



Biotech Daily

Wednesday September 9, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: IMPEDIMED UP 20%; MICRO-X DOWN 15%**
- * **ECHO IQ: 'FDA REFUSES ECHOSOLVE FOR HEART FAILURE'; FALLS 63%**
- * **MEDMAGLABS: TGA FRAMEWORK FOR WOUND CARE MEDICAL MAGGOTS**
- * **AUSTRADE: RESMED FOR EXPORT AWARDS HALL OF FAME**
- * **RMIT DEVELOPS 'EARLY-STAGE BIONIC EYE PROTOTYPE'**
- * **RADIOPHARM: 'RAD301 SAFE, SIGNIFICANT SELECTIVE UPTAKE'**
- * **ONCOSIL MANUFACTURER CYCLOTEK WINS ISO13485 CERTIFICATION**
- * **EBR: 'FDA NO ACTION AGAINST WISE SYSTEM'**
- * **OSTEOPORE PRODUCTS APPROVED IN THAILAND**
- * **NEURIZON: US NIH 'MULTIMILLION-DOLLAR NUZ-001 GRANT FOR ALS'**
- * **NEUROSCIENTIFIC NAME CHANGE AGM**
- * **ANTEOTECH LOSES SCOTT WADDEL; NEW CFO, CO SEC WANTED**

MARKET REPORT

The Australian stock market fell 0.11 percent on Wednesday September 9, 2026, with the ASX200 down 9.4 points to 8911.4 points. Nine of the Biotech Daily Top 40 companies were up, 21 fell and 10 traded unchanged. All four Big Caps were down.

Impedimed was the best, up 0.1 cents or 20.0 percent to 0.6 cents, with 2.5 million shares traded. Curvebeam climbed 11.1 percent; Medical Developments was up four percent; 4D Medical was up 3.3 percent; Artrya rose 2.8 percent; Clinuvel and Telix were up more than one percent; with Aroa and Nanosonics up by less than one percent.

Micro-X led the falls, down 0.3 cents or 15.0 percent to 1.7 cents, with 3.1 million shares traded. Actinogen lost 6.35 percent; Avita was down 5.7 percent; Botanix, Lumos, Resonance and Syntara fell four percent or more; Cochlear, Dimerix, Imugene and Mesoblast were down more than three percent; CSL, Emvision, Immutep and Resmed shed more than two percent; Compumedics, EBR, Paradigm, Pro Medicus and Racura were down more than one percent; with Clarity, Imricor, Neuren, Orthocell and Polynovo down by less than one percent.

ECHO IQ

Echo IQ says that the US Food and Drug Administration has issued a 'not substantially equivalent' determination for its Echosolv HF, or heart failure, 510(k) application.

Echo IQ fell as much as 81 cents or 63.3 percent to 47 cents on the news, at the open.

The company said it had not received FDA clearance for commercial use of its artificial intelligence (A.I.) technology for cardiology decision-making "at this time ... [and was] assessing multiple administrative and regulatory options available".

Last night, after the market closed, Echo IQ said it was "well-funded" with more than \$105 million in July 2026 and "strong underlying business momentum continues, including growing US uptake of FDA-cleared Echosolv AS [arterial stenosis], expanding commercial activities and advancement of [a] broader [research and development] pipeline."

The company said that, with its US regulatory and legal advisors, study partners, and independent statistical experts, it had begun a review of the regulatory matters raised.

Echo IQ said there was "a pathway forward for clearance under the 510(k) route and intends to engage with the FDA to further clarify the matters identified in the determination and assess all administrative and regulatory options available".

The company said it was "confident in the clinical rationale underpinning Echosolv HF and the significant unmet clinical need in the identification of patients with heart failure".

Echo IQ said it intended to progress the Echosolv HF regulatory program, while maintaining its broader US commercial strategy and the FDA decision "does not impact the FDA-cleared Echosolv AS platform or its ongoing commercialization in the US."

In 2024, the company said it had FDA 510(k) clearance to market and sell the artificial intelligence-based Echosolv AS for detecting aortic stenosis saying the FDA had determined that the company showed "substantial equivalence to the predicate device cited in this submission (BD: Oct 8, 2024).

Last year, Echo IQ said an FDA clearance for heart failure would "unlock a significant ... market opportunity for Echosolv HF in the US healthcare sector, where heart failure is the leading cause of hospitalization and accounts for 17 percent of US healthcare expenditure" (BD: Dec 15, 2025).

In June, the company said it had an up-to \$20 million convertible note facility with Pro Medicus, with Pro Medicus to be a US Echosolv reseller (BD: Jun 25, 2026).

In 2023, Echo IQ said that a retrospective 9,189 sample trial showed Echosolv AS identified 72 percent more patients with severe aortic stenosis, a narrowing of the exit from the left ventricle of the heart, than human diagnosis alone (BD: Apr 21, 2023).

Last night, Echo IQ said it would advance its US commercial infrastructure, reimbursement pathway, customer pipeline and strategic relationships, providing a platform to support the future commercialization of Echosolv HF, subject to regulatory clearance.

The company said it would continue to invest in its broader research and development pipeline, including the development of products targeting additional disease states and new clinical modalities.

Echo IQ chief executive officer Dustin Haines said: "While we are disappointed in the decision on our initial application and our view differs on certain aspects, the determination provides us with detailed feedback that we can now assess with our US regulatory and legal advisors and, importantly, discuss directly with the FDA".

"Our immediate priority is to understand the matters raised in full and determine the most efficient pathway forward," Mr Haines said. "We remain confident in the underlying technology, the clinical rationale for Echosolv HF and the significant opportunity to improve the identification of patients at risk of heart failure."

Echo IQ closed down 64 cents or 50 percent at 64 cents with 67.7 million shares traded.

[MEDMAGLABS](#)

Medmaglabs says the Australian Therapeutic Goods Administration has established a new regulatory framework for medical maggots.

The Wollongong, New South Wales-based Medmaglabs founder and director Dr Frank Stadler said that the wound eating maggots would be classifying as Class 2 biologicals, introducing a two-year transitional exemption from good manufacturing practice (GMP) manufacturing licencing for eligible domestic manufacture.

Dr Stadler told Biotech Daily said that the change was effective from September 8, 2026, he would prepare an application under the new pathway and hoped to have a GMP manufacturing licence "before the end of this year".

In a media release, Medmaglabs said that maggots were "live larvae, typically of the greenbottle blowfly *Lucilia sericata*, bred under controlled conditions for therapeutic use". The company said that the TGA described their clinical role as "selectively removing necrotic tissue, reducing bacterial burden and supporting wound healing".

Dr Stadler said the decision was "an important milestone for Australian wound care".

"For years, one of the greatest obstacles to establishing a sustainable Australian pathway for maggot therapy wasn't the science or the clinical history of the treatment, it was regulatory uncertainty," Dr Stadler said.

Medmaglabs said that under the new framework, maggots used therapeutically in humans are explicitly regulated as Class 2 biologicals; and the TGA had introduced a two-year exemption from the requirement for eligible domestic manufacturers to hold a GMP manufacturing licence where maggots were manufactured for patient-by-patient, case-by-case supply.

Medmaglabs said that maggot products were not included in the Australian Register of Therapeutic Goods (ARTG) and remained unapproved therapeutic goods.

The company said that the TGA had identified pathways including the special access scheme (SAS) and authorized prescriber (AP) scheme "through which registered health practitioners may access unapproved therapeutic goods for patients in appropriate circumstances".

Dr Stadler said that "Medmaglabs was founded because we believed Australia needed a reliable and properly regulated framework for medicinal maggot therapy".

"That required more than producing maggots," Dr Stadler said.

"It required helping to build the regulatory and quality infrastructure around the therapy," Dr Stadler said.

Medmaglabs is a private company.

[AUSTRADE, RESMED](#)

Austrade says it has inducted five businesses, including Resmed, into the 2026 Australian export awards hall of fame.

Austrade said the awards were Australia's "longest-running export awards program" and recognized the achievements of Australian exporters and their contribution to the Australia's economy and international reputation.

The Federal Government agency said that Resmed had won Australian exporter of the year and large advanced manufacturer awards in 2002 and 2006, and was a finalist in 1995, 1998, 2004, 2005 and 2009.

The other four companies were Almondco Australia, PWR (Paul Weel Radiators) Advanced Cooling Technology, Sunrice Group and UOW (University of Wollongong) Global Enterprises

Resmed fell 67 cents or 2.1 percent to \$30.74 with one million shares traded.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

RMIT says it has an “early-stage” prototype that can capture and combine sensory, memory and information processing in one system and recognize patterns.

RMIT said the “neuromorphic” prototype could “see, remember and interact” like the human brain, with the technology potentially underpinning bionic eyes using less energy than today’s technologies.

The Institute said the research was published in two articles, the first titled ‘PVA-Mediated Transfer of MoS₂ and Au Electrodes: A Lithography-Free Route to Ultraclean van der Waals Interfaces for High-Performance Electronics and Optoelectronics’ and published in ACS Applied Materials and Interfaces, with an abstract available at: <https://bit.ly/4du5GxJ>.

RMIT said the second article, ‘Photoactive Monolayer MoS₂ for Spiking Neural Networks Enabled Machine Vision Applications’, was published in Advanced Materials Technologies, with the full article available at: <https://bit.ly/4h1ABTj>.

The Institute said the prototype, built using atom-thin semi-conductor molybdenum disulfide, could eventually support advanced machine vision systems, autonomous vehicles, robotics and intelligent sensors, and reduced the need to constantly move data between separate sensors, memory banks and processors.

RMIT said the prototype could detect changes in what it sees, store that information as memory and process it locally.

RMIT researcher Dr Taimur Ahmed said “this is not just a sensor that captures information, it’s a sensor that can also process information”.

“Rather than constantly moving data between separate memory and processing units, much of that work happens much closer to where the information is generated,” Dr Ahmed said.

RMIT said it had filed a patent for the invention.

RADIOPHARM THERANOSTICS

Radiopharm says its phase I trial of RAD301 for pancreatic cancer shows a favorable safety profile and bio-distribution, with “significant and selective” tumor uptake.

In 2023, Radiopharm said the US Food and Drug Administration had accepted an amended investigational new drug application, allowing it to begin a nine-patient imaging trial of RAD301, or gallium-68-triethylenetriamine, for detecting pancreatic ductal adenocarcinoma lesions (BD: Oct 17, 2023).

Today, the company said its phase I study of RAD301 in healthy volunteers and subjects with pancreatic ductal adenocarcinoma (PDAC) showed “significant and selective tumor uptake in pancreatic cancer metastases”, with low background uptake observed in liver, lung and bowel, where pancreatic cancer most often spreads, supporting RAD301’s potential to distinguish metastatic lesions from surrounding normal tissue.

Radiopharm said the unmet medical need in the earlier stages of the disease, as well as its high mortality, provided a rationale for a future phase II imaging trial of RAD301.

Radiopharm chief executive officer Riccardo Canevari said “given the limited imaging and treatment options available for patients with PDAC, these findings highlight the potential role of RAD301 in improving disease detection, patient selection, and future [therapeutic and diagnostic] applications”.

“The results from this phase I study support the potential of alpha-v-Beta-6-integrin-targeted imaging to provide a more tumor-specific approach to detecting pancreatic cancer, further supporting the advancement of RAD 301 into phase II development,” Mr Canevari said.

Radiopharm was unchanged at 0.9 cents with 3.5 million shares traded.

ONCOSIL MEDICAL

Oncosil says its contract manufacturer, the Melbourne-based Cyclotek, has been granted International Organization of Standardization (ISO) 13485 certification.

Oncosil said certification was an “important step” in the regulatory pathway for manufacturing its device, and it expected the certification process to be completed and production at Sydney’s Macquarie Park by July 2027, subject to approvals.

The company said Cyclotek’s certification meant it had shown its quality management system met specific international standards.

Oncosil chief executive officer Nigel Lange said “ISO13485 certification is an important achievement in establishing our Macquarie Park manufacturing capability and brings us another step closer to commencing production”.

“Our focus now moves to adding the Macquarie Park site to OncoSil Medical’s existing certification, with the aim of completing this process and commencing production of the Oncosil device [this year],” Mr Lange said.

Oncosil was down half a cent or 0.5 percent to \$1.06.

EBR SYSTEMS

EBR says the US Food and Drug Administration agrees that no immediate field corrective action or recall against its Wise system is warranted following a data breach.

In July, EBR said an event involving ventricular fibrillation in two patients implanted with its Wise leadless pacemaker was not related to its device, and that the FDA would review the events (BD: Jul 24, 2026).

Later that month, EBR said its final internal assessment concluded that the death of a patient and complications in another were “an isolated event related to a disclosed risk that can be mitigated when following recommended [transthoracic echocardiogram] procedures per the device labelling and training” (BD: Jul 31, 2026).

Today, the company said that the FDA “advised that the incident aligns with a controlled risk classification under Section VI of the FDA’s 2016 guidance, Post-market Management of Cybersecurity in Medical Devices”.

EBR chief executive officer John McCutcheon said that “patient safety, device integrity and responsible post-market management remain EBR’s highest priorities”.

The company said it would continue to provide updates to the FDA as requested.

EBR fell half a cent or 1.7 percent to 29.5 cents with 3.1 million shares traded.

OSTEOPORE

Osteopore says it has approval to sell its range of orthopedic products in Thailand through a deal with Hong Kong’s DCH Auriga.

Osteopore said that Auriga would be its market authorization holder and import its devices into Thailand, supplying hospitals and clinics as directed by Osteopore, with the next step to be product listing in targeted public and private hospitals in Bangkok.

The company said demand for bone-repair ortho-biologics and bone graft substitutes were “propelled by expanding access to reconstructive procedures under Thailand’s universal healthcare coverage, a rising orthopaedic disease burden, and one of the world’s highest road-trauma rates, generating sustained demand for materials that reconstruct bone defects arising from high-energy fractures”.

Osteopore said the Thai orthopaedics market was valued at \$US749 million (\$A1,037 million) in 2025 and was projected to reach \$US1.5 billion (\$A2.08 billion) by 2033.

Osteopore was unchanged at 0.4 cents with 2.96 million shares traded.

NEURIZON THERAPEUTICS

Neurizon says the US National Institutes of Health has awarded a “multimillion-dollar,” grant for expanded access for NUZ-001 for amyotrophic lateral sclerosis (ALS).

Neurizon said the expanded access program was expected to provide up-to 200 people living with amyotrophic lateral sclerosis, who would otherwise be ineligible for clinical trials with access to NUZ-001, running in parallel with regimen one of its phase II/III Healey ALS 250-patient trial.

The company said the expanded access program would continue beyond topline results from the main trial, which were expected by July 2027, dependent on a positive trial outcome, with the National institutes of Health (NIH) funding drug supply, manufacturing and specified regulatory, safety monitoring and operational costs.

Neurizon said expanded access, also referred to as “compassionate use”, provided a pathway for people with serious or life-threatening diseases to access an investigational therapy that was not approved by the US Food and Drug Administration where participation in an appropriate trial was not available.

The company said data from the program was expected to “significantly expand the long-term safety database for NUZ-001 and provide additional survival, biomarker and clinical data to inform its ongoing clinical development”, and would be conducted at about 20 physical ALS clinical trial sites as well as a national virtual study site, providing potential access in all 50 US states.

Neurizon said sites would include those in the Healey ALS Platform Trial, with a virtual model designed to facilitate participation for people living with ALS who may have difficulty accessing clinical research, including those in rural and underserved areas.

Neurizon chair Sergio Duchini said “Neurizon is proud to support the Healey and [Affiliated Managers Group] Center in this important initiative, which will provide up to 200 people living with ALS who are otherwise ineligible to participate in clinical trials with access NUZ-001 for up to 96 weeks”.

“The [expanded access protocol] will also significantly expand our long-term safety database and generate valuable biomarker, survival and real-world clinical data from a broader ALS population,” Mr Duchini said.

Neurizon was up 2.3 fell cents or 37.1 percent to 8.5 cents with 3.8 million shares traded.

NEUROSCIENTIFIC BIOPHARMA

Neuroscientific says its annual general meeting will vote to change its name to Miro Sciences

Neuroscientific said that the name change vote was a special resolution, effective from the date that the Australian Securities and Investments Commission ASIC) alters the details of the company’s registration.

The company said the name change “more accurately reflects the proposed future ambitions of the company following its acquisition of the Stemsmart patented stem cell technology via its acquisition of Isopogen WA in June 2025 (BD: Jun 27, 2025).

Neuroscientific said that the company’s ASX code was proposed to be changed from NSB to MSX.

The company said that shareholders would vote to adopt the remuneration report, re-elect director Dr Anton Uvarov, approve the 10 percent placement capacity, and approve the change of auditor.

The meeting will be held at Level 1, 216 St Georges Terrace Perth Western Australia on October 15, 2026 at 10am (AWST).

Neuroscientific fell 0.1 cents or 1.6 percent to six cents.

ANTEOTECH

Anteotech says chief financial officer and company secretary Scott Waddell has resigned to “pursue other business interests”.

Anteotech said it would undertake a process to identify Mr Waddell’s successor.

The company thanked Mr Waddell for his contribution and wished him “the very best in his future endeavors”.

Anteotech was unchanged at 2.1 cents with 7.6 million shares traded.