



Biotech Daily

Monday October 5, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: IMUGENE UP 16%; IMPEDIMED DOWN 17%**
- * **CSL UP-TO \$2.2b TO ALENTIS FOR LIXUDEBART KIDNEY, LIVER DRUG**
- * **OPTISCAN FILES INVUE SYSTEM 510(k) TO US FDA**
- * **CONTROL BIONICS WINS NEUROSTRIP CE MARK**
- * **AROA: 'SYMPHONY IMPROVES HEALING FOR DIABETIC FOOT ULCERS'**
- * **VICTORIA \$2m FOR CLINICAL TRIAL ACCESS FELLOWS**
- * **IMUGENE: '2 MORE PHASE Ib AZER-CEL RESPONSES'**
- * **ALTERITY 'ATH434 SLOWS MSA FUNCTIONAL DECLINE CSF-NFL-ADJUSTED'**
- * **DIMERIX: 1st PATIENT COMPLETES 2-YEAR DMX-200 FSGS EXTENSION**
- * **RADIOPHARM RAD101 END-OF-PHASE II FDA MEETING**
- * **HYDRIX 1st NIOA COUNTER-DRONE PROTOTYPE**
- * **ADALTA OK FOR FDA BRIEFING PACK, MANUFACTURING TRANSFER**
- * **FISHER & PAYKEL \$37m LAND SALE TO NZ GOVERNMENT**
- * **AROVELLA 8m CHAIR DAVID WILLIAMS RIGHTS AGM**
- * **ENTROPY 50m BOARD OPTIONS AGM**
- * **CONNEQT CHAIR NIALL CAIRNS, CEO CRAIG COOPER TAKE 41.5%**
- * **IMMUTEP LOSES DIRECTOR PETE MEYERS**

MARKET REPORT

The Australian stock market edged up 0.05 percent on Monday October 5, 2026, with the ASX200 up 4.3 points to 8,686.4 points. Twenty-two of the Biotech Daily Top 40 companies were up, 10 fell, six traded unchanged and two were untraded.

Imugene was the best (see below), up 0.6 cents or 16.2 percent to 4.3 cents, with 34.65 million shares traded. Curvebeam climbed 14.3 percent; Avita, Cochlear, Dimerix, Proteomics and Syntara were up more than four percent; Emvision, Imricor, Nova Eye and Optiscan improved three percent or more; Medical Developments, Polynovo, Resonance and Telix rose more than two percent; Aroa, Cyclopharm, Pro Medicus, Saluda and Starpharma were up one percent or more; with Clinuvel, CSL, Nanosonics, Neuren and Racura up by less than one percent.

Impedimed led the falls, down 0.1 cents or 16.7 percent to 0.5 cents, with 1.95 million shares traded. Artrya lost 12.2 percent; Micro-X was down 11.3 percent; 4D Medical shed 6.2 percent; Botanix fell 5.6 percent; EBR, Immutep and Prescient were down three percent or more; with Clarity, Mesoblast and Resmed down by less than one percent.

CSL

CSL says it will pay up-to \$US1,555 million (\$A2,237 million) to co-develop and commercialize Alentis Therapeutics' lixudebart for rare kidney and liver disease.

CSL said it would pay \$US355 million up-front to the Basel, Switzerland-based Alentis, with an additional \$US1.2 billion in commercial milestone payments.

The company said lixudebart was in development in an ongoing phase II trial in patients with anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis and rapidly progressive glomerulo-nephritis "a rare and potentially life-threatening auto-immune disease that can cause irreversible kidney damage and end-stage renal disease".

CSL said the drug had a "novel mode of action designed to target both inflammation and fibrosis, two key drivers of long-term organ injury".

The company said with Alentis, it planned to advance lixudebart as a potential treatment for the chronic kidney diseases focal segmental glomerulo-sclerosis (FSGS) and primary sclerosing cholangitis (PSC).

CSL said it would fully-fund completion of the phase II trial, a planned phase III trial, phase II trials in FSGS and PSC, support other development activities, and, if commercialized, profits would be shared 55 percent to CSL and 45 percent to Alentis.

CSL head of research and development Dr Bill Mezzanotte said the company believed lixudebart had "the potential to become an important new therapeutic option to help improve kidney function and prevent progression to end-stage kidney disease".

"Our collaboration with Alentis reflects CSL's commitment to building a leading global nephrology franchise," Dr Mezzanotte said.

CSL was up \$1.64 or 0.9 percent to \$176.99 with 575,653 shares traded.

OPTISCAN IMAGING

Optiscan says it has filed a US Food and Drug Administration 510(k) submission for its Invue surgical microscope system.

In 2024, Optiscan said it had released its Invue microscope for providing "real-time, digital pathology access" to surgeons during surgery (BD: Jun 4, 2024).

At the time, the company said Invue could be used in cancer diagnosis and treatment and was designed to put digital pathology "directly in the hands of surgeons as they operate, to enable on-the-spot decision making and treatment adjustments".

Last week, Optiscan said it filed an FDA 510(k) submission with the FDA for its Inform pathology microscope system (BD: Oct 1, 2026).

Today, the company said its application for Invue would move to formal FDA review, where the US regulator would assess the technical, performance and clinical evidence supporting its application.

Optiscan said it would continue its clinical and commercial programs, "including further evidence generation, engagement with surgeons and clinical partners, and preparation for potential US market entry".

Optiscan managing-director Prof Camile Farah said lodgment of an Invue 510(k) submission was "yet another key deliverable in the broader development strategy for our medical technology platform".

"It means we are now much closer to making a technology designed to give surgeons microscopic insight in real-time commercially available in the world's most important healthcare markets," Prof Farah said. "The Invue submission, along with the earlier FDA submission for the Inform digital pathology device, are both powerful validations of how far our platform has progressed."

Optiscan was up half a cent or three percent to 17 cents.

CONTROL BIONICS

Control Bionics says it has Conformité Européenne mark registration for its Neurostrip wearable electro-myography device.

Earlier this year, Control Bionics said the US Food and Drug Administration had registered and listed Neurostrip as a medical device; and later, said it had UK registration to commercialize the Neurostrip device (BD: Aug 4, 25, 2026).

Today, the company said the CE mark allowed Neurostrip and its software to be supplied to clinicians, rehabilitation providers, researchers and sports organizations.

Control Bionics said under the European Union's Medical Device Regulation (MDR) Neurostrip was "classified as Class I medical device, reflecting its intended purpose as a non-diagnostic [surface electro-myography] measurement and bio-feedback tool".

The company said that an application to Australia's Therapeutic Goods Administration was pending.

Control Bionics managing-director Jeremy Steele said Europe was "home to some of the world's largest clinical rehabilitation, sports science and research communities, where customers and partners expect an established regulatory foundation before adopting a new platform".

"With the US, Great Britain and the EU now in place, our focus is on rapidly building our customer and partner base," Mr Steele said.

Control Bionics was up 0.2 cents or 3.3 percent to 6.3 cents.

AROA BIOSURGERY

Aroa says a 143-patient trial shows adding Symphony to standard-of-care "substantially improved healing outcomes for diabetic foot ulcers".

Last year, Aroa said US local coverage determinations allowed its Symphony skin graft for foot and leg ulcers to be covered until "at least the end of 2026" (BD: Dec 19, 2025).

In March, the company said preliminary findings showed that its trial of Symphony for diabetic foot ulcer wound healing achieved its primary endpoint (BD: Mar 30, 2026).

Today, Aroa said 55 percent of diabetic foot ulcers in the Symphony arm achieved complete wound closure within 12 weeks, compared with 35 percent in the standard-of-care-only arm ($p = 0.039$).

The company said mean time to complete wound closure was 65.4 days with Symphony, compared with 73.2 days for standard-of-care-only, a reduction of 7.8 days ($p = 0.041$).

Aroa said the study, titled 'A Composite Ovine Forestomach Matrix and Hyaluronic Acid CAMP for the Treatment of Full Thickness Wounds of the Foot in People with Diabetes: A Randomized Controlled Trial' was published in the International Wound Journal and was available at: <https://pubmed.ncbi.nlm.nih.gov/42823610/>.

The company said the trial "treated challenging diabetic foot ulcers classified as Wagner Grade 1 or 2, ranging from superficial ulcers involving the full thickness of the skin to deeper ulcers extending into ligaments, tendons, joint capsules, or deep fascia".

Aroa said patients were treated for up-to 12 weeks or until complete wound closure.

Aroa managing-director Brian Ward said the result was "a major milestone for Symphony".

"The multi-centre design and involvement of recognized key opinion leaders strengthen the evidence's credibility and clinical relevance," Mr Ward said.

"Amid growing demand from clinicians, payors, and reimbursement authorities for robust [randomized-controlled trial] data, this publication places Symphony among a small group of [cellular, acellular, and matrix-like products] with Level I effectiveness data, strengthening its differentiation and commercial value proposition," Mr Ward said.

Aroa was up half a cent or one percent to 49.5 cents with 1.2 million shares traded.

VICTORIA GOVERNMENT

The Victoria Government says it will provide \$2 million to 15 Future Leader Fellows for Clinical Trials' to fund research into increasing participation in clinical trials.

A media release from Victoria's Minister for Medical Research Anthony Carbines said the first six fellows were Dr Lucy Attwood, Dr Michelle Gooley, Dr Anna Watts, Dr Anna Cunliffe, Prof Justin Yeung and Dr Violet Mukaro.

The Government said the recipients were "frontline health professionals ... [and would] work directly with clinical trial sponsors, health services, researchers and communities".

The Victoria Government said the focus of the fellows would "be on multicultural communities, First Nations people and regional Victorians access to clinical trials".

The Government said the fellowships were delivered through the Victorian Research Translation Centre Collaborative, which included the Monash Partners Health Translation Network, Western Alliance Academic Health Science Centre and the Melbourne Academic Centre for Health.

The Victoria Government said the State had "about 30 percent of national clinical trials, more than any other state".

Mr Carbines said the funding of the six clinicians would "help deliver faster medical breakthroughs that could save lives and help expand Victoria's role as the medical research capital of Australia".

IMUGENE

Imugene says its phase Ib trial of azer-cel has reported one complete response in mantle cell lymphoma and one partial response in chronic lymphocytic leukaemia.

Earlier this year, Imugene said that it had enrolled the first Bruton tyrosine kinase (BTK) inhibitor patient in its phase Ib basket study of its azer-cel chimeric antigen receptor (CAR)-T for various blood cancers (BD: May 28, 2026).

Today, the company said two additional evaluable patients, one with Richter's Transformation, and one with mantle cell lymphoma, had stable disease and progressive disease, respectively.

Imugene said the four additional patients evaluated in cohort three of the phase Ib trial, which combined azer-cel with BTK inhibitor in patients whose disease had progressed on a BTK inhibitor therapy, brought the total to seven patients.

The company said all patients enrolled had received and progressed on BTK inhibitor therapy, and were "a heavily pre-treated population with high unmet medical need and fewer remaining treatment options".

Imugene said in the phase Ib study, azer-cel had shown a 75 percent overall response rate in a total of 55 patients.

The company said the results reinforced the "consistent therapeutic potential of azer-cel across diverse, difficult-to-treat patient populations" with patient enrolment was ongoing at 10 US and five Australian sites.

Imugene executive chair Paul Hopper said observing additional responses in the BTK inhibitor combination cohort provided "compelling further validation of this strategy".

"The key here is that we are treating patients who have all progressed on BTK inhibitors and who have high unmet need hematologic cancer with few therapeutic options," Mr Hopper said.

"With the combination of azer-cel and continuation of the BTK inhibitor, we are seeing a high response rate including in challenging tumor types like [mantle cell lymphoma] and [chronic lymphocytic leukaemia]," Mr Hopper said.

Imugene was up 0.6 cents or 16.2 percent to 4.3 cents with 34.65 million shares traded.

ALTERITY THERAPEUTICS

Alterity says its phase II trial shows ATH434 “significantly slowed functional decline” of multiple system atrophy (MSA) when adjusted for baseline CSF-NFL.

Alterity said additional analysis from a poster included clinical, biomarker, and imaging results from the trial after adjusting for baseline disease severity, measured by cerebrospinal fluid neuro-filament light chain (CSF-NFL).

The company said the analysis showed that CSF-NFL predicted functional decline in individuals with MSA and after adjustment for baseline CSF-NFL, ATH434 50mg “significantly slowed functional decline ... at week 52 with a negative 4.64-point difference versus placebo in change from baseline ($p = 0.032$)”.

Last year, Alterity said its 77-patient, phase II ATH434 MSA trial showed a “statistically significant improvement” on function, mobility, living and progression; and further analysis showed ATH434 slowed functional decline in MSA ($p = 0.035$) (BD: Jan 30, Oct 9, 2025). Earlier this year, Alterity said further data from 71 patients showed 50mg and 75mg doses of ATH434 led to a beneficial effect for low blood pressure (BD: May 19, 2026).

Alterity said the higher baseline CSF-NFL predicted greater decline at week 52, with each 1,000 picograms per millilitre (pg/mL) increase associated with about 0.9 additional points of worsening on the ‘unified multiple system atrophy rating scale part I (Umsars I)’ “an effect that was significant ($p=0.033$)”.

The company said the 75mg dose of ATH434 “also slowed functional decline with a negative 2.81-point difference compared with placebo in change from baseline at week-26 ($p = 0.072$) and week-52 ($p = 0.179$)”.

Alterity fell one cent or 2.6 percent to 37 cents.

DIMERIX

Dimerix says the first patient has completed its two-year open label extension study of DMX-200 in focal segmental glomerulo-sclerosis (FSGS).

In 2022, Dimerix said it had recruited the first of 286 patients in the phase III trial of DMX-200 for kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).

In April, the company said a review of its 333-patient, phase III study confirmed the study had more than 90 percent statistical power for the primary endpoints (BD: Apr 28, 2026).

Today, Dimerix said the first patient to complete its open-label extension study had four years of continuous participation in the DMX-200 clinical development program.

The company said all participants in the open-label extension study received DMX-200, regardless of whether they received DMX-200 or placebo during the blinded phase of the study, with data to support future regulatory and commercial activities.

Dimerix said of the 96 patients who completed the phase III trial to date, 89 had elected to join the open-label extension study, a continuation rate of 93 percent.

The company said the high level of participation in the extension study reflected “the commitment of patients, investigators and study sites to the ... program and DMX-200”.

Dimerix managing-director Dr Nina Webster said “the completion of four years of study participation by the first patient in our DMX-200 clinical program represents an important milestone for both Dimerix and the broader FSGS community”.

“Long-term participation of this nature reflects the commitment of patients, their families and clinical investigators, and provides an opportunity to gather valuable longer-term information on DMX-200,” Dr Webster said.

Dimerix was up one cent or 4.4 percent to 23.5 cents with one million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has completed an end-of-phase II meeting with the US Food and Drug Administration on RAD101 for the detection of brain metastases.

Earlier this year, Radiopharm said it dosed all 30 patients in its US, phase IIb trial of its fluorine-18 (18F)-pivalate, or RAD101, for imaging recurrent brain metastases from solid tumors; and later, said the trial showed RAD101 had 93 percent concordance with magnetic resonance imaging (MRI) for imaging brain tumors (BD: Apr 16, Jul 22, 2026). Later, Radiopharm said it would conduct an end-of-phase II meeting with the FDA on October 1, 2026 for the design of a phase III RAD101 trial (BD: Aug 17, 2026).

Today, the company said it expected to receive the FDA's minutes within about 30 days, which would provide the formal record of the meeting and the agency's feedback on the proposed pivotal clinical development program.

Radiopharm managing-director Riccardo Canevari said meeting the FDA was "a pivotal milestone for RAD101 and an important inflection point in the evolution of our company".

Radiopharm fell 0.1 cents or 14.3 percent to 0.6 cents with 31.5 million shares traded.

HYDRIX

Hydrix says it has delivered the first kinetic effector payload prototype to Brisbane's Nioa Group for counter-drone applications in defence.

In May, Hydrix said it had a \$1,000,000 to \$1,200,000 agreement with Nioa for the design and development of a proximity fuse and payload package for drones (BD: May 14, 2026).

According to Wikipedia, Nioa chief executive officer Robert Nioa was the son-in-law of the Federal Member of the House of Representatives Bob Katter, and the company was involved with importing Adler shotguns into Australia during the 2010s.

Today, the company said it had completed the preliminary design review "delivering a benchtop integration system that enables software development, platform-interface communications and integration with key payload subsystems", providing Nioa with a platform to evaluate the integration between the payload and the host uncrewed aerial systems (UAS) ahead of design and prototype manufacture.

Previously, Hydrix executive chair Gavin Coote told Biotech Daily: "We've been doing defence projects for more than a decade, but they are less than 15 percent of revenue."

"We are definitely remaining focused on medical technologies, with cardiac and advanced interventional surgical robotics, the two largest client sub-sectors," Mr Coote said.

Hydrix was unchanged at 0.3 cents with 8.5 million shares traded.

ADALTA

Adalta says its joint development committee has approved its US Food and Drug Administration meeting briefing pack and the transfer of manufacturing to Melbourne.

Adalta said the joint development committee formed with the Shanghai Cell Therapy Group, for EW-001 (formerly BZDS1901) for mesothelioma and other mesothelin-expressing cancers had approved the briefing pack for its pre-investigational new drug meeting with the FDA, and the plan to transfer EW-001 manufacturing technology from Shanghai Cell Therapy Group to Cell Therapies Pty Ltd in Melbourne.

Adalta said the joint development committee oversaw the program, and steps must be approved by the committee before they proceed.

Adalta managing-director Dr Tim Oldham said the approvals were "needed to take EW-001 to its next stage".

Adalta fell 0.1 cents or 25 percent to 0.3 cents.

FISHER & PAYKEL HEALTHCARE

Fisher & Paykel says it will sell 13 hectares of its 105-hectare site on Karaka Road in Drury, New Zealand for \$NZ45.3 million (\$A36.5 million) to Health New Zealand.

Fisher & Paykel said the New Zealand Government's Health New Zealand intended "to use the land to develop a future hospital facility to serve the growing South Auckland population".

The company said the site it would "retain the remaining land for the development of its planned second campus in New Zealand"; and had a rezoning application for the site under review by Auckland Council.

Fisher & Paykel said the sale was expected to settle between March and June 2027 and would not impact its full-year earnings guidance.

Fisher & Paykel managing-director Lewis Gradon said the company "worked closely with local healthcare providers since Dr Nigel Rankin at Middlemore Hospital first suggested working with our research and development team ... [and] locating a major new hospital alongside a world-class research and development campus creates a strong foundation for innovation in medical technologies".

Fisher & Paykel was up 54 cents or 1.5 percent to \$37.33 with 423,191 shares traded.

AROVELLA THERAPEUTICS

Arovella says its annual general meeting will vote to issue 8,000,000 long-term incentive performance rights to chair David Williams.

Arovella said Mr Williams' performance rights were exercisable at six cents each within three years from the issue date, and would vest on share price related conditions.

The company said investors would vote to adopt the remuneration report, elect Mr Williams, Mark Diamond and Michael Thurn as directors, amend the constitution to pay directors non-cash benefits as part of their fees, the renewal of the proportional takeover provisions, approve the long-term incentive plan, ratify the prior issue of options to Blue Equities and approve the 10 percent placement capacity.

The meeting will be held online and at Minter Ellison, Level 20, 447 Collins Street, Melbourne on November 4, 2026 at 11am (AEDT).

Arovella was up 0.1 cents or 2.1 percent to 4.8 cents.

ENTROPY NEURODYNAMICS

Entropy says its annual general meeting will vote to issue 50,000,000 options to its chair Herwig Janssen and four directors.

Entropy said shareholders would vote to issue Mr Janssen and directors Jason Carroll, Chris Ntoumenopoulos, Gage Jull and Dr Daniel Tillet 10,000,000 options, each, exercisable at five cents each within five years.

The company said half of the options would vest on the beginning of a TRP-8803 clinical study in the US and the rest vesting 100 participants dosed, before December 31, 2027.

Entropy said the options were in addition to Mr Jansen's fees, Mr Carroll's annual pay, Mr Ntoumenopoulos and Dr Tillet's yearly remuneration and Mr Jull's annual fees.

The company said investors would vote to adopt the remuneration report, re-elect Chris Ntoumenopoulos as director, approve the 10 percent placement facility and modify the existing constitution.

The meeting will be held at Bio101, 117 Camberwell Road, Hawthorn East on November 12, 2026 at 4pm (AEDT).

Entropy was up 0.1 cents or 2.6 percent to four cents.

CONNEQT HEALTH (FORMERLY CARDIEX)

Conneqt chair Niall Cairns and chief executive officer Craig Cooper say they increased their holding from 222,446,757 shares (38.69%) to 421,860,898 shares (41.51%).

Through the Sydney-based C2 Ventures, Mr Cairns and Mr Cooper said on April 14 they bought 26,666,666 shares for \$1,200,000 in a placement, or 4.5 cents a share, received 3,555,555 shares in a share issue for no consideration and bought 101,010,102 shares through a convertible note conversion for \$2,000,000, or 2.0 cents a share, as well as purchasing 68,181,818 shares on October 25, 2026 for \$1,500,000, or 2.2 cents a share. Earlier this year, Conneqt said it raised \$379,000 in a share plan at 2.2 cents a share, taking the total raised to \$5,879,000 and leaving a \$121,000 shortfall (BD: Aug 6, 2026). Conneqt was up 0.1 cents or 7.1 percent to 1.5 cents.

IMMUTEP

Immutep says non-executive director and deputy chair Pete Meyers has resigned, effective from October 2, 2026.

Immutep said it had begun a process to appoint a replacement director and would “update the market in due course”.

Immutep fell 0.1 cents or 3.1 percent to 3.1 cents with 13.7 million shares traded.