Biotech Daily

Friday February 16, 2024

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: $284.00

Shares on issue: 483,093,257

Market cap: $137.2 billion

Financials (first half to December 2023): record H1 revenue $US8,053 million (up 12%), record H1 net profit $US1,920 million (up 17%), earnings before interest, tax depreciation and amortisation $US3,042 million (up 21%), dividend per share $US1.19 (up 11%), cash $1,017 million (down 34%), net debt $US11,090 million (up 4%)

Chief executive officer: Dr Paul McKenzie

Board: Dr Brian McNamee (chair), Dr McKenzie, Prof Andrew Cuthbertson, Prof Duncan Maskell, Dr Megan Clark, Bruce Brook, Caroline Hewson, Marie McDonald, Alison Watkins, Samantha Lewis

Identifiable major shareholders: Blackrock Group 5.6%, State Street 5%, Vanguard Group 4.9%.

When announcing disappointing drug trial results, most drug developers take the Bing Crosby approach of accentuating the positive, eliminating the negative and not messing with Mr In Between.

So, kudos to CSL this week for getting to the point and declaring its well-anticipated heart attack megatrial failed its primary endpoint and there were "no plans for a near-term regulatory filing".

CSL shares shrank 4.8 percent after Monday's announcement, reflecting broker estimates that a successful drug could be worth perhaps $50 per CSL share.

The next day, sellers wiped off a further 2.75 percent after CSL's robust half-year numbers, which showed an "excellent" performance from the core plasma business but substandard returns from the Seqirus influenza arm and the acquired Vifor iron and kidney heart business.

Chief executive Dr Paul McKenzie was unfazed: "CSL is in a strong position to deliver annualised double-digit earnings growth over the medium term," he cooed.

Ve haf come for your blood

CSL has expanded its scope but the business still revolves around its core Behring blood plasma arm. The company collects blood plasma - notably from centres in the US where donors are paid - and makes specialist products.

The therapies are relevant for disorders such as haemophilia, primary immune deficiencies, hereditary angio-oedema and inherited respiratory disease. CSL's leading immunoglobin products are the intravenously-delivered Privigen and the subcutaneous Hizentra

Coagulation products include Idelvion, an albumin fusion protein for haemophilia B. CSL's albumin range includes Alburx and Albuminar, used for purposed such as replacing blood loss after trauma and surgery.

Specialty products include Haegarda, an esterase inhibitor for hereditary angio-oedema (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).

CSL through the ages

CSL was founded as the Government-owned Commonwealth Serum Laboratories in 1916. CSL dosed Allied soldiers with influenza vaccines and penicillin in World War Two; and helped stave off the Spanish 'flu after the Great War.

The Hawke government privatised CSL and the company listed at $2.30 in 1994.

CSL underwent a three-for-one share split in 2007, so today's shares would be worth about $870 - a 3,760 per cent gain since listing.

Formerly known as Bio-CSL, the Seqirus division makes influenza vaccines.

On listing, CSL was steered by CEO Dr Brian McNamee, who ceded to Paul Perreault in August 2013. Dr McNamee then returned as chair. Mr Perreault stepped in March last year and was succeeded by Dr McKenzie, formerly the company's chief operating officer.

In its most transformative deal to date, in 2004 CSL acquired German plasma rival Aventis Behring. Five years later, the company tried to take over major rival Talecris Biotherapeutics, but the US competition regulator said ‘no bloody way’.

The Seqirus business was engorged by the 2015 purchase of Novartis’s ’flu drug arm.

In late 2021, the company paid $17 billion for the Swiss based, publicly-listed Vifor Pharma Group a global leader in nephrology and iron deficiency.

With a $140 billion market cap, CSL is the second biggest ASX-listed company behind the Commonwealth Bank and for a period was the biggest.

Finances and performance

CSL posted a 12 percent revenue surge to a record half year $US8,050 million ($A12,333 million), with net profit perking up 17 percent to $US1,920 million ($A2,940) - another half year record.

The bottom line was attributable partly to the cost of blood collections ‘trending down’ (see below). This helped the company to bolster its gross profit margin to 55.8 percent, with the aim of restoring it to the pre Covid level of 57 percent.

The powerhouse Behring plasma arm posted revenue of $US5,238 million, up 14 percent. This was on the back of immunoglobulin product revenue of $US2,757 million, up 23 percent with strong sales across all geographies.

Sales of Hizentra, the “clear market leader” in subcutaneous immunoglobulin products, gained 18 percent. Ditto, sales in haemophilia market leader Idelvion gained seven percent. CSL also has “successfully” launched Hemgenix - the world’s first haemophilia gene therapy - in the US.

Meanwhile, Seqirus increased revenue by a less impressive two percent to $US1,804 million, with growth tempered by factors including falling vaccination rates.

Low demand has resulted in an oversupply of ’flu vaccines, leading to providers discounting the doses to move stockpiles before they have to throw them out.

Broker Wilsons opines Seqirus looks to have missed an opportunity with its new quadrivalent vaccine Flucelvax “costing them market share and margin”.

Over the last year, CSL shares have traded between $308 (mid-June last year) and a low of $232 (late October). They peaked at $336 in February 2020.

Shareholder frustration at CSL’s sluggish share performance was evident at last October’s AGM, with investors almost kyboshing the remuneration report and delivering a 25 percent protest vote against the proposal to issue performance shares to Dr McKenzie.

A few issues to iron out

While management was clear about the future - or non-future - of the heart program, it was more equivocal about the headwinds faced by Vifor.

Dr McKenzie says the near-term growth aspirations for Vifor have been “dampened”, but maintains that in the longer term the business is just as promising as when it was acquired.

Space constraints preclude getting into detail, but the issues relate to reimbursement in the US, loss of exclusivity in Europe and the need for lower-margin products over more profitable ones. Some products in Vifor’s late-stage development pipeline did not meet clinical objectives.

Dr McKenzie says the business “continues to generate strong revenues and margins and synergies” while synergies [cost savings] are above expectations.

“While our strategic vision remains compelling [achieving it] will take longer than expected,” he chimes.

Vifor contributed $US1,006 million of half-year revenue - 13 percent of the group total - and a gross profit of $US670 million (15 percent of the total).

As with Resmed, CSL has also tackled concerns that the advent of ‘fat busting’ drugs such as Ozempic will crimp Vifor’s performance.

The rationale? There will be less diabetes and kidney disease.

Unlike with the sleep disorders house, the issue didn’t rate a mention during Tuesday’s results briefing. Last October, Dr McKenzie said he did not expect the obesity drugs to have a material impact on the business.

Arrested development

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

A plasma-derived infusion therapy, CSL112 was aimed at the 10 percent or so of heart attack victims who have a second attack within 90 days of the first.

The outcome of the trial was considered binary - the drug either would work or not - and sadly CSL112 proved no better than placebo in avoiding secondary heart attacks.

As the results were top-line only, we can’t know how big the miss, before they are aired at a US cardiac get-together on April 6. But there’s no suggestion the drug has a future with, say, a specific patient cohort.

Cracking hardy, CSL research and development head Dr Bill Mezzanotte says the learnings of the well-constructed trial would assist CSL's other development pursuits.

"We are disappointed with the results, but not in the efforts of our people."

During the half year, CSL spent $US669 million - 8.3 percent of its revenue - on research and development and has other potions bubbling away in the cauldron.

Dr McKenzie cites a pending phase III trial of clazakizumab, for end-stage kidney disease. By the end of calendar 2024, the company hopes to win approval for garadacimab (hereditary angio-oedema), while investors should also expect phase III data for the use of Hizentra for the rare disease dermatomyositis.

And lest we have forgotten about Covid – Cov-what?- the company expects to roll out enhanced vaccine across four geographies between 2024 and 2026.

CSL's Eu-Rika moment?

CSL's improved earnings were helped by a 10 percent reduction in the cost of collecting blood from donors.

During the pandemic, the company was forced to pay more for blood donations in the US, given folk were less inclined to leave home.

Low unemployment also crimped the propensity of America's working poor to part with their claret.

CSL's weapon is Rika, a long-awaited plasmapheresis collection system that has been rolled out across 30 collection centres and is expected to be installed in all 300-plus US centres within 18 months.

The project has been plagued by technical delays.

CSL is also seeking regulatory consent to extract 10 percent more blood from a donor. This would entail extracting blood based not just on the donor's weight, but other factors including the red cell count.

In the words of one colourful analyst during an otherwise beige profit briefing: "You are sucking out 10 percent more volume from their veins as before."

Asked whether CSL would boost donor fees to reflect this, but Dr McKenzie notes that Rika has also reduced the donor's time in the chair by 30 percent.

We will take that as a 'no' - but the party pies and sandwiches will stay.

According to broker Jarden, CSL's current collection system (Nexsys) costs an average $7 to $8 per donor in $A terms, but Rika could bring this down to as low as $1.

Dr Boreham's diagnosis:

At face value, this week's sell off looks a tad harsh, given management also reaffirmed expectations of a full-year profit of $US2.9 billion to $US3 billion (up 9-11%).

But the company may well have unveiled plans to start a business on the Moon, as investors weren't listening.

It's also worth remembering that while the heart news is a nasty jolt, most CSL analysts had not factored a successful heart drug result into their valuations in the first place.

As we posited after last year's interim numbers, CSL shares look perennially expensive but the company's performance has always justified the high trading multiples.

In the past, CSL used share buy backs liberally to improve earnings per share, but it no longer has buckets of unused cash. In fact, S&P Global Ratings grumbles about CSL's "heightened financial leverage".

CSL may have bled this week, but our Mr In Between view is that a steady flow of new products should staunch the wounds in the short to midterm. With a bit of iron will, Vifor's problems also look fixable.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. That's his perfect excuse for saying that his musings in no way constitute investment advice … and you can't suck blood from a stone.