



Biotech Daily

Friday February 14, 2020

Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: CSL

By Tim BOREHAM

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

Share price: \$331.19

Market cap: \$150.3 billion

Shares on issue: 453,882,387

Financials (first half to December 2019): revenue \$US4,910.6 million (\$A7,297.7 million, up 9%), net profit \$US1,248.0 million (\$A1,854.7 million, up 7.5%), earnings per share \$US2.74 (up 6.9%), interim dividend 95 US cents (up 12%), cash and cash equivalents \$US659.7million (up 2.3%)

Chief executive officer: Paul Perreault

Board: Dr Brian McNamee (chairman), Mr Perreault, Prof Andrew Cuthbertson; Bruce Brook, Dr Megan Clark; Abbas Hussein, Marie McDonald, Christine O'Reilly, Carolyn Hewson*

* Ms Hewson replaced Dr Tadataka Yamada who stepped down in October

Identifiable major shareholders: Blackrock Group 5.02%, Vanguard Group 5.1%.

With the blood products group vying with the Commonwealth Bank of Australia to be Australia's biggest company - listed or otherwise - CSL chief Paul Perreault could be excused for displaying a coronavirus-sized outbreak of hubris.

After revealing a 7.5 per cent profit surge for the half year and upgrading full year guidance this week, he was keeping the proverbial lid on it - but only just.

“We expect strong demand for our therapies to continue and we expect to outpace the market as far as plasma collection is concerned,” he said.

Justifiably or not, investors are ascribing a supersized valuation to CSL relative to the so-called Big Four banks that have long cluttered the ASX top-10 rankings.

On the same day CSL bared all, the Commonwealth Bank of Australia disclosed a \$4.5 billion interim cash profit compared with CSL's \$1.85 billion.

Yet, with a circa \$150 billion market capitalization CSL is not far off the \$156 billion ascribed to CBA, Australia's biggest listed company.

This means that CBA shares are trading on a price-earnings multiple of 17 times - high for a bank historically - while CSL is on 48 times.

But with CSL shares trading at record levels, investors clearly believe the banks are going nowhere and nothing can stop the growth trajectory of our global wonder stock.

For the record, CSL is the world's fifth biggest biotech and its plasma arm CSL Behring is the biggest in the \$30 billion a year plasma industry

What's the fuss about?

CSL makes an array of products but the core of its business is simple: the company collects blood plasma - notably from centres in the US where donors are paid for their claret - and slices and dices it into specialist therapeutics.

Plasma is the substance that carries red and white blood cells through the body so it's kind of, like, important.

The therapies are relevant for disorders such as haemophilia, primary immune deficiencies, hereditary angioedema and inherited respiratory disease.

In the immunoglobulin bracket, leading products are the intravenously-delivered Privigen and the subcutaneous Hizentra

Coagulation products include Idelvion, an albumin fusion protein cited as the new standard of care for haemophilia B.

CSL's albumin range includes Alburx and Albuminar, used for purposes such as replacing blood loss after trauma and surgery. Albumin is a protein derived from blood (and also found in egg whites).

Specialty products include Haegarda, an esterase inhibitor for hereditary angioedema (severe swelling of the face and throat) and Kcentra for urgent warfarin reversal (that is, when a patient on the blood thinning medication is bleeding to death).

This week, the US Food & Drug Administration approved Privigen for the investigational treatment of the autoimmune disease systemic sclerosis.

The 'flu vaccine arm was formerly known as Bio-CSL but was re-named Seqirus after CSL bought pharma giant Novartis's influenza vaccine business in 2015.

Seqirus is Latin for 'made up name because all the sensible ones were taken'.

Seqirus sells season vaccines such as the quadrivalent Flucelvax that is effective against four strains and the adjuvanted (supercharged) Fluad for high risk populations.

The company cites a seasonal vaccine market of \$US4 billion, or 500 to 600 million doses (150 million in the US).

Just popping down to the (blood) bank

CSL is perceived as a no-brainer business because a growing population will ensure a market of sick people in need of the therapeutics.

As Dracula would attest, efficient plasma collection is the key and there's a dark art in terms of centre location. CSL claims to be the best in the business and who are we to argue?

Currently CSL has 235 collection centres, mainly in the US, but also in Germany, Hungary and China.

The company opened 30 new US centres in 2018-'19 and a further 20 in the December half, bang on target for 40 openings for the full year.

According to broker Citi, the four plasma collectors opened 67 US outlets in the December half, with CSL accounting for 28 of them.

Dissecting the results

CSL's half-year profit bounce was underpinned by the 10 percent sales surge for the core Behring division.

In particular, sales of immunoglobulin products rose by 26 percent, with Privigen turnover up 28 percent and Hizentra sales soaring 37 percent.

Demand for primary immune deficiencies remains robust, but the company also benefited from Privigen and Hizentra being approved in the US for chronic inflammatory demyelinating polyneuropathy (CIDP), a rare neurological disorder.

The key weakness was a 33 percent decline in albumin-based products, owing to a change in distribution arrangements in China. This disruption had been well-flagged and should already have been accounted for in analysts' spreadsheets.

"Sales are expected to return to more normalized levels in 2021," Mr Perreault says.

CSL's fortunes are also being bolstered by the fortunes of the Seqirus division, with revenue up nine percent to \$US1.018 billion.

In particular, both quadrivalent and adjuvanted doses both rose by 21 percent, bearing in mind the seasonal nature of the division.

And seeing you asked, the company is not affected by the coronavirus – now formally named Covid-19 – in either positive or negative ways.

"We have been closely watching development and have been supporting our long-standing partner, the University of Queensland, in their vaccine program," Mr Perreault says.

The company also has a facility in the virus epicentre province of Wuhan, but this does not appear to be causing supply problems. Chinese collection centres are also closed for the time being and management is waiting for Beijing's nod to re-open them.

Ahead of the results, management guided to net earnings of \$US2.05 billion to \$US2.11 billion for the full year to June 2020.

Despite the albumin issue and supply constraints in some specialty lines, management has cheerfully upped guidance to \$US2.11 billion to \$US2.17 billion (up 10 to 13 percent on the previous year).

Sizing up the rivals

It's sometimes easy to forget that CSL does have competitors, notably Takeda, Grifols, Octapharma and Baxter.

But Mr Perreault says CSL isn't striving for world domination because it can't service all the demand.

He notes that when you become entrenched in a market, patients are loath to change if you have showed reliability of supply.

"We launched the first subcutaneous [immunoglobulin] product in the US in 2005," he says.

“It’s taken us from then until now to grow the primary immunodeficiency to half the [patient] population.

“We think we are clearly the market leader in subcutaneous. We have a great product for patients but it has to be the right patient and it has to be able to be administered at home.”

What’s cooking?

CSL’s post profit pow-wows these days follow a different script to a couple of years ago, when analysts and reporters would grill management on where it would find tomorrow’s profits.

Management would respond by unveiling yet another share buyback to reduce shares on issue and thus boost earnings per share.

Now, the company has turned to the lab: in the six months to December 31 it spent \$US446 million on research and development, having expended \$US832 million in the full 2018-’19 year.

So, there’s plenty of stuff bubbling away on the Bunsen burners at CSL’s Bio21 research hub at company HQ in Melbourne’s leafy Parkville.

For a start, CSL is halfway through a massive \$800 million clinical trial of its experimental heart drug trial known prosaically as CSL112 (a plasma-derived infusion therapy).

The phase III trial has enrolled 7,000 patients across 90 hospitals in 46 countries. In all 17,000 patients are expected to enrol and as far as clinical trials go it doesn’t get much more expansive and costlier than this.

Aimed at 10 percent or so of heart attack victims who have second attack within 90 days of the first - often fatally - the trial is seen as binary. It will work or it won’t. Expect the results of a “futility analysis” at CSL’s August full-year results.

If CSL112 were to be brought to market it would be worth billions.

CSL also has a phase I trial of an asthma therapy - let’s call it CSL311 because that’s what it’s named - aimed at zapping the agents that inflame the airways.

This one targets 235 million asthma sufferers, notably children.

CSL is also developing Privigen and Hizentra as a treatment for scleroderma and Hizentra for dermatomyositis.

As for new therapies, the non-exhaustive list of targets includes sickle cell anaemia, contact-mediated thrombosis, diabetic nephropathy, neutrophilic dermatoses, systemic lupus and erythematosus.

My there are a lot of ailments in the world, aren’t there?

Dr Boreham's diagnosis:

CSL shares have had a monster 12 months and are now trading at a record \$331 a share, compared with \$188 in February 2019. Five years ago, they traded at a "mere" \$88 or so.

CSL's naysayers point out that the company was gifted to private investors when the then Keating government privatised it in 1994 at \$2.30.

To say the Government left some money on the table is a gross understatement: allowing for a three for one share split in 2007, the original shares are now worth close to \$1,000 apiece.

Indeed, the company quietly made multimillionaires of former staff availing of the employee share scheme, in what turned out to be the ultimate 'get rich slowly' scheme.

On balance though, are CSL shares now overvalued? Given the lofty earnings multiple the stock trades on, the obvious answer is: "Yes".

But we thought the same when the stock was trading at \$30 ... and then \$100 ... and then \$200.

Beyond commercialization of the heart drug, it's hard to see a transformational 'big bang' event for CSL, such as a mega acquisition.

As with fellow home-grown hero Resmed, it's all about developing extension products and some new ones as well. If a fraction of the stuff at Bio21 works out, CSL could well lay claim to the mantle of Australia's biggest company.

In the longer term, gene therapies may well supplant some plasma-based therapies- but that's a bit like saying air travel will be replaced by transmat beams or the like.

"I wouldn't be opening more plasma centres if I didn't think growth in demand wasn't going to continue," Mr Perreault says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But he does own a modest wad of CSL shares, acquired at somewhat north of \$2.30 a share.