Biotech Daily

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Daily news on ASX-listed biotechnology companies

Dr Boreham's Crucible: CSL

By TIM BOREHAM

ASX code: CSL

Share price: $274.43

Market cap: $124.9 billion

Shares on issue: 454,997,506

Chief executive officer: Paul Perreault

Board*: Dr Brian McNamee (chairman), Paul Perreault, Dr Andrew Cuthbertson (CSO), Bruce Brook, Dr Megan Clark, Shah Abbas Hussain, Marie McDonald, Carolyn Hewson

***** Astrazeneca CEO Pascal Soriot resigned from the board, effective February 1, 2021. Christine O'Reilly retired from the board in October 2020

Financials (December half): revenue $US5.7 billion (up 16%), net profit $US1.8 billion (up 45%), earnings per share $US3.98 (up 44%), dividend $US1.04 (up 9%), cash of $US2.4 billion (up 100%)

Identifiable major shareholders: Blackrock 6.02%, Vanguard Group 4.9%, Australian Foundation Investments 0.44%, Argo Investments 0.25%.

While CSL has been in the news because of its role in the coronavirus vaccine rollout, yesterday's half-year results highlight the real life-blood of the company: plasma.

Industry wide, things are getting interesting in terms of collection of the yellow-colored liquid component of our claret, from which CSL derives so many therapies.

In essence, the pandemic has dented plasma collections in CSL's key US market, posing the risk of a shortage of key drugs such as immunoglobulin (IG) products.

CSL chief executive Paul Perreault says "collecting plasma is one of the hardest things we do at CSL" - a weighty observation given the scope of the company's activities across its core Behring (plasma) business and its vaccine/biotherapies arm Seqirus.

Speaking of which, the pandemic had the overall effect of "crimping" the Behring side of the business and generating a bonanza profit for Seqirus.

But - hey - they both did more than okay: CSL's reported net profit soared 44 percent to $US1.81billion ($AUD2.35 billion), exceeding investor expectations.

Some pundits now reckon the company is playing it safe with its (reaffirmed) full-year profit guidance. Nothing is ever simple with CSL, which has more moving parts than a Meccano set.

The problem with plasma

CSL runs 280 plasma collection centres, mainly in the US where, unlike here, donors are paid. As an essential service along with bottle shops, these centres remained open but the various mobility restrictions meant donor traffic still declined, with donors harboring concerns about safety and hygiene.

Management revealed that donations declined 20 percent in December, while the per-litre cost of collection increased by a similar amount. The company is tackling the issue with measures such as easier device-based registration for existing donors, to reduce waiting times.

Lapsed donors are being contacted again, while 17 new US collection centres were opened during the six months (with an expected 12 more in the second half-year).

While collections are improving month-on-month, Mr Perreault says "plasma collections have been challenging and will continue to be challenging".

Presumably the higher unemployment created by the pandemic would have boded well for collections, given the imperative for people to make a quick buck.

But donor frequency also falls when government stimulus cheques (or tax returns) land in the mail - as they are now.

IG therapies led the way

The raw material issue aside, Behring did well with the product - an overall 11 percent sales boost to $US4.3 billion. The division's underlying earnings grew 24 percent, to $US1.7 billion.

Demand was led by the core immunoglobulin portfolio, up seven percent to $US2.2 billion.

Immunoglobulins are antibodies (proteins) produced by the plasma cells and most notably are used to treat primary immune deficiency (PID) and chronic inflammatory demyelinating polyneuropathy (CIDP).

CSL's IG sales were led by the subcutaneous therapy Hizentra, which allows PID and CIDP patients to self-administer at home.

"This has allowed patients to better control their disease during the current lockdown measures," Mr Perreault says.

Albumin sales grew by a "seemingly amazing" 93 percent, but this result was skewed by the company's move to an own-distribution model in China, which had adversely affected results last time around. Albumin is the protein that makes up 60 percent of plasma, used in critical care including fluid resuscitation.

Fewer doctor consultations during the pandemic meant that demand for haemophilia products was a tad anaemic, up one percent.

Among the specialty products, Haegarda starred with a 17 percent sales increment. Launched in 2019, Haegarda treats patients with hereditary angioedema (severe swelling of the face and throat).

Demand for CSL's coagulation product Kcentra should have been impacted by reduced hospital procedures and fewer accidents, but sales rose six percent. Kcentra reverses effects of blood thinning drugs, in effect to stop patients from bleeding to death.

Toilet paper rationing one day, drugs the next?

The industry-wide dip in plasma collections poses the risk of drug shortages, especially in the IG sector which accounts for half of Behring's sales.

Mr Perreault says the company is managing the situation tightly to avoid disruptions, including not signing on new customers and ensuring "fair and equitable" supply to existing ones.

"IG supply was tight even before the pandemic," he says.

Or do we C-IDP a competitive IG threat?

In early February, Dutch biotech Argenx said it would push on with enrolling 130 patients in a late-stage trial evaluating subcutaneous efgartigimod, to treat chronic inflammatory demyelinating polyneuropathy (CIDP).

The compound has also been successful with myasthenia gravis (MG) and immune thrombocytopenic purpura (ITP).

Broker Goldman Sachs reckons these ailments account for 10 to 15 percent of IG demand. A $US13 billion market, CIDP accounts for 25 to 35 percent of demand and "plays an important role in industry economics".

Efgartigimod is in a new class of drug called an FcRn inhibitor - and no we're not being rude.

A shot in the arm for 'flu vaccine sales

While social distancing reduced the incidence of influenza, Seqirus still benefited from record dose volumes (more than 100 million) as governments sought to protect vulnerable citizens from the "twindemic" of the coranavirus and the traditional winter lurgy.

Seqirus's revenue grew 38 percent to $1.4 billion, while underlying earnings more than doubled to $US693 million. The US and Europe accounted for 80 percent of Seqirus sales. The division's revenue is also 80 percent skewed to the six months to December 31, while expenses are spread through the year, which means the current (second half) will be loss making.

Then there's the whole Covid-19 vaccine saga which involved Seqirus hastily changing tack from being a vaccine developer to a "fill and finish" manufacturer of the Oxford-Astrazeneca prophylactic.

CSL was in cahoots with the University of Queensland to develop a vaccine, with a phase I trial of 216 participants eliciting a "robust response" with a strong safety profile.

The trouble is the jabs had the potential to elicit "false positive" HIV responses in later trials and that was enough to kybosh development.

CSL is now contracted to make (or, technically, fill and finish) 50 million doses of the Astrazeneca Oxford vaccine on behalf of the Australian government.

The terminated vaccine program delivered a one-off revenue benefit of $US80 million for Seqirus. However, there was also a hefty "opportunity cost" with 400 people re-deployed or recruited and more than 11 million doses produced. Presumably these will go down the drain.

Meanwhile, the Astrazeneca vaccine is on track to be available by late March.

CSL is also preparing to trial a plasma-based experimental Covid-19 therapy to treat severe respiratory complications. Known as CSL760, the drug candidate has been developed using donations of plasma from people who have recovered from the virus.

"If successful this will become one of the earliest treatment options for hospitalized Covid-19 patients," Mr Perreault says.

Pollie takes a jab at CSL no-show

Being a former government enterprise, CSL is usually quite adept at handling politicians and we all saw the photo-opportunity yarns when the Broadmeadows vaccine facility cranked up.

But management copped a rare broadside in late January, when independent senator Rex Patrick accused the company of disrespecting the Parliamentary Covid-19 inquiry by not sending a body to the first hearing. CSL said everyone was simply too busy gearing up to manufacture the 30 million doses and no one could be spared – not even the mail room boy.

Finances and performance

While the result was well received - CSL stock rose by as much as five percent after Thursday's announcement - the outlook is somewhat clouded by the plasma availability issue and the costs of procuring the donations.

The products manufactured now are based on plasma donated last year, at a higher per-litre cost. And the cost of plasma now will shape CSL's fortunes next financial year.

One unintended benefit of the decline in donations was an 87 percent improvement in cash flow, to $US2.3 billion. In some investing circles, cash is king.

Management has re-affirmed guidance of $US2.17 billion to $US2.26 billion for the full year to June 2021, up three percent to eight percent on the previous year.

Given the $US1.81 billion first-half profit, this implies a subdued second half even allowing for an expected seasonal loss for Seqirus.

Unlike most other biotech stocks, CSL's have not been coronavirus heroes. They've traded around the $270 to $280 level and are yet to re-test their all-time peak of $331, on February 14 last year.

In case anyone needs reminding, the then Australian Government-owned CSL listed at $2.30 in 1994. Given CSL also underwent a three-for-one share split in 2007, today's shares would be worth about $878 each - or a 380-bagger.

Dr Boreham's diagnosis:

The pandemic-era share decline means that CSL has lost its mantle of the biggest ASX-listed company, with the Commonwealth Bank of Australia restoring its status at the top of the pile.

But fundamental demand for CSL's life-saving therapies looks to continue unabated, because they're - well - life saving therapies.

However, there are enough swirling doubts about costs and plasma supply to put a lid on things for the time being.

Perhaps the most uplifting aspect of the results is the bold showing of Seqirus, which looked like a dog when it was delineated as a separate division five years ago.

By any measure it’s a howling success. Despite the emphasis on Covid-19 vaccine production, don’t expect the vaccines to be a big money spinner, with no expected earnings impact for the current year.

As always, CSL trades on a seemingly toppish earnings multiple of more than 40 times expected current earnings. But the company has always justified such a premium with steady earnings increases, aided and abetted by share buy-backs that increase earnings per share.

Ultimately, valuations are in the eye of the beholder, with CSL’s $130 billion market cap not looking at all lavish, compared to market hero Afterpay, the unprofitable buy-now-pay later stock valued at $43 billion, or Facebook’s $US767 billion or Apple’s $US2.3 trillion.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He would never snub a parliamentary committee in the unlikely event of being invited to one.