Biotech Daily

Friday February 14, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 11%; COCHLEAR DOWN 14%**

*** DR BOREHAM'S CRUCIBLE: CSL**

*** COCHLEAR H1 REVENUE UP 7% TO $1.2b; PROFIT UP 7% TO $205m**

*** AVITA REVENUE UP 28% TO $102m; LOSS UP 38% TO $98m**

*** ARTRYA RAISES $15m**

*** MONASH DISSOLVABLE ZINC BONE REPAIR IMPLANTS**

*** IMUGENE 2 MORE COMPLETE AZER-CEL BLOOD CANCER RESPONSES**

*** AVECHO PLEADS 'SCHULTZ, RESULTS' TO ASX 40% PRICE QUERY**

*** GOODBYE VISIONEERING**

*** HORTICAN (CRONOS) DILUTED TO 8.4% OF VITURA (CRONOS)**

*** MEDLAB 2023 AGM DEFEATS REM REPORT; 2024 AGM PASSES REPORT**

*** EMYRIA 2.5m CHAIR RIGHTS, 5m OPTIONS; 2m M-D OPTIONS EGM**

MARKET REPORT

The Australian stock market was up 0.19 percent on Friday February 14, 2025, with the ASX200 up 15.8 points to 8,555.8 points. Nineteen of the Biotech Daily Top 40 companies were up, 14 fell and seven traded unchanged.

Avita was the best, up 31 cents or 11.2 percent to $3.07, with 791,751 shares traded. Compumedics and Imugene climbed more than 10 percent; Alcidion was up 8.6 percent; Emvision improved 7.8 percent; Amplia and Percheron were up more than six percent; Medical Developments was up 4.6 percent; EBR, Nanosonics, Paradigm and Prescient rose two percent or more; Clinuvel, CSL, Immutep, Micro-X, Polynovo, Pro Medicus and Universal Biosensors were up more than one percent; with Orthocell, Proteomics and Resmed up by less than one percent.

Cochlear led the falls, down $41.81 or 13.7 percent to $262.73, with 637,490 shares traded. Clarity lost 9.1 percent; Actinogen was down 7.7 percent; Dimerix and Syntara fell five percent or more; Starpharma was down 4.8 percent; Cyclopharm and Mesoblast were down more than three percent; Cynata and Impedimed both shed two percent; with Aroa, Genetic Signatures, Neuren, Opthea and Telix down by less than one percent.

DR BOREHAM'S CRUCIBLE: CSL

By TIM BOREHAM

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

Share price: $256.90; **Shares on issue:** 484,206,716; **Market cap:** $124.4 billion

Financials (first half to December 2024): revenue $US8,483 million (up 5%), net profit $US2,056 million (up 7%), earnings before interest and tax $US2,795 million (up 4%), dividend per share $US1.30 ($A2.08, up 16%), cash of $US1,524 million (up 50%), total debt $US11,964 million (down 2%).

Chief executive officer: Dr Paul McKenzie

Board: Dr Brian McNamee (chair), Dr McKenzie, Prof Andrew Cuthbertson, Dr Megan Clark, Caroline Hewson, Marie McDonald, Alison Watkins, Samantha Lewis, Elaine Sorg, Dr Brian Daniels.

Identifiable major shareholders: State Street 7.1%, Blackrock Group 5.6% Vanguard Group 5%.

If the newly-minted US Health and Human Services Secretary and anti-vaxxer Robert F Kennedy Junior really wants vaccination rates to fall, he won't have to try too hard because the American populace is doing his work for him.

While otherwise robust, CSL half-year results on Wednesday revealed the impact of an "alarming" fall off in influenza vaccination rates, especially in the US.

CEO Paul McKenzie attributes the drop-off to post-pandemic apathy and shrinking availability as fewer medical centres offer the jab.

The trend – which has resulted in a spike in deaths and hospital admissions – resulted in revenue from CSL's flu arm Seqirus plunging nine percent.

Luckily for investors, CSL's core plasma business Behring came to the rescue with a stellar showing.

The acquired, oft-maligned Vifor Pharmaceuticals iron/kidney health business also took up the slack - unexpectedly. The bottom line is that management has maintained full-year revenue and earnings guidance.

"The fundamentals of CSL's underlying business are robust and we are in a strong position to deliver annualized, double-digit earnings growth over the medium term," Dr McKenzie declared.

Unconvinced, investors carved five percent from the stock price, on the back of what Wilsons analyst Dr Shane Storey dubbed a "compositionally wild" result.

Complex, but simple

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

The country's biggest biotech and the third biggest ASX-listed company overall, CSL seems complex but at its heart is a simple story.

The company's core Behring division takes blood (plasma) from donors and turns it into dozens of life-saving therapies for conditions pertaining to immunology, haematology, cardiovascular, neurology, respiratory and transplants.

Complementing this, the Seqirus arm markets 'flu vaccines and a few other bits and bobs.

The song has remained the same over the years, but the $US12 billion ($A17 billion) acquisition of Vifor in 2021 added a different - and at times discordant - tone.

Vifor specializes in the renal (kidney) market, notably dialysis and iron deficiency.

A century of achievement

Believe it or not, CSL was once a sleepy government-owned entity called the 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.

Along the way the company developed snake antivenom, launched plasma fractionation, produced insulin for diabetes, the tetanus vaccine and co-developed Gardasil for human papillomavirus.

In 1994, the then Keating Government privatized the company at a bargain-basement $2.30 a share.

This means each of those shares is now worth circa $770 when a three-for-one share split (carried out in 2007) is considered.

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.

If that one had come off, CSL would have been the Bunnings of the plasma world: omnipotent.

Formerly known as CSL Bio, the UK-based Seqirus is a leader 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.

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

To the surprise of many investors, Mr Perreault pulled-up stumps in March 2023, in favor of anointed internal candidate Dr Paul McKenzie (only the third CEO at CSL in three decades).

CSL's greatest hits

Of CSL's plasma products, the immunoglobulin franchise is the biggest component of revenue.

These include the subcutaneously-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 found in egg whites). Specialty products include Haegarda, an esterase inhibitor for hereditary angioedema (severe swelling of the face and throat).

Then there's Kcentra for urgent warfarin reversal (that is, when a patient on the blood thinning medication is bleeding to death).

Hemgenix treats haemophilia B bleeding with a single one-time infusion.

That's a game changer given the standard-of-care - including CSL's own Idelvion - requires a dose as frequent as every 48 hours to 72 hours.

Regulatory wins …

In December 2024, the local Therapeutics Goods Administration approved CSL's Andembry (garadacimab) for treating hereditary angioedema (HA) attacks.

The UK's MHRA followed suit, while the FDA, and European and Japanese authorities, are mulling approval.

The approvals follow a phase III trial, Vanguard, which met its primary endpoint of reducing HA attacks (61 percent of trial patients were free of them). The company expects FDA approval by June 2025.

This consent should reverse CSL's loss of HA market share over the last five years, owing to the launch of two rival products, Takhzyro and Orladeyo.

Andembry offers a more convenient monthly subcutaneous dosing.

And trial misses …

The benefit of being a jolly large company is that even humungous failures are not material.

In February 2024, CSL declared the failure of its clinical trial for CSL112, a short-term plasma derived infusion therapy for patients who have suffered a recent heart attack and are at risk of another.

Sadly, CSL112 proved no better than placebo in avoiding secondary heart attacks.

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

On broker estimates CSL112 could have added $50 to CSL's share price.

Bugger! – but that's the high-stakes world of drug development.

Finances and performance

CSL posted a five percent revenue surge to $US8,483 million - another record result. Reported net profit climbed seven percent to $US2,056 million, reflecting margin expansion in the Behring business.

Behring sales rose 10 percent to $US5,743 million. Immunoglobulin product sales spiked 15 percent, to $US3,174 million.

Sales of Hizentra, gained 16 percent on uptake of a new 50 millilitre pre-filled syringe.

Idelvion sales gained six percent.

Spurred by Chinese demand, albumin sales grew nine percent.

However, revenue from specialty products declined 20 percent to $US920 million, the main culprit being a lost US contract to supply Kcentra.

Plasma collections "continued to grow", with the cost of squeezing out the claret deceasing. This reflected the early benefits from 'Rika', a collection system that increases yields by 10 percent and reduces the time the donors need to be hooked up.

Seqirus revenue retracted nine percent to $US1,661 million and operating profit shrank 17 percent $US937 million.

The oft-maligned Vifor boosted revenue by six percent to $1,079 million, on the back of strong European sales of its iron deficiency treatments (such as its lead product, Ferinject).

Group research and development expenditure fell 3.6 percent to $US646 million, equating to 7.6 percent of revenue.

Management expects to ramp R&D costs to 10 percent of revenue for the full year.

Dr McKenzie points “confidently” to previously proffered full year earnings guidance (adjusted net profit) of $US3.2 billion to $US3.3 billion, up 10 to 13 percent.

Revenue should increase by five to seven percent.

Over the last year, CSL shares have oozed between $317 in mid-July last year and the current nadir.

The stock peaked at $336 a share during the Covid-19 pandemic in mid-February 2020.

Threats …

Tuesday’s investor jamboree focused on CSL’s ability to maintain gross margins in the face of currency headwinds (a low US dollar - especially relative to the Euro - is not favorable).

But - hey! - currency is currency and CSL faces other growth challenges in the mid-term.

The Vifor purchase dealt CSL into the on-going debate about the anti-obesity class of drugs known as semiglutides, the thesis being that a bout of thinness improves kidney health.

Then there’s the ‘T’ issue - as in Trump and tariffs.

The tariff issue is impossible to quantify, given Trump’s position varies from hour to hour.

But on the question of migration, one danger is Mexican day visitors - a major source of CSL’s paid blood donations - being denied access to its southern US centres.

The issue wasn’t mentioned by the company - or raised by analysts - but debt watcher S&P Global Ratings had this to say about tariffs: “Given the company specializes in products and therapies that treat rare and serious diseases, we expect CSL to be less affected by potential tariffs than other major global pharmaceutical companies.

“However, we note there is a degree of unpredictability around policy implementation by the US Administration in relation to tariffs and their potential effects.”

You can say that again.

… and opportunities

Can the influenza business recuperate with a bit of chicken soup and TLC?

Dr McKenzie says the spike in hospitalizations - not to mention 50 paediatric deaths in the US - should shock everyone out of their complacency.

“These [fatalities] are a really sober reminder of the importance of immunization and hopefully that will re-energize healthcare providers in the coming season.”

He adds that the company has maintained premium pricing for what it regards as its top-shelf products.

CSL has also won mandates to provide vaccines for the H5 zoonotic bird ’flu - a disease we probably should be more of a flap about than we are.

Still on Seqirus, a new treatment for certain types of vasculitis called Tavneos is on track to be launched in 30 countries this year.

Seqirus will also launch its Fluad vax in Germany this year.

Dr Boreham’s diagnosis:

CSL derives the lion’s share of revenue from the US, with dependencies on reimbursement procedures, FDA approval policies and official attitudes towards vaccinations.

So, it’s interesting times ahead.

As acting chief finance officer John Levy quipped in relation to choppy foreign exchange rates: “We see unprecedented volatility in markets and a lot of it is coming out of 1600 Pennsylvania Avenue [the White House].”

Given those astronomical returns over the long term, CSL has a deserved reputation as a market darling.

Bell Direct market analyst Grady Wulff says given Behring accounts for more than 70 percent of CSL’s revenue and is going from “strength to strength”, the investor reaction should have been more positive.

“It wasn’t a bad result.”

Broking analysts are largely positive, valuing the stock at anywhere between $250 and $360.

But as was evidenced by Tuesday’s post-results sell off - and the first ‘strike’ against the remuneration report delivered at last year’s AGM - investors are about as happy as a camper with a leaking Lilo [tr: air mattress].

If CSL does not meet its “confident” guidance, the ‘campers’ will be throwing management on the bonfire at this year’s AGM.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. His notion of ‘camping out’ is a hotel rated less than three stars

COCHLEAR

Cochlear says revenue for the six months to December 31, 2024 was up 6.7 percent to $1,171,800,000, with net profit after tax up 7.2 percent to $205,100,000.
Cochlear said the increased sales revenue was “driven by strong growth in cochlear and acoustic implants, moderated by a decline in services revenue”.
The company said cochlear implant sales were up 11.7 percent to $724.5 million and acoustic sales rose 21.0 percent to $140.4 million, with services revenue including sound processor upgrades falling 12.6 percent to $305.0 million.
Cochlear said services revenue declined due to lower upgrade rates to its Nucleus 8 sound processor, “with the rate of uptake slowing over the past 12 months”.
The company said lower upgrade rates were a result of “continuing high satisfaction with the … Nucleus 7 sound processor [and] … in the US, cost of living pressures have been a factor delaying the replacement of ageing sound processing technology”.
Cochlear said an interim dividend of $2.15 a share, franked at $1.72, for investors on the record date of March 21 would be paid on April 14, 2025, compared to a $2.00 interim dividend franked at $1.40 in the prior corresponding period.
The company said research and development spending was up 13.4 percent to $144,400,000, or 12.3 percent of total revenue.
Cochlear said it expected its next generation cochlear implant to be commercially available from mid-2025, subject to approvals, and it expected “solid market growth rates to drive cochlear implant unit growth of around 10 percent in 2024-’25”.
Last year, Cochlear chief executive officer Dig Howitt said the company was targeting a net profit guidance for the year to June 30, 2025 of $410 million to $430 million, which was a six percent to 11 percent increase (BD: Aug 15, 2024).
Today, the company said it expected net profit to be at the lower end of guidance due to a lower contribution from services revenue and higher cloud-related investment.
Cochlear said diluted earnings per share rose 7.3 percent to $3.125, with net tangible assets per share up 5.9 percent to $21.394, and it had cash and cash equivalents of $383,100,000 at December 31, 2024 compared to $485,200,000 at December 31, 2023.
Cochlear fell $41.81 or 13.7 percent to $262.73 with 637,490 shares traded.

AVITA MEDICAL

Avita says revenue for the year to December 31, 2024 was up 28.1 percent to $US64,251,000 ($A101,630,000) with net loss after tax up 37.9 percent to $US61,897,000 ($A97,894,000).
Avita said the increased revenue was driven by the transition to its Recell Go for full-thickness skin defects and burn wounds.
The company said it received no revenue from the US Biomedical Research and Development Authority, compared to the previous year’s $US1,428,000.
Avita said that sales and marketing expenses were up 56.1 percent to $US58,195,000 and administrative costs rose 17.2 percent to $US33,195,000.
Avita said revenue for the year to December 31, 2025 was “expected to be in the range of $US100 million to $US106 million, reflecting growth of approximately 55 percent to 65 percent” compared to the year to December 31, 2024.
The company said diluted loss per share was up 70.7 percent to $US2.39, with the previous year’s positive net tangible asset backing per share of $US1.82 turned to a negative 17 US cents, and it had cash and cash equivalents of $US14,050,000 at December 31, 2024 compared to $US22,118,000 at December 31, 2023.
Avita was up 31 cents or 11.2 percent to $3.07 with 791,751 shares traded.

ARTRYA

Artrya says it has “binding commitments” to raise $15 million at 73 cents a share in a placement to professional and sophisticated investors for its Salix coronary software.
Artrya said the issue price was a 10.4 percent discount to the five-day volume weighted average price.
The company said the funds would be used for regulatory applications for its Salix coronary plaque and Salix coronary flow products, customer implementation, clinical studies, research and development, regulatory costs and working capital.
Artrya said with the funding it would begin a plaque study to support clinical credibility and accelerate commercial adoption of its Salix software at US hospital centres.
The company said Petra Capital was the sole lead manager and bookrunner.
Artrya chief executive officer Mathew Regan said “clearance from the US Food and Drug Administration in relation to regulatory approval for the Salix coronary anatomy product is expected in March 2025”.
“The company continues the regulatory pathway to expand FDA approvals this year with a portion of placement proceeds applied to accelerate regulatory applications for our [Salix] products, along with customer implementation costs including the Sonic Healthcare Australia Radiology commercial agreement,” Mr Regan said.
Artrya fell four cents or 4.65 percent to 82 cents.

MONASH UNIVERSITY

Monash University says it has developed a zinc-based dissolvable material “that could replace the metal plates and screws typically used to hold fractured bones together”.
Monash University said surgeons “routinely use stainless steel or titanium, which stay in the body forever, can cause discomfort and may require follow-up surgeries”.
The University said its biomedical engineers had designed a zinc alloy which could “solve these problems by being mechanically strong but gentle enough to degrade safely over time while supporting optimal healing”.
Monash University said a research article showed that by engineering the size and orientation of the material’s grains, the zinc alloy could “bend and adapt in unique ways to accommodate the shapes of its neighboring tissues”.
The University said the zinc alloy was as “strong as permanent steel implants and more durable than other biodegradable options like magnesium-based implants”.
Monash University said it would spin-out a start-up company with a focus on developing biodegradable implants using the zinc-alloy technology.
The University said the study, titled ‘Stronger and coarser-grained biodegradable zinc alloys’ was published in Nature, with an abstract available at: https://bit.ly/42UwNNW.
Monash University lead researcher Prof Jian-feng Nie said the material had the potential to transform orthopaedic care by reducing complications, minimizing the need for additional surgeries, and offering a sustainable alternative to permanent metallic implants.
“Our zinc alloy material could revolutionize orthopaedic care, opening the door to safer, smaller implants that not only enhance patient comfort but also promote better healing outcomes by minimizing disruption to surrounding tissues,” Prof Nie said.
“An implant that never disappears will always be a risk to the patient … [but] one that degrades too fast won’t allow adequate time for the bones to heal,” Prof Nie said.
“With our zinc alloy material, we can achieve the optimal balance between strength and controlled degradation of the implant to promote better healing,” Prof Nie said.
“This made it not only stronger but more flexible, offering a game-changing alternative for orthopaedics,” Prof Nie said.

IMUGENE

Imugene says it has two more complete responses in cohort B of its phase Ib trial of azer-cel for blood cancer, taking the total to four of seven evaluable patients.
In 2023, Imugene said it would acquire 'azer-cel', or azercabtagene zapreleucel, CD19 chimeric antigen receptor T-cell therapy for blood cancers (BD: Aug 16, 2023)
Last year, the company said "three complete responses" had been recorded out of the 10 patients treated at that time in its phase Ib trial of azer-cel for large B-cell lymphoma, with azer-cel safe and tolerable (BD: Sep 2, 2024).
At that time, Imugene said four patients in cohort B had been treated with azer-cel, chemotherapy and interleukin-two; with the first two patients treated achieving a complete response, one lasting more than 90 days and the other more than 120 days.
Last month, the company said the trial would dose 129 patients (BD: Jan 19, 2025).
Today, Imugene said that a complete response was the disappearance of all signs of cancer in response to the treatment, cohort B was "showing promising results with evidence of meaningful clinical activity, and durability of response" and that the safety profile was manageable and generally well tolerated.
Imugene was up 0.4 cents or 10.3 percent to 4.3 cents with 103.4 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said that the company's share price rose 40 percent from a low of 0.5 cents at the close of trading yesterday, February 13, to a high of 0.7 cents today, and noted a "significant increase in the volume" of shares traded.
Avecho said the recent trading "may be a result of market speculation around the disclosures" in its Appendix 4C announced on January 30, 2025, regarding its "potential to achieve a significant industry milestone by becoming the first company to report positive results in a phase III clinical trial with a [cannabidiol], product for insomnia".
The company said positive results "could open up substantial opportunities for partnership discussions and licensing agreements, both locally and globally".
In the Appendix 4C for the three months to December 31, 2024, Avecho said that 70 patients had received cannabidiol (CBD) in the phase III insomnia trial.
In May 2024, the company said the trial would enrol 519 patients (BD: May 16, 2024).
Avecho was up 0.2 cents or 40 percent to 0.7 cents with 107.3 million shares traded.

VISIONEERING TECHNOLOGIES

The ASX says Visioneering will be removed from the official list at the close of trading today following shareholder approval of the company's delisting.
In January, Visioneering said an extraordinary general meeting approved the scheme to delist from the ASX with 94.1 percent support (BD: Dec 20, 2024, Jan 19, 2025).
Visioneering last traded at 6.6 cents.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Toronto, Canada's Hortican Inc, formerly Cronos Group Holdings Inc, says its 55,176,065 share-holding in Vitura has been diluted from 10.06 percent to 8.40 percent.
This week, Vitura said it raised $5,171,196 at 6.912 cents a share (BD: Feb 12, 2025).
Vitura was up 2.1 cents or 22.3 percent to 11.5 cents with 2.6 million shares traded.

MEDLAB CLINICAL

Medlab says its remuneration report was defeated by 51.75 percent of its 2023 annual general meeting and passed by 85.15 percent of its 2024 annual general meeting.
Medlab said its 2023 annual general meeting defeated the remuneration report with 11,024 votes (51.75%) against and 10,278 votes (48.25%) in favor.
The company said the remaining 2023 resolutions, including the election of directors and appointment of its auditor, were passed with more than 440,217 votes in favor, or 98.58 percent.
Medlab said its 2024 annual general meeting passed the remuneration report with 62,140 votes (85.15%) in favor and 10,834 votes (14.85%) against, and the spill resolution was withdrawn.
The company said the remaining resolution to re-elect a director was passed with 456,716 votes, or 99.07 percent of the meeting.
In 2022, Medlab said an extraordinary general approved a 150-to-one share consolidation (BD Jun 30, 2022).
According to its most recent notice, Medlab had 2,283,502 shares on issue, meaning that the 11,024 votes against the remuneration report at the 2023 meeting amounted to about 0.5 percent of the company, not sufficient to requisition extraordinary general meetings.
Medlab was in a suspension and last traded at $6.60.

EMYRIA

Emyria says shareholders will vote to issue 2,500,000 rights and 5,000,000 options to chair Greg Hutchinson and 2,000,000 options to managing-director Dre Michael Winlo.
Emyria said its extraordinary general meeting would vote to issue Mr Hutchinson 2,500,000 performance rights, vesting on share price-related milestones, as well as 5,000,000 options exercisable at 5.1 cents each within three years.
The company said the meeting would vote to issue Dr Winlo 2,000,000 options under the same conditions as Mr Hutchinson's options.
Emyria said that the securities were in addition to Mr Hutchinson's $190,000 yearly salary, inclusive of superannuation, and Dr Winlo's $260,000 annual pay, exclusive of superannuation.
The company said investors would vote to ratify the issue of placement shares, issue placement shares to Mr Hutchinson and ratify the issue of lead manager shares.
The meeting will be held at Stantons International, Level 2, 40 Kings Park Road, Perth on March 19, 2025 at 3pm (AWST).
Emyria was up 0.1 cents or 2.9 percent to 3.6 cents.