



Biotech Daily

Friday February 17, 2023

Daily news on ASX-listed biotechnology companies

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- * **DR BOREHAM'S CRUCIBLE: CSL**
- * **BTC GROUP H1 REVENUE UP 10% TO \$4.8m, LOSS DOWN 68% TO \$117k**
- * **TRUSCREEN 1-FOR-5 ISSUE FOR UP-TO \$2m**
- * **CRESO 'FIRM COMMITMENTS' FOR \$2m PLACEMENT**
- * **GENETIC TECHNOLOGIES RECEIVES \$2m FEDERAL R&D TAX INCENTIVE**
- * **DIMERIX TAKES \$2.8m RADIUM RDTI LOAN**
- * **OPTHEA TELLS ASX: OPT-302 ARTICLE 'NOT MATERIAL'**
- * **AUSTRALIAN ETHICAL REDUCES TO 8.6% IN COGSTATE**
- * **ZELIRA REQUESTS 'DIRECTOR APPOINTMENT' TRADING HALT**

MARKET REPORT

The Australian stock market fell 0.86 percent on Friday February 17, 2023, with the ASX200 down 63.5 points to 7,346.8 points. Twelve the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and one was untraded.

Dimerix was the best, was up one cent or 8.3 percent to 13 cents, with 328,478 shares traded. Emvision and Starpharma climbed more than four percent; Antisense and Imugene improved more than three percent; Next Science rose 2.1 percent; Amplia, Nanosonics and Paradigm were up more than one percent; with Neuren, Pro Medicus, Proteomics and Resmed up by less than one percent.

Yesterday's 13.9 percent best, Compumedics, led the falls, down two cents or 9.8 percent to 18.5 cents, with 20,000 shares traded. Actinogen and Mesoblast lost seven percent or more; Kazia fell four percent; Alcidion and Immutep were down more than three percent; Oncosil, Opthea, Orthocell and Polynovo shed more than two percent; CSL, Cynata, Impedimed, Medical Developments, Micro-X, Pharmaxis, Resonance, Telix, Universal Biosensors and Volpara were down one percent or more; with Clinuvel and Cochlear down by less than one percent.

[DR BOREHAM'S CRUCIBLE: CSL](#)

By **TIM BOREHAM**

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

Share price: \$298.40; **Shares on issue:** 482,216,193; **Market cap:** \$143.9 billion

Financials (first half to December 2022): revenue \$US7.18 billion (up 19%), net profit \$US1.62 billion (down 8%), adjusted net profit \$US1.82 billion (up 2%), basic earnings per share \$US3.37 (down 12%), dividend per share \$US1.07 (up 3%), cash \$US1.508 billion (down 85%), net debt \$US10.61 billion (previously \$US779 million net cash).

* \$US1 equals \$A1.42

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, Dr Paul McKenzie (chief operating officer)

** Mr Perreault retires on March 6 to be succeeded by Dr Paul McKenzie

Identifiable major shareholders: Blackrock Group 6.02%, State Street 5.05%, Australian Foundation Investment Company 0.46%, Argo Investments 0.25%.

Rather like last year's changing of the throne at Buckingham Palace, regime change is a rarity at CSL, so investors will be keen to see in which direction the diversifying blood plasma giant heads.

To the surprise of many investors last December, chief executive Paul Perreault declared he would call stumps in early March, in favor of anointed internal candidate Dr Paul McKenzie (only the third CEO at CSL in three decades).

Paul is 'dead', long live Paul.

Mr Perreault steps down after 'only' 10 years - and how time flies - having taken over from the legendary Dr Brian McNamee, who headed the company since listing in 1992 (Brian is not a Paul, but his legendary tennis champ brother is).

Change is gaining pace throughout the organization - albeit at a similar measured pace. While bedding down its \$17 billion Vifor acquisition - see below - the company is furthering a cluster of self-developed, potential blockbuster treatments.

We'll have to wait a tad longer for a formal manifesto from Dr McKenzie, who tuned in to Tuesday's half-year profit briefing but left Mr Perreault to soak up the glory in his swansong performance. And there was plenty of room for the accolades, with both the key Behring (plasma) division recovering from the pandemic era and the Seqirus (vaccines) arm benefiting from a rebound in influenza cases during the Northern Hemisphere winter.

“The impacts of Covid-19 are largely behind us at this point,” Mr Perreault declared. “The strong growth we have seen in plasma collections and our immunoglobulin franchise is expected to continue.”

Strictly speaking, CSL’s formal reported net profit was off the pace, due to the increased cost of collecting blood. On management’s preferred measure of adjusted profits, earnings crept up slightly - and in any event Mr Perreault, like Edith Piaf, bows out with few regrets.

My, how you have grown

Currently the third largest ASX-listed company after the Commonwealth Bank and BHP, CSL was once the sleepy government-owned 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.

Despite a plethora of medical achievements, including the development of snake anti-venom, launching plasma fractionation, the production of insulin for diabetes, development of the tetanus vaccine and co-development of Gardasil for human papillomavirus (HPV), financially nothing much kinda happened until 1994, when the Hawke/Keating government - yep - another Paul - privatized CSL along with a slew of other public assets.

CSL then acquired German plasma rival Aventis Behring, which has become the core of CSL’s plasma business.

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

In 2015, CSL gave its influenza vaccine business an shot in the arm buying Novartis’s ‘flu vaccine business for around \$400 million - a deal definitely not to be sneezed at.

In the pandemic era, CSL aligned itself to a University of Queensland vaccine project - with some hoo-ha we must say - before the project was shelved because of evidence the prophylactic caused false positive results on HIV tests.

In 2022, CSL completed the \$US12 billion Vifor Pharmaceuticals acquisition. The accompanying \$US6.3 billion institutional placement and \$US750 million share purchase plan was the biggest secondary raising in history for an ASX-listed company.

With a presence in 22 countries and 2,200 employees, Vifor is a leader in nephrology (kidneys) and iron deficiency treatments. The company is the world’s biggest dialysis provider, with 54 million treatments annually across 4,000 clinics.

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

Seqirus is now based in England – closer to those Northern Hemisphere winter coughs and sniffles.

Life-saving products

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

Just over half of our blood consists of plasma, which is collected across 300 centres, mainly in the US (unlike here, donors are paid). Of the multitude of plasma products, the immunoglobulin franchise is by far the biggest component of revenue.

CSL's key products include the subcutaneously-delivered Hizentra and the intravenously-dispensed Privigen, for primary immune-deficiencies and the rare neurological disorder chronic inflammatory demyelinating polyneuropathy.

Idelvion is an albumin fusion protein to treat 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 is also found in egg whites).

Specialty products include Haegarda, a treatment 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).

Finances and performance

CSL's reported earnings for the six months to December 2022 easing 7.8 percent to \$US1.62 billion, but after adjustments for acquisition costs and non-cash intellectual property impairments, the result was pretty much steady.

Group revenue bounded 19 percent to \$US7.18 billion, with sales from immunoglobulin products - the biggest part of the business - also rising by that degree.

The star product was the haemophilia B treatment Idelvion, up 22 percent.

The sector breakdown shows that Behring contributed 63 percent of total revenue, with Seqirus chipping in 24 percent.

The results also reflected five months of Vifor revenue contribution, amounting to \$US889 million (roughly 15 percent higher and 13 percent of the total).

The US remained by far the most important market, accounting for 52 percent of CSL's overall revenue. The next biggest market, Britain, chipped in seven percent while Australia batted above its league with a six percent contribution.

The bottom line is that management has affirmed previously stated full-year adjusted net profit guidance of \$US2.7 to \$US2.8 billion. Full year revenue is expected to increase by 20 to 30 percent, which takes into account an 11-month Vifor contribution and a seasonably subdued second half (the six months to June 30) for Seqirus.

While management clearly was chuffed with the numbers, investors were only modestly so, sending the stock up by less than one percent.

Over the last year, CSL shares have traded between \$243 (February last year) and \$314 (early February this year). The stock hit an all-time peak of \$336 in February 2020.

Investors dating back to the privatization - and there are still a few - will fondly recall the offer price of \$2.30 a share. This means that taking into account a three-for-one share split in 2007, their shares are worth more than \$900 each.

No longer a chili reception for Mexican donors

The result was underpinned by a 36 percent boost in plasma collections to record levels, mainly because Mexicans are able to return to southern US donor centres. Collections are now 10 percent above pre-pandemic levels.

In September 2022, CSL and rival group Grifols won a year-old legal action that overturned a US Customs ban on Mexicans crossing the Rio Grande to donate blood.

The issue is not small beer, or burritos: CSL has 60 centres near the border and the \$US50-per-hit fees are a valuable source of income for many Mexicans, who arrive on visitor visas for the day. Mexicans account for five to 10 percent of CSL's US collections.

As with its rivals, CSL has had to pay more for donors' claret, but says the pricing pressures are easing. The company is also on a drive to make collections quicker and more efficient, with a new whiz-bang plasmapheresis process. (As Australian Greens Adam Bandt famously told a reporter: "Google it, mate".)

What's bubbling away in CSL's vat?

More so than in the past, investors are likely to focus on the new products bubbling away in CSL's labs. The company spend 10 to 11 percent of its revenue on research and development - a cool \$US577 million during the half-year - and the fruits of its labors are becoming apparent.

In May last year, the US Food and Drug Administration accepted CSL's biologics licence application for a gene therapy called Hemgenix to treat haemophilia B bleeding with a single one-time infusion. The standard-of-care - including CSL's own Idelvion - requires a dose as frequent as every 48 hours to 72 hours.

CSL is reportedly eyeing a list price of \$US3.5 million for Hemgenix - making it the world's most expensive drug. While this sounds excessive, put in context a haemophilia B patient currently can cost the system more than \$US20 million to treat over a lifetime.

In late clinical stage is CSL112, a short-term plasma derived infusion therapy for patients who have suffered a recent cardiac arrest 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 fully-enrolled the expected 17,000 patients across 90 hospitals in 46 countries.

Then there's a potion called CSL312, or garadacimab, a monoclonal antibody in development for hereditary angioedema prevention.

Top line results from a phase III clinical trial suggests that garadacimab's performance compared favorably with that of the category leader, with a monthly rather than fortnightly dosing. Trial results are to be presented to the American Academy of Allergy, Asthma and Immunity's knees-up in San Antonio next week and the company hopes to file for FDA registration later in the year.

Broker Wilsons opines that if commercialized, CSL312 could boost CSL's standalone valuation by \$50 a share, with peak sales of \$US600 million per annum, and RBC estimates getting CSL112 to market would boost CSL's valuation by a similar degree.

Vifor's box of tricks include the intravenous iron deficiency treatments Ferinject and Injectafer. Vifor also has four advanced stage drugs in the pipeline, mainly for chronic kidney disease and related ailments such as anaemia.

Meanwhile, CSL is building a dedicated research and development campus in Marburg, Germany. And speaking of facilities, CSL's \$800 million cell culture vaccine plant at Melbourne's Tullamarine is due to complete in in 2026.

Dr Boreham's diagnosis:

One almost feels sorry for the incoming Paul McKenzie - aka King Charles III – who has to take CSL to the next level after Mr Perreault's blood-y good effort.

But as Mr Perreault assures investors, there's some powerful growth levers beyond the mainstay businesses.

"In all my time at CSL I have never seen the pipeline in such a strong position and it really sets the company up for sustainable profitable growth," he purrs.

With demand for CSL's life saving products almost assured, the storied company's ongoing prosperity hinges on x-factors such as competitors' pricing behavior and management's execution of the Vifor purchase.

Oh - and the new stuff coming out of the vats. According to broker Goldman Sachs, Vifor contributes to CSL's "richest ever" drug pipeline "meaning the company now has more clinical/commercial catalysts than at any time in the recent past".

All in all, we expect King Paul's March 6 coronation to be a smooth one. Put another way, like his predecessor his reign should be far from a-Paul-ling.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His name is not Paul and the only throne he sits on is the porcelain one, but his sign-off lines can be appalling.

BTC HEALTH

BTC says that group revenue for the six months to December 31, 2022 was up 10.1 percent to \$4,750,711 with net loss before tax down 67.7 percent to \$117,149.

BTC said it was a pooled development fund and as an investment entity it did not consolidate the operating results of its investments.

The company said the ASX-listed entity's net loss after tax was down 27.7 percent to \$258,005 with diluted loss per share down 30.8 percent to 0.09 cents.

BTC said that it had two wholly-owned investment entities Bioimpact Pty Ltd and BTC Speciality Health Pty Ltd and said the operating results were a consolidated, unaudited, financial view of it and its wholly owned investee companies.

The company said that net tangible asset backing per ordinary security fell 2.8 percent to 4.49 cents, and it had cash and cash equivalents of \$1,175,400 at December 31, 2021 compared to \$2,366,403 at December 31, 2021.

BTC was untraded at three cents.

TRUSCREEN GROUP

Truscreen says it will offer a one-for-five pro-rata renounceable rights issue to raise up to \$NZ2.2 million (\$A2.0 million) at 3.0 NZ cents (2.9 Australian cents).

Truscreen said eligible shareholders who elected to take up all of their rights would have an opportunity to apply for additional shares, at an issue price to be determined through an over-subscription book-build facility, which could be more than the issue price, but could not be less.

The company said that the rights offer had a record date of February 27, would open on February 28 and close on March 15, 2023.

Truscreen said that CM Partners was acting as its adviser for the rights issue, but did not state the purpose of the capital raised.

Truscreen was untraded at 2.9 cents.

CRESO PHARMA

Creso says it has "firm commitments" to raise \$2 million in a placement to institutional, professional and sophisticated investors at 1.506 cents a share.

Creso said the share price was a 16.33 percent discount to the last closing price of 1.8 cents on February 14, 2023.

The company said that subject to shareholder approval, investors would receive two options for each share bought, with one exercisable at three cents within 18 months of issue, and the other exercisable at eight cents by January 31, 2027.

Creso said the placement included a \$100,000 commitment from managing-director William Lay, subject to shareholder approval.

Creso said that funds would be used for sales and marketing in the US, completion of its phase II trial of psilocybin on treatment resistant post-traumatic stress disorder, as well as general working capital.

The company said that Everblu Capital Corporate Pty Ltd was the lead manager to the placement and would receive a \$120,000 fee, as well as two million shares for each \$1 million raised and the attaching options, subject to shareholder approval.

Former Creso chair Adam Blumenthal is the chair of Everblu.

Creso fell 0.1 cents or 5.6 percent to 1.7 cents with 44.7 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has received \$1,959,147 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program. Genetic Technologies said the rebate related to research and development expenditure for the year to June 30, 2022.

Genetic Technologies was unchanged at 0.35 cents with 13.2 million shares traded.

DIMERIX

Dimerix says it has a \$2,842,500 loan from with Radium Capital for “early access” to its Federal Research and Development Tax Incentive.

Dimerix said it would be able to access 80 percent of its expected Federal Research and Development Tax Incentive for the six months to December 31, 2022, at a compound interest rate of 1.17 percent per month, with the repayment to coincide with the receipt of the Incentive, expected by September 30, 2023.

The company said that the agreement allowed for a further advance payment at the end of each financial quarter.

Dimerix managing-director Dr Nina Webster said the loan “allows us to continue to progress towards commercialization of our lead candidate, DMX-200”.

Dimerix was up one cent or 8.3 percent to 13 cents.

OPTHEA

Opthea has told the ASX it did not believe the contents of a February 14, 2023 announcement to have a “material effect on the price or value of its securities”.

In an aware query, the ASX asked Opthea if it believed that the information released would have a material effective on the price of its shares, and noted that it lodged the announcement as “market sensitive”?

Opthea said that it did not consider the information to have a material effect on the price of its shares, and that there was “no material effect on the price or value of [its] securities after the release of the announcement”.

Opthea said that on February 14, it released an announcement of an article published on February 5, 2023 containing a peer manuscript article describing the results of its phase IIb study, which it announced in September and October 2019.

In 2019, Opthea said its 366-patient, phase IIb trial of OPT-302 for wet age-related macular degeneration met its primary endpoints with statistical significance ($p = 0.0107$), with the higher dose of 2.0mg OPT-302 showing statistically significant difference at 24 weeks of treatment, compared to both low dose 0.5mg OPT-302 with ranibizumab and control with ranibizumab (BD: Aug 7, Oct 11, 2019).

Today, Opthea said that the announcement was “purely factual and informs the market that the peer review of the outcomes of the phase IIb study had been published in the article, and informed the market where that article could be accessed if any investors wished to read it”.

Opthea said that “while the announcement did not contain new and material information, it did contain new information being that the data had undergone peer review, was accepted for publication and the article had been published”.

The company did not disclose why the announcement was market sensitive.

Opthea fell 2.5 cents or 2.7 percent to 89.5 cents.

COGSTATE

Australian Ethical says it has reduced its holding in Cogstate from 16,691,357 shares (9.62%) to 14,875,475 shares (8.58%).

The Melbourne-based Australian Ethical says it sold shares between February 10, and 15, 2023, with the single largest sale on February 15 of 680,000 shares for \$1,521,223 or an average of \$2.24 a share.

Cogstate was unchanged at \$2.32 with 1.2 million shares traded.

ZELIRA THERAPEUTICS

Zelira has requested a trading halt “pending an announcement by the company in relation a director appointment”.

Trading will resume on February 21, 2023, or on an earlier announcement.

Zelira last traded at \$1.18.