]."

Given those astronomical returns over the long term, CSL has a deserved reputation as a market darling.

Bell Direct market analyst Grady Wulff says given Behring accounts for more than 70 percent of CSL's revenue and is going from "strength to strength", the investor reaction should have been more positive.

"It wasn't a bad result."

Broking analysts are largely positive, valuing the stock at anywhere between \$250 and \$360.

But as was evidenced by Tuesday's post-results sell off - and the first 'strike' against the remuneration report delivered at last year's AGM - investors are about as happy as a camper with a leaking Lilo [tr: air mattress].

If CSL does not meet its "confident" guidance, the 'campers' will be throwing management on the bonfire at this year's AGM.

***Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His notion of 'camping out' is a hotel rated less than three stars***