Biotech Daily

Friday August 8, 2025

Daily news on ASX-listed biotechnology companies

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

*** DR BOREHAM'S CRUCIBLE: CLARITY PHARMACEUTICALS**

*** AVITA H1 REVENUE UP 40% TO $57m; LOSS DOWN 30% TO $36.5m**

*** NEUREN ADDS SRD TO NNZ-2591 PIPELINE**

*** OSTEOPORE, MALAYSIA UNI PCL WISDOM TEETH SURGERY TRIAL**

*** PYC APPROVED FOR 4th PYC-003 KIDNEY DISEASE COHORT**

*** ANTERIS: ASX LISTING RULE 7.1 STOCK ISSUE WAIVER**

MARKET REPORT

The Australian stock market fell 0.28 percent on Friday August 8, 2025, with the ASX200 down 24.3 points to 8,807.1 points.

Eleven of the Biotech Daily Top 40 companies were up, 22 fell, six traded unchanged and one was untraded. Three of the four Big Caps were down, with Resmed unchanged.

Amplia Therapeutics was the best, up two cents or 10.8 percent to 20.5 cents, with 6.9 million shares traded.

Cynata climbed 8.8 percent; Curvebeam improved 4.55 percent; Botanix, Nova Eye and Optiscan were up more than three percent; Dimerix and Micro-X rose two percent or more; Cyclopharm and Neuren were up more than one percent; with Clinuvel up by 0.2 percent.

Avita led the falls (see below), down 23.5 cents or 13.6 percent to $1.49, with 3.05 million shares traded; followed by Clarity down 58 cents or 13.2 percent to $3.80, with 7.9 million shares traded.

4D Medical fell 10.5 percent; Atomo lost five percent; Actinogen, Paradigm, Prescient and Starpharma fell more than four percent; Genetic Signatures, Immutep, Imugene, Orthocell, Pro Medicus and Telix were down more than three percent; Mesoblast, Polynovo and SDI shed more than two percent; Cochlear, Compumedics, CSL, Medical Developments, Nanosonics and Proteomics were down more than one percent; with EBR and Emvision down by less than one percent.

DR BOREHAM'S CRUCIBLE: CLARITY PHARMACEUTICALS

By TIM BOREHAM

ASX code: CU6

Share price: $3.80

Shares on issue: 371,893,943

Market cap: $1.4 billion

Financials (June quarter 2025): receipts nil, cash outflows $9.1 million, cash balance $84.1 million (ahead of $203 million placement)

Chief executive officer: Michelle Parker

Board: Dr Alan Taylor (executive chair), Dr Thomas Ramdahl, Dr Colin Biggin, Dr Chris Roberts, Rosanne Robinson, Ms Parker

Identifiable major shareholders: TM Ventures Pty Ltd 4.5%, Cabbit Pty Ltd (Dr Chris Roberts) 4.8%, Alan Taylor Family 4.4% (post the $203 million placement)

There's nothing like a great biotech rivalry, such as the one between radio-pharmaceutical peers Clarity and Telix Pharmaceuticals.

Raising the stakes, Clarity executive chairman Dr Alan Taylor makes a bare-all promise pertaining to Telix's proposed prostate cancer therapy TLX-591.

"I'm willing to say that if that gets to market, I will run down (Sydney's) Pitt Street with no clothes on," he says.

Dr Taylor's 'nudie run' promise is inspired by Clarity's progress with its own phase II therapeutic trial, which resulted in a "phenomenal response" from pre-chemotherapy patients (including a complete response).

But the lesions need to be 'seen' first, with effective imaging.

Clarity contends that despite commercialized therapies including Telix's Illuccix and Lantheus's Pylarify, there's a vast untapped diagnosis opportunity.

Fresh from a $203 million capital raising, Clarity is undertaking two phase III diagnostic trials and an adjunct study of its diagnostic agent, 64-Cu-SAR-bis-PSMA.

The prostate specific membrane antigen (PSMA) is present in most prostate cancers.

The therapeutic variant, 67Cu-SAR-bis-PSMA is subject to a phase II trial (see below).

About Clarity

Clarity was formed in 2010 by TM Ventures and listed on August 24, 2021, having raised $92 million at $1.40 apiece.

The company, based in Sydney's now-gentrified inner-city Redfern, is based on the work of the late Dr Alan Sargeson at the Australian National University; and Prof Paul Donnelly at the University of Melbourne's Bio21 Institute of Molecular Science and Technology.

Dr Taylor trained at the Garvan Institute in Sydney before spending 15 years in investment banking (including at boutique firm Inteq Ltd). He was keen on commercializing Australian life sciences and decided sitting in an investment bank "ivory tower" wasn't going to cut it.

He joined Clarity as executive chair in late 2013.

Clarity's current chief scientific officer, Dr Matt Harris was part of TM Ventures and was Clarity CEO between 2010 and 2018.

Dr Colin Biggin then took over and was replaced by current CEO Michelle Parker last October. Dr Biggin remains as chief operating officer and an executive director.

In April this year, Clarity dropped a neuro-blastoma program (Sartate) and a prostate cancer program (Bombesin), to focus on three key efforts. They are programs for prostate cancer, neuro-endocrine tumours (Sartate) and breast cancer (Bombesin).

Let's get (a bit) sciencey

Clarity's SAR-bis-PSMA reflects a "novel approach of connecting two PSMA-targeting agents to Clarity's proprietary sarcophagine (SAR) technology".

SAR securely holds copper isotopes inside a cage-like structure, called a chelator. This prevents copper leakage into the body. It also is able to bind a targeting agent - anything from a small molecule to a large antibody.

The imaging agent is for improved positron emission tomography (PET) scanning.

Dr Taylor says Clarity's molecule developed for PSMA targeted imaging was similar to other products such as Pylarify and the unpatented gallium-68 PSMA-11 (the basis of Illuccix).

But the first product was just as bad as the others.

"So, we went back to the benchtop and re-built that molecule into a bispecific, with two targeting agents instead of one," he says.

"That increased the uptake to the lesion by two to three times, one hour after administration … and allowed for significantly better imaging at 24 hours."

Get a (half) life

Clarity claims a half-life of 12.7 hours for copper-64, compared with less than two hours for the standard of care gallium-68 or fluorine-8.

Patients can be administered and imaged the same day, next day or even the day after.

Crucially, with a 48-hour shelf-life, the doses can be made further from the patient, at central or regional facilities.

Another benefit is the nuclear material can be produced in electron accelerators and cyclotrons for therapy and diagnostics respectively, rather than nuclear reactors and generators.

Clarifying Amplify

Following two successful lead-in trials dubbed Propeller and Cobra, Clarity is undertaking two prostate cancer phase III trials, aimed at US Food and Drug Administration approval.

One underserved segment is blokes who have had a radical prostatectomy (prostate removal) and have low - but rising - level of the tell-tale prostate specific antigen (PSA) in the blood.

In the US alone, one million men might be walking around with the recurring cancer, dubbed bio-chemical recurrence. Current detection rates are low.

Enrolling 220 patients, Amplify is a single-arm, open-label study at multiple US and Australian sites.

The patients are evaluated on the day of administration and 24 hours later.

In late April, the trial dosed its first patient, at a US site.

Clarifying Clarify

The second phase III effort, the similarly-structured Clarify, is enrolling 383 patients across 23 sites, mainly in the US, with recruitment is expected to close early next year.

This one is for high-risk prostate cancer, prior to radical procedures such as prostate removal.

Such a procedure can leave a patient impotent and/or incontinent. So, if they end up still having cancer, that’s the worst of all worlds.

Canaccord expects a read-out on both Clarify and Amplify as early as March or April next year, with potential commercialization as early as June 2027.

Co-PSMA

An investigator-led study, Co-PSMA benchmarks 64-Cu-SAR-bis-PSMA head to head against the standard-of-care.

The 50 enrolled patients are also being measured for “potential curative outcomes” with targeted radiotherapy.

The study is being carried out at Sydney’s St Vincent’s Hospital, under the auspices of the investigator, Prof. Louise Emmet.

Dr Taylor says the patients already have had a prostatectomy but are concerned about rising PSA levels with undetectable disease.

“We want to avoid aggressive therapies such as chemical castration (testosterone blockers),” he says. “The earlier we can find the lesions and have external beam radiation and nip it in the bud, the longer quality of life we can have.”

The previous Cobra trial showed 64-Cu-SAR-bis-PSMA detected tumors as small as 1.9 millimetre in diameter, with sub-5.0mm lesions detected in 14 percent of patients.

Co-PSMA is scheduled to read out in the next couple months.

Secure-ing a better prostate treatment?

We shouldn’t forget the phase I/IIa therapeutic trial, Secure.

Carried out in the US, Secure is a multi-centre, single arm, dose escalation study enrolling 24 patients with (advanced) metastatic, castration-resistant, prostate cancer.

Participants in the first three cohorts in the dose escalation stanza have been treated with three strengths, with no “dose limiting toxicities”.

Even at the low dose, pre-chemo patients saw a PSMA reduction of 50 percent.

At double the dose all patients had an 80 percent-plus PSMA reduction; two of them 90 percent plus. One patient with “no hope” had a complete response, that is, the tumor disappeared.

The company is likely to begin a phase III trial if the positive trends continue.

NET agent is a Disco hit

In mid-June, Clarity revealed top-line data from the jazzily titled Disco, a phase II effort for patients with known or suspected neuro-endocrine tumors (NETs).

“Patients with NETs are often misdiagnosed and experience delays in receiving the correct diagnosis,” the company says.

Comparing Clarity’s 64-Cu-Sartate with the gallium-based, standard of care 68-Ga-Dotatate, the results showed Clarity’s agent to be more effective, either four or 20 hours post-administration.

Across the 45 study participants, 64-Cu-Sartate detected 393 to 488 lesions, compared with 186 to 265 for 68-Ga-Dotatate.

More that 90 percent of the “discordant” lesions were Sartate positive and all of the biopsied legions were verified as cancer.

“In the Disco trial, we continue to observe the substantial limitations of the current generation of short half-life isotope products,” Dr Taylor says.

Clarity is planning a phase III study and has a therapeutic trial in mind as well.

Sartate targets the somatostatin receptor SSTR2, present in other cancers such as certain breast and lung tumours.

Finances and performance

Last month’s $203 million raising was through a placement at $4.20 a share, a hefty 18 percent premium to the 15-day weighted average price.

“I have never done a deal that fast,” says Dr Taylor, who dubs the raising as “fast, well executed and sizeable”.

The raising was one of the biggest in ASX biotech history.

In a similar supersized vein, in April last year the company raised $121 million in a rights issue and placement (at $2.55 a share).

Last December, Clarity shares were promoted to the ASX200 index.

Over the last year its shares have ranged from a record high of $8.79 on September 23 last year to a low of $1.46 on April 9 this year (amid the Trump tariff turmoil).

The stock hit an all-time low of 40 cents in May 2022.

Clarity shares have been affected by the build-up of short-sellers who account for about 10 percent of the register.

Short sellers borrow shares and sell them, in the hope of buying them back at a lower price and restoring them to the lender.

Size of the prize

With prostate cancer, Canaccord estimates Clarity's total addressable market at $US5 billion in the next three to five years, with sales of $US730 million.

The firm estimates the current (poorly served) biochemical recurrence (BCR) market at between 110,000 and 200,000 patients, who on average have 1.7 to 2.2 scans per year, equating to a potential scan volume of 187,000 to 440,000 per year. A further 500,000 BCR patients may benefit in future.

The firm reckons that in the first year of launch, 64-Cu-SAR-bis-PSMA could generate $US17 million of revenue, rising to $US580 million by year three.

Canaccord says while there's pent-up demand in the BCR population, the overall market for prostate imaging and therapies is crowded.

"Clarity will be required to show data in line - or improved on - those available therapies, especially as a later entrant."

Meanwhile, Clarity estimates the US neuro-endocrine tumor diagnostic at around 100,000 scans per year, increasing to about 120,000 scans a year by 2029.

Dr Boreham's diagnosis:

Dr Taylor says that taking expanded indications into account, the neuro-endocrine tumor opportunity is "as large, if not larger" than the prostate cancer imaging potential.

He initially viewed the prostate cancer diagnosis market as low risk and low reward. Given the unserved needs, especially from the BCR cohort, he now concurs it's a "blockbuster market".

Two years ago, your columnist compared Clarity to the fifth Wiggle, in that the company's profile was overshadowed by that of the commercialized Telix.

"We are now more like AC/DC than the Wiggles, looking to make it big in the US with Australian tech," he says.

As AC/DC would attest, it's a Long Way To The Top in terms of cracking the US market. But it's a lovely view when you get there. We're confident Clarity can reach the summit - at least with a diagnostic approval. On the therapy side, hopefully TLX-591 *and* Clarity's candidate can get to market.

For the benefit of Sydney CBD passers-by, we also hope Dr Taylor keeps his gear on.

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. He will perform a 'nudie run' down Melbourne's Collins Street in Winter if his footy team wins a premiership – which on their current form means he's safe from frostbite for decades

AVITA MEDICAL

Avita says revenue for the six months to June 30, 2025 was up 40.4 percent to $US36,932,000 ($A56,620,000), with net loss after tax down 30.2 percent to $US23,779,000 ($A36,454,000).

Avita said that revenue from sales of its spray-on-skin Recell wound treatment, Permeaderm biosynthetic wound matrix and Cohealyx collagen-based dermal matrix for the three months to June 30, 2025 rose 20.0 percent to $US18,226,000, compared to the previous corresponding period.

The company said the increase “in commercial revenue was largely driven by deeper penetration within customer accounts, new accounts for trauma wounds and, to a lesser extent, new product launches”.

Avita said operating expenses for the three months fell 9.1 percent to $US26.1 million “due to a $US2.0 million reduction in sales and marketing expenses, which resulted from lower employee-related costs … due to cost reduction initiatives”.

The company said due to operational efficiencies it expected “to continue to reduce operating expenses by approximately $US2.5 million per quarter”.

Avita chief executive officer Jim Corbett said “although the first half of 2025 tested our resilience and slowed our pace, a resolution is now underway and our strategic direction hasn’t changed”.

The company said diluted loss per US share, equivalent to five Australian shares, fell 31.8 percent to 90 US cents for the six months to June 30, 2025.

Avita said it had net tangible asset backing per share of negative 80 US cents compared to positive 76.41 US cents in the prior corresponding period.

The company said it had cash and cash equivalents of $US12,216,000 at June 30, 2025 compared to $US17,452,000 at June 30, 2024.

Avita fell 23.5 cents or 13.6 percent to $1.49 with 3.05 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has added SYNGAP1-related disorder (SRD) to its neuro-developmental disorders pipeline for NNZ-2591, following a positive in-vitro study.

Neuren said SRD was caused by “a variant on the SYNGAP1 gene located on chromosome 6, which is responsible for producing the SYNGAP1 protein”.

The company said the SYNGAP1 protein was a regulator in the synapses and insufficient production led to impaired communication between neurons.

Neuren said that the neuro-developmental SYNGAP1-related disorder resulted in neurological issues including intellectual disability, low muscle tone, global development delay, epilepsy, sensory processing disorder, gross and fine motor skill delays, coordination disorder, speech delay, sleep and behavior disorder and autism spectrum disorder.

Neuren said there were “no approved treatments for SRD” and that the incidence of the genetic cause of SRD has been reported as one in 16,000 individuals.

The company said that in an in-vitro model of SRD in human induced pluripotent stem cell (IPSC)-derived neurons, treatment with NNZ-2591 reversed the neuronal dysfunction caused by SYNGAP1 insufficiency.

Neuren said it was developing NNZ-2591 to treat multiple neuro-developmental disorders for which there are no approved treatments, including Pitt Hopkins and Angelman syndromes as well as hypoxic-ischemic encephalopathy, with a phase III Phelan-McDermid syndrome preparing to begin (BD: Feb 24, Mar 27, May 13, 2025).

Neuren was up 23 cents or 1.3 percent to $17.78 with 1.1 million shares traded.

OSTEOPORE

Osteopore says it will begin an 18-patient trial with Kuala Lumpur's University of Malaysia of its poly-capro-lactone membrane for secondary socket healing in third molar surgery.
Osteopore said the study would compare the wound healing effects of its poly-capro-lactone (PCL) product against collagen membrane at the third molar, also known as 'wisdom teeth', surgical site of the lower jaw.
The company said the surgical removal of impacted third molars of the lower jaw was a commonly performed procedure, but was "often associated with post-operative morbidities such as pain and facial swelling" as well as the compromised periodontal health of the adjacent second molar.
Osteopore said "while collagen membranes are commonly used for socket healing in such procedures, its degradation profile may result in early loss of barrier function that impedes bone healing".
The company said its PCL membrane offered "the distinct advantage of gradual degradation over a longer period of time, thereby enhancing the barrier function of a membrane to facilitate bone healing".
Osteopore said it had ethics approval for the study, which was expected to recruit 18 participants with a post-procedure follow-up period of six months for all participants.
Osteopore chief executive officer Dr Yujing Lim said the company was "delighted that Universiti Malaya recognizes the value of our dental membrane in supporting socket healing".
"This study provides us with a great opportunity to benchmark our dental innovation against current practice" Dr Lim said.
Osteopore was unchanged at 1.1 cents with 3.4 million shares traded.

PYC THERAPEUTICS

PYC says it has approval to dose the fourth and final cohort of healthy volunteers with 4.0mg/kg of PYC-003 and begin dosing patients in its single-ascending dose study.
Earlier this year, PYC said it had approval for human trials of PYC-003 for polycystic kidney disease in a phase Ia/b single ascending dose study, with a primary endpoint of safety, with data expected by 2026 (BD: Feb 10, 2025).
Later, the company said it had approval to proceed to the second, 1.2mg/kg dose cohort of healthy volunteers in the study (BD: May 26, 2025).
In July, PYC said it had approval to dose the third cohort of volunteers with 2.4mg/kg and the first cohort of kidney disease patients with 0.4mg/kg of PYC-003 (BD: Jul 7, 2025).
Today, the company said that the safety review committee had reviewed the four-week safety data of the healthy volunteers in cohort three and had approved the trial to continue to cohort four.
PYC did not disclose patient numbers.
The company said that the primary objective of the phase Ia/b study was to evaluate the safety and tolerability of PYC-003 in healthy volunteers with a secondary objective to evaluate the efficacy of the drug candidate in polycystic kidney disease patients.
PYC said following the phase Ia/b single-ascending dose study it would conduct an open-label, multiple-ascending dose trial for repeat dosing and evaluating an optimal dosing regimen of PYC-003, which was expected to begin by 2026.
The company said once it had completed the phase Ia/b single-ascending dose trial, it would conduct a registrational, combined phase II/III trial to support a new drug application for PYC-003 in polycystic kidney disease with the US Food and Drug Administration.
PYC was up eight cents or 6.4 percent to $1.325.

ANTERIS TECHNOLOGIES GLOBAL CORP

Anteris says it has “a waiver from ASX Listing Rule 7.1 on an ongoing basis to permit the company to issue new securities without obtaining security holder approval”.

Anteris said ASX Listing Rule 7.1 restricted “listed entities from issuing securities in excess of 15 percent of their issued share capital without security holder approval over a 12-month period unless an exception applies”.

The company said the waiver provided “additional flexibility when evaluating financing options and capital raising transactions, consistent with US public companies that are not subject to the ASX Listing Rules and are generally able to offer and sell their securities without restrictions comparable to the 15 percent limitation applicable under ASX Listing Rule 7.1”.

Anteris said the waiver was for a three-year period and subject to shareholder approval, with the company remaining subject to the listing rules of the Nasdaq and relevant US federal and state securities laws.

Anteris said it considered the granting of the ASX waiver “in the best interests of the company and its stockholders”.

Anteris fell one cent or 0.2 percent to $5.55.