

Biotech Daily

Thursday October 2, 2025

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: OPTISCAN UP 30%; ATOMO DOWN 10%
- * FEDERAL \$14m FOR MEDICAL RESEARCH, TRIALS
- * ORTHOCELL RECORD \$3m 3-MONTH REVENUE
- * AVITA RECELL US CMS 'NEW TECHNOLOGY ADD-ON'
- * IMPEDIMED: UNNAMED US INSURER COVERS SOZO
- * CHIMERIC '2 MORE AML COMPLETE RESPONSES IN NK CELL TRIAL'
- * CLARITY: 'CU-64, CU-67 SAR-BIS FAP DOUBLES CANCER SURVIVAL, IN MICE'
- * AROVELLA 'CLDN18.2 CAR T-CELLS KILL PANCREATIC CANCER, IN-VITRO'
- * RACE UP 46% ON BISANTRENE-RCDS1 MECHANISM-OF-ACTION
- * VITASORA, IRIS PATIENT CARE DEAL
- * ALTERITY TO PRESENT PHASE II ATH434 MSA DATA
- * MEMPHASYS DISCLOSES \$1.1m RIGHTS AT 1-FOR-6 RATIO
- * NEUROSCIENTIFIC 10m DIRECTOR OPTIONS AGM
- * ARTRYA EX M-D JOHN BARRINGTON BELOW 5%
- * CLEVER CULTURE M-D BRENT BARNES TAKES 7%
- * CLEVER CULTURE DIRECTOR DANIEL HILL, VIKING DILUTED TO 11%
- * ECHO IQ APPOINTS DR PHILLIPPE GENEREUX, DR ASIF ALI ADVISORS

MARKET REPORT

The Australian stock market was up 1.13 percent on Thursday October 2, 2025, with the ASX200 up 100.2 points to 8,945.9 points. Twenty-three of the Biotech Daily Top 40 companies were up, 10 fell, six traded unchanged and one was untraded.

Optiscan was the best, up 2.8 cents or 30.4 percent to 12 cents, with 1.1 million shares traded. Impedimed was up 27.0 percent; Starpharma climbed 22.2 percent; Clarity was up 12.0 percent; Imugene improved 11.7 percent; Compumedics climbed 10.9 percent; both Paradigm and Proteomics were up 9.0 percent; Resonance rose 8.3 percent; Immutep and Syntara were up more than seven percent; Cyclopharm, Imricor and Orthocell climbed more than six percent; Avita and Mesoblast were up more than five percent; Neuren and Polynovo were up more than four percent; CSL was up 3.7 percent; Prescient rose 2.4 percent; Nova Eye and Telix were up more than one percent; with Clinuvel, Cochlear, Nanosonics and Pro Medicus by up less than one percent.

Atomo led the falls, down 0.3 cents or 10 percent to 2.7 cents, with 1.7 million shares traded. 4D Medical lost 6.6 percent; Curvebeam was down 5.7 percent; Cynata fell 4.35 percent; Alcidion and Amplia shed more than two percent; Micro-X, Resmed and SDI were down more than one percent; with Aroa and EBR down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it is investing \$13.6 million "to progress key national health and medical research reforms" including clinical trials.

A media release from the Minister for Health, Disability and Ageing Mark Butler said the funding would "improve earlier access to emerging treatments, strengthen Australia's clinical trials and deliver better health outcomes for Australia".

The Government said the funding would "progress the design of the National One Stop Shop for clinical trials, develop national standard operating procedures for clinical trials, implement the National Clinical Trials Governance Framework and develop an accreditation scheme for the human research ethics committees".

Last year, the Federal Budget papers said that there would be "funding to support an intergovernmental agreement for the cooperative governance and development of the National One Stop Shop for Clinical Trials and Human Research" (BD: May 15, 2024).

This year's Federal Budget papers said there would be "funding to support an intergovernmental agreement for the cooperative governance and development of the National One Stop Shop for Clinical Trials and Human Research".

Today, the Federal Government said the reforms would support Australia's "world class health and medical researchers while making sure all Australians benefit from the results of cutting-edge research in diagnosis, treatment and care earlier".

Mr Butler said the Government was "investing in once-in-a-generation reforms to improve health and medical research operations".

"This funding will help to make Australia a leading destination for more clinical trials and better health outcomes," Mr Butler said.

"The national reforms will give more Australians access to potentially life changing treatments and emerging therapies," Mr Butler said.

ORTHOCELL

Orthocell says it has record revenue of \$3.0 million for the three months to September 30, 2025, up 47.8 percent from \$2.03 million in the previous corresponding period. Orthocell said "while the result includes a modest but strategically significant financial contribution from early Remplir surgical cases in the US, the record revenue performance was primarily driven by increased market penetration in existing markets, particularly Australia and Singapore".

The company said the expected increase in Remplir use by US was the potential for a material increase in revenue, expected from the December quarter, with Remplir sales "expected to be further supplemented by market entry in Canada".

Orthocell said with the recent appointment of the first Canada distributor, initial sales were targeted by 2026, with adoption expected to increase (BD: Sep 30, 2025).

Orthocell managing-director Paul Anderson said the record revenue result was "a particularly pleasing result, given it has largely been achieved from our existing markets in Australia and Singapore".

"It's a tangible confirmation that surgeons are growing increasingly comfortable using Remplir in nerve repair procedures," Mr Anderson said.

"Our US Remplir rollout remains on target with early surgical cases having been successfully undertaken during the quarter," Mr Anderson said.

"As expected, these cases represented a modest financial contribution in the September quarter, but we see significant upside in our revenue growth potential as US momentum builds and Canada comes online," Mr Anderson said.

Orthocell was up 9.5 cents or 6.6 percent to \$1.53 with 2.8 million shares traded.

AVITA MEDICAL

Avita says the US Centers for Medicare and Medicaid Services (CMS) has covered Recell for up-to \$US4,875 (\$A7,369) under the New Technology Add-on Payment.

Avita said the New Technology Add-on Payment provided hospitals with supplemental reimbursement for the use of Recell when used to treat acute, non-burn trauma and surgical full-thickness wounds in addition to the standard CMS payment.

The company said the reimbursement was effective from October 1, 2025 until September 30, 2026 and eased "financial barriers, supporting broader use of Recell".

Avita chief executive officer Jim Corbett said that "with only a select number of technologies reaching this milestone each year, CMS's [New Technology Add-on Payment] decision underscores the clinical value and innovation of Recell".

"By lowering financial barriers for hospitals, CMS is helping ensure that more patients can benefit from Recell, which treats acute wounds effectively while requiring less donor skin and easing the challenges of recovery," Mr Corbett said.

Avita was up nine cents or 5.75 percent to \$1.655 with 1.2 million shares traded.

IMPEDIMED

Impedimed says "one of the largest health insurers in the US has issued positive coverage" for its Sozo bio-impedance spectroscopy for lymphoedema testing. Impedimed said the insurer was "the largest customer-owned insurer in the US, and licencee of Blue Cross Blue Shield Association in five states ... [providing] access to care nationwide through plans in Illinois, Montana, New Mexico, Oklahoma and Texas". According to the Chicago-based Health Care Service Corporation's website it is the "largest customer-owned health insurer in the US, providing access to care nationwide through our plans in Illinois, Montana, New Mexico, Oklahoma and Texas" and an independent licencee of the Blue Cross Blue Shield Association.

The company said the additional insurance coverage meant "more than 86 percent of all US patients are now reimbursed for their treatment".

Impedimed said the addition meant an additional 16 million covered lives and bringing total reimbursed coverage for Sozo lymphoedema testing to more than 301 million covered lives, with and 86 percent coverage, nationwide.

The company said that it meant that five more US states were above 80 percent coverage with three covering more than 90 percent.

Impedimed said that Texas and Illinois were among the five largest population states in the US.

Impedimed managing-director Dr Parmjot Bains said "during my US travels, I consistently meet dedicated clinicians who are eager to integrate Sozo into their patient care pathways".

"In today's financially constrained healthcare environment, hospitals face a difficult balancing act, managing tight budgets while striving to deliver the best possible clinical outcomes," Dr Bains said.

"Decisions from major insurance companies to recognize the medical necessity of using bioimpedance spectroscopy for lymphoedema assessment are pivotal," Dr Bains said. "These greatly enhance the commercial feasibility of implementing a Sozo-based lymphoedema prevention program across many hospital systems and progress toward our goal: ensuring every cancer patient at risk of lymphoedema has access to prospective surveillance through Sozo," Dr Bains said.

Impedimed was up one cent or 27.0 percent to 4.7 cents with 9.5 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says it has two more complete responses in its up-to 20-patient, phase Ib trial of its Core natural killer (NK) cells for acute myeloid leukaemia (AML).

Last year, Chimeric said it had dosed the first of up-to 20-patients, in its phase lb trial of its CHM0201 natural killer (NK)-cells therapy in combination with standard-of-care azacitidine and venetoclax for AML (BD: Feb 8, 2024).

In May, the company said two of three evaluable blood cancer patients in the trial had a complete response and were in remission (BD: May 15, 2025).

Today, Chimeric said seven evaluable subjects had been treated in its ongoing cohort of high-risk patients with newly diagnosed acute myeloid leukaemia.

The company said that in the actively enrolling cohort, four clinical responses had been reported including two complete responses, one complete response with incomplete count recovery and one partial response.

Chimeric said there were "no unexpected safety findings ... and the combination of Core-NK with azacitidine and venetoclax continues to be well-tolerated by patients".

The company said it had reported one complete response in the six patients who had received two-to-four prior lines of therapy in the original portion of the study of Core NK cells for relapsed or refractory acute myeloid leukaemia.

Chimeric chief executive officer Dr Rebecca McQualter told Biotech Daily that the "new part of the study is first-line cell therapy in previously untreated patients" and that the company believed it was a "world-first" for patients with acute myeloid leukaemia.

The company said the study was open to patients with newly diagnosed acute myeloid leukaemia who were ineligible for chemotherapy or stem cell transplant.

Chimeric was unchanged at 0.3 cents with 31.3 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says its copper-64 diagnostic and copper-67 therapeutic Sar-Bis FAP show improved efficacy "with a doubling in the median survival time" in mice with cancer. Last year, Clarity said it developed a FAP-targeted radio-pharmaceutical for use with its copper isotopes for diagnosing and treating cancers (BD: Dec 18, 2024).

At that time, the company said FAP was "expressed on cancer-associated fibroblasts, a particular cell type found in the tumor micro-environment".

Today, the company said it had developed and assessed two versions of the FAP-targeted product, one with a singular targeting molecule, called Sar-FAP, and one with a dimeric version of the same molecule, called Sar-Bis FAP.

Clarity said both molecules showed "high tumor-specific uptake and targeting [but] the dual-targeting Sar-Bis FAP has shown superior tumor targeting and retention in FAP-expressing mouse models".

The company said based on the data and results it would progress the dual-targeting Sar-Bis Fap products to human studies, with an initial focus on the diagnostic.

Clarity said it would present data on copper-64 and copper-67 Sar-Bis FAP at the World Molecular Imaging Conference, in Anchorage, Alaska, September 29 to October 3, 2025. Clarity executive chair Dr Alan Taylor said FAP-targeted products had "the potential to target a range of cancer indications with high unmet needs".

Dr Taylor said copper-64 and 67 had shown "high tumor targeting and retention in FAP-expressing xenograft mice ... with the dual-targeting copper-64 Sar-Bis FAP showing improved retention compared to the monomer alone, and copper-67 Sar-Bis FAP ... [improving] efficacy compared to both copper-67 Sar-FAP and an industry benchmark". Clarity was up 45 cents or 12.0 percent to \$4.20 with 4.6 million shares traded.

AROVELLA THERAPEUTICS

Arovella says an in-vitro study shows its chimeric antigen receptor (CAR)-T cells are equivalent to existing CAR in eliminating CLDN18.2-expressing pancreatic cancer cells. Arovella said the in-vitro proof-of-concept study showed its CLDN18.2 CAR cells were able "to induce effective killing of pancreatic cancer cells when incorporated into T-cells" and it expected the anti-tumor activity "to be superior in-vivo".

The company said the CLDN18.2 CAR-T cells were produced from three independent donors and cultured in-vitro for three days, with the degree of cytotoxicity measured and the results showing "robust killing of pancreatic cancer cells".

Arovella managing director Dr Michael Baker said that "seeing the robust activity of our novel and proprietary CLDN18.2-targeting CAR against pancreatic cancer cells has the team excited as we expand our pipeline to target difficult to treat solid tumors".

"This supports the robust performance of our CAR and supports us incorporating it into our [invariant natural killer T-cell] platform," Dr Baker said.

Arovella was up 0.3 cents or 3.1 percent to 10 cents with 8.6 million shares traded.

RACE ONCOLOGY

Race says its E,E-bisantrene, or RCDS1, binds and stabilizes regulatory DNA and RNA structures called G-quadruplexes, which reduce cancer genes.

Last month, Race said it filed three patent applications following its discovery of three photo-isomers with biological and anti-cancer activities from bisantrene, with only one, called RCDS1, having "significant anti-cancer activity" (BD: Sep 16, 2025).

Today, the company said studies with collaborators had discovered the mechanism-of-action of RCDS1 and had shown that it was "not a doxorubicin-like chemotherapeutic". Race said the anti-cancer activity of RCDS1 resulted from the binding and stabilizing of G-quadruplexes, which were found throughout the human genome and regulated the expression and translation of many genes in involved in causing cancer.

Race managing-director Dr Daniel Tillett said the RCSD1 mechanism of action "fundamentally changes our thinking on how to best use this drug in the clinic". Race was up \$1.42 or 45.7 percent to \$4.53 with 3.1 million shares traded.

VITASORA HEALTH (FORMERLY RESPIRI)

Vitasora says the Brentwood, Tennessee-based Iris Medical Group will use integrate its remote patient monitoring and chronic care management services.

Vitasora said Iris was a physician-owned provider of in-home primary, transitional, and chronic care services to more than 12,000 patients, in Tennessee, Mississippi, Texas, Indiana, and Alabama.

The company said Iris Medical's more than 65 practitioners would enrol patients into its care programs, with an expected more than 50 percent enrolment rate, "well above industry averages", with first patients expected to be enrolled this year.

Vitasora said it expected Iris Medical to enrol between 500 and 1,000 patients by 2026, with between \$US50 and \$US90 (\$A76 and \$A136) expected in per patient, per month fee-for-service revenues.

The company said the 12-month deal automatically renewed at the end of the term. Vitasora chief executive officer Marjan Mikel said the partnership was "a great example of innovation in action ... [with Iris delivering] trusted care inside the home, and Vitasora brings the digital layer to extend that care 24-7".

Vitasora was up 0.1 cents or 3.45 percent to three cents with 1.7 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it will present data from its phase II clinical trial of ATH434 for multiple system atrophy at the International Congress of Parkinson's Disease and Movement Disorders. In January, Alterity rose 137.5 percent on its 77-patient, phase II ATH434 trial showing a "statistically significant improvement" on MSA function and daily living (BD: Jan 30, 2025). Today, the company said the data would be released in an oral presentation, titled

'Slowed Disease Progression in a phase II study in Multiple System Atrophy'.

Alterity said it would present two posters at the event, the first titled 'Relationship Between Alpha-Synuclein Aggregation Profiles, Imaging Biomarkers, and Disease Severity in a Phase 2 Study of ATH434 in MSA'.

The company said that the second poster was titled 'Differences Between Clinical and Imaging Phenotypes in Phase 2 Study of ATH434 in Multiple System Atrophy'. Alterity said that the International Congress of Parkinson's Disease and Movement Disorders would be held in Honolulu, Hawaii, from October 5 to 9, 2025. Alterity was up 0.1 cents or 11.1 percent to one cent with 133.9 million shares traded.

MEMPHASYS

Memphasys says its previously announced entitlement offer to raise up-to \$1,120,549 at 0.3 cents a share will be at an entitlement ratio of one new share for six shares held. In September, Memphasys said that it had raised about \$840,000 in a placement at 0.3 cents a share, with a rights offer for a further up-to \$1.12 million, but did not disclose the ratio (BD: Sep 22, 2025).

In a prospectus announced today, the company said the funds raised would be used to commercialize its Felix sperm separation system for in-vitro fertilization, settle debts and working capital.

Memphasys said that the entitlement offer had a record date of October 2, would open on October 7 and close on October 29, 2025.

Memphasys was unchanged at 0.4 cents with 4.5 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its annual general meeting will vote to issue 5,000,000 options, each, to chair Robert McKenzie and director Paul Fry.

In June, Neuroscientific said it acquired Perth's Isopogen WA and its Stemsmart technology and had replaced its chair Christopher Ntoumenopoulos and director Tony Keating with Isopogen's Mr Mckenzie and Mr Fry (BD: Jun 27, 2025).

Today, the company said investors would vote to issue 5,000,000 options to Mr McKenzie and Mr Fry, exercisable at seven cents each within three years, in addition to their \$80,000 and \$50,000 annual fees, respectively.

Neuroscientific said shareholders would vote on the remuneration report, elect Mr McKenzie, Mr Fry and Clarke Barlow as directors, the proportional takeover bid approval provisions, the 10 percent placement facility, the employee incentive plan and potential termination benefits.

The meeting will be held at 216 St Georges Terrace, Perth on November 12, 2025 at 11.30am (AWST).

Neuroscientific was up half a cent or 3.1 percent to 16.5 cents.

ARTRYA

Artrya co-founder and former managing-director John Barrington says he has ceased his substantial shareholding in the company.

The Perth-based Mr Barrington said that he sold 50,000 shares on September 29 for \$113,275, or \$2.265 a share, and on September 30, 2025 sold 50,000 shares for \$114,652, or \$2.29 a share.

Last month, Mr Barrington said that his 7,475,253 shares-holding had been diluted from 6.42 percent to 5.08 percent (BD: Sep 23, 2025).

According to its most recent filing, Artrya had 148,023,796 shares on issue, meaning that Mr Barrington retained about 4.98 percent of the company.

Artrya was up 16 cents with seven percent to \$2.45 with one million shares traded.

CLEVER CULTURE SYSTEMS

Clever Culture managing-director Brenton Barnes says he has increased his substantial holding from 98,713,606 shares (6.10%) to 135,713,606 shares (7.11%).

Mr Barnes said that with Hawkeye Self-Managed Superfund and Barnes' Love Work Live he acquired 2,000,000 shares through the exercise of options on September 9, 2024 for \$10,000, or 0.5 cents a share and on October 1, 2025 he acquired 35,000,000 shares through the exercise of options for \$280,000, or 0.8 cents a share.

Mr Barnes said his holding was diluted due to the successive issue of shares between August 17, 2024 and October 1, 2025.

Yesterday, in an application for quotation of securities, Clever Culture said it would issue 81,734,852 shares due to "options being exercised or other convertible securities being converted".

Clever Culture was unchanged at 3.5 cents with 2.55 million shares traded.

CLEVER CULTURE SYSTEMS

Clever Culture director Daniel Hill says with Viking BCM Pty Ltd his 212,665,188 share-holding has been diluted from 12.34 percent to 11.14 percent (see above).

The Brisbane-based Viking BCM said it was diluted due to the successive issue of shares between September 12, 2024 and October 1, 2025.

ECHO IQ

Echo IQ says it has appointed Dr Phillippe Genereux and Dr Asif Ali as strategic advisors for the commercialization of Echosolv in the US.

Echo IQ said Dr Genereux was medical director of the structural heart program at New Jersey's Morristown Medical Center and Dr Ali was a professor of cardiovascular medicine at Houston's University of Texas Medical School.

The company said Dr Genereux would "assist in driving Echosolv uptake through his extensive US network and assist in pending regulatory submissions", with Dr Ali to advise on further refining Echosolv's "commercial offering for the US market, as well as unlock integration opportunities".

Echo IQ was up 1.5 cents or 8.3 percent to 19.5 cents with 7.9 million shares traded.