Biotech Daily

Friday February 18, 2022

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: $265.57; **Shares on issue:** 481,706,266; **Market cap:** $127.9 billion

Financials (first half to December 2021): revenue $US6.04 billion ($A8.5 billion) (up 5%), earnings before interest tax depreciation and amortization $US2.48 billion (down 8%), net profit $US1.76 billion (down 2.8%), diluted earnings per share $US3.84 (down 3%), dividend per share $US1.04 (steady)

Chief executive officer: Paul Perreault

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

Identifiable major shareholders: Blackrock Group 6%, Australian Foundation Investment Company 0.45%, Argo Investments 0.24%.

We mean this in a nice way, but there's been a strong element of sameness about CSL's results for some years: steady growth in plasma-derived revenues, sensible product iterations, a solid Seqirus 'flu vaccine arm and a few bits and bobs elsewhere.

In the words of Led Zeppelin: The Song Remains the Same: or it has remained the same. After years of kicking tyres, the cash-rich CSL last year moved on the Swiss based Vifor Pharmaceuticals with a friendly $US12 billion ($A17 billion) offer.

Vifor specializes in the renal (kidney) market, notably dialysis and iron deficiency. The business is pretty distinct from CSL's core activities, so it's quite a diversification and as far as investors go the jury's still out.

In the meantime, CSL's half year results this week were better than expected despite a margin squeeze for the core Behring plasma arm.

This contraction resulted from the increased cost of blood (plasma) collections, as folk preferred to stay at home rather than get (another) needle jabbed in their arm.

The numbers would have been worse had it not been for better-than-expected influenza vaccine sales in the lead up to the Northern Hemisphere winter.

"We are a still a growth company," says CEO Paul Perreault. "The fundamentals of our business are strong and the diversity of our [product] pipeline is robust."

About CSL

CSL's powerhouse Behring arm makes plasma protein-based medicines to treat rare and serious diseases pertaining to immunology, haematology, cardiovascular, neurology, respiratory and transplant therapies.

That covers a world of woes!

Just over half of our blood consists of plasma, which is collected across 300 centres, mainly in the US, where donors can be paid for their claret (here, it's collected by the Red Cross from cheery volunteers such as Mrs Crucible).

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

Then known as 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.

In 1994 - yep, we're fast forwarding somewhat - the then Keating government privatized the sleepy company at a bargain-basement $2.30 a share. This means each of those shares is now worth circa $750 when a three-for-one share split (carried out in 2007) is taken into account.

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

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.

Life-saving products

CSL's key products include the sub-cutaneously-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 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).

Formerly known as CSL Bio, the UK-based Seqirus plays 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.

Vifor? Vi not?

After weeks of speculation, in mid-December, CSL announced it would buy the Swiss-based, publicly-listed Vifor Pharma Group for $US12.3 billion ($A17.2 billion), after Vifor's largest shareholder agreed to sell its holdings.

With a presence in 22 countries and 2,200 employees, Vifor is a leader in nephrology and has treatments for iron deficiency. Via a tie-up with Fresenius Health Care, Vifor is the world's biggest dialysis provider, with 54 million treatments annually across 4,000 clinics.

In 2020, Vifor chalked up 1.7 billion Swiss francs of revenue ($A2.58 billion or $US2 billion), with 55 percent derived from the US and 33 percent from Europe. In US dollar terms Vifor contributed 16 percent of the combined Vifor/CSL's theoretical revenue of $US12 billion

Product-wise in 2020, Vifor gleaned 39 percent of revenue from dialysis, 36 percent from iron treatments and the remainder from nephrology. Vifor has four advanced stage drugs in the pipeline, mainly for chronic kidney disease and related ailments such as anaemia.

About the results

CSL's reported first (December 2021) half earnings declined three percent to $US1.76 billion despite revenue increasing five percent to $US6.04 billion.

The key culprit was the Behring arm's gross margin decline, to 54 percent from 58.8 percent previously. While immunoglobin product revenue dived nine percent, Idelvion and Kcentra acquitted themselves with gains of 17 percent and 15 percent, respectively.

While Behring’s underlying earnings declined 22 percent to $US1.33 billion, those of Seqirus perked up 24 percent to $US884 million.

This is mainly because of strong seasonal influenza vaccines sales in the US and Europe: up 20 percent to 110 million doses.

We thought Covid had drastically curtailed ’flu numbers, but Mr Perreault has a different explanation: “Covid has bought a reawakening of the benefit of vaccines and the reduction of disease and death and hospitalizations if you are vaccinated.”

He adds that citizens are starting to heed what Mother told them to do: wash their hands, stay home if unwell and wear a mask to cover coughing and sneezing.

Bloody Mexican standoff

CSL’s collection centres are mainly in the US, but also in Germany, Hungary and China.

The good news is that CSL’s plasma collections rose by 18 percent, compared with the December 2020 half year.

The bad news is that they’re still below 2019 pre-pandemic levels, although the gap is narrowing.

Management has pulled a few levers by increasing donor fees and opening 18 new collection centres, including near the Mexico border.

Why do we mention Mexico? That’s because CSL and rival Grifols are challenging a US Customs ban on blood from Mexicans, who used to cross the Rio Grande on visitor visas to supplement their incomes. CSL and Grifols have launched a court appeal, which looks like grinding on for some time.

With the blood of America’s southern neighbors accounting for five to 10 percent of CSL’s collections, it’s a Mexican standoff the company would like to see resolved rapidamente.

Meanwhile, broker RBC (Royal Bank of Canada) estimates CSL’s donor fee rose 20 percent during the December half-year - and believes they will surge a further 33 percent in the current half.

Finances and performance

The bottom line is that management has affirmed previously stated full-year guidance of $US2.15 billion to $US2.25 billion, which at the midpoint would be seven percent lower than previously.

(Analysts point out that given the guidance includes $US90 million to $US110 million of Vifor acquisition costs, in effect, it’s an upgrade).

Geographically, the US accounted for just under half of total revenues, with Australia, Germany, the UK and China each contributing six to eight percent of the top line.

RBC expects Vifor to contribute 16 percent for the 2022-'23 year - the same as Seqirus - with Vifor contributing underlying earnings of just under $US1.5 billion (38 percent of the total).

Hitherto famed for its share buy-backs to soak up excess capital, CSL funded the Vifor purchase with an underwritten $6.3 billion institutional placement, a $750 million share purchase plan and $8.4 billion of debt.

Both the placement and the share plan were struck at $273 a share, although share plan participants were offered the shares at the lower of that price or a two percent discount to the weighted average price over a crucial five-day pricing period.

That's just as well, because the shares drifted during the offer period and the price ended up at $253.57. Despite the lack of a premium between the market price and the share plan price, the raising was oversubscribed.

CSL shares bounced 8.5 percent after Wednesday's results release, as investors took succor at the normalizing plasma collection numbers, the influenza vaccine boost and the strength of core product sales.

In the pipeline

CSL spends a hefty 10.5 percent of its revenue on research and development and it has some interesting potions bubbling away in the labs at its Bio21 research hub at company HQ in Melbourne's leafy Parkville.

Perhaps the most important is CSL112, a short-term plasma derived infusion therapy for patients who have suffered a recent heart attack and are at risk of another. About one in 10 heart attack victims have a second attack within 90 days of the first - often fatally.

Costing $800 million, a phase III trial has enrolled 80 percent of the expected 17,000 patients across 90 hospitals in 46 countries.

Etranadez is a gene therapy for haemophilia B. Trials to date have hit primary endpoints and the drug may well be approved this year.

Garadacimab is a monoclonal antibody for hereditary angioedema (as well as interstitial lung disease and idiopathic pulmonary fibrosis). Phase III trial enrolment is complete and the compound has US Food and Drug Administration fast-track approval.

The stakes are high.

Broker RBC estimates getting CSL112 to market would add $24 billion to CSL's valuation, or $53 a share. Etranadez would be worth $11.2 billion, or $25 a share.

Dr Boreham's diagnosis:

To borrow again from the aforementioned ageing rockers, there hasn't been a Whole Lotta Love for CSL given the 13 percent share price decline over the last six months.

Of course, we acknowledge the company completed a chunky capital raising which typically subdues share valuations.

As the pandemic recedes - hopefully - there are grounds for optimism that CSL will resume its impressive long-term growth trajectory.

Indeed, Behring's flat revenue is at least partly due to the plasma shortage which is in the throes of being rectified.

As Mr Perreault notes, there's no shortage of patients to be treated if more plasma becomes available. However, the recovery in plasma volumes may take longer than expected.

There's also the execution risk of bedding down a big acquisition, bearing in mind that big companies tend to make a big hash of it.

With Vifor's patents rolling off from 2028, management won't have the luxury of time to bury any mistakes (or patients), but we're confident they're up for the task.

Otherwise, the coast looks clear for CSL's in terms of new competing products in its core product areas.

"I remain optimistic that once Covid recedes we will emerge stronger than ever," Mr Perreault says.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. But hopefully the Stairway to Investor Heaven remains open as he winds on down the ASX road.