



Biotech Daily

Thursday September 24, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: BOTANIX UP 6%; CURVEBEAM DOWN 17%**
- * **NEXSEN HALTS STREPSURE PIVOTAL TRIAL; REQUESTS SUSPENSION**
- * **PARADIGM TO RETURN \$2.8m TO OBSIDIAN, CANCEL 2m NOTES**
- * **CLEO BEGINS EARLY-STAGE OVARIAN CANCER TEST DEVELOPMENT**
- * **MESOBLAST: FDA APPROVES RYONCIL MSC POTENCY ASSAY**
- * **QUEENSLAND UNI TRIALS NANOAM FARM WASTE ANTI-MICROBIAL**
- * **4D MEDICAL: 1.7m DIRECTORS RSUs, 957 OPTIONS, 60% PAY HIKE AGM**
- * **4D: PROF JENKINS IN; BIANCHI OUT; SUTTON, DR PLUNKET, COX UP**
- * **ANTERIS, HARVEY EXTEND SUPPLY AGREEMENT**
- * **DIRECTOR SIMON PANTON INCREASES, DILUTED TO 17% IN RESONANCE**
- * **SALUDA APPOINTS CEO MIKE MATHIAS DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.72 percent on Thursday September 24, 2026, with the ASX200 down 63.3 points to 8702.0 points. Eleven of the Biotech Daily Top 40 companies were up, 19 fell, nine traded unchanged and one was untraded.

Botanix was the best, up 0.1 cents or 5.6 percent to 1.9 cents, with 7.9 million shares traded. Both Proteomics and Syntara climbed 4.35 percent; Alcidion and Artrya rose more than two percent; Actinogen, Cochlear, Orthocell, Pro Medicus and Resonance were up by more than one percent; with 4D Medical, Mesoblast, Polynovo and Resmed up by less than one percent.

Curvebeam led the falls, down 0.5 cents or 16.7 percent to 2.5 cents, with 6.045 million shares traded. Micro-X fell 14.6 percent after three days of being the best of the BDI-40, down 0.7 cents or 14.6 percent to 4.1 cents with 4.1 million shares traded.

Immutep and Optiscan lost more than seven percent; EBR was down 5.7 percent; Lumos fell 4.35 percent; Avita and Racura were down more than three percent; Telix shed 2.1 percent; Clarity, Cyclopharm, Medical Developments and Nova Eye were down one percent or more; with Aroa, Clinuvel, CSL, Emvision, Imricor, Nanosonics and Neuren down by less than one percent.

NEXSEN

Nexsen says it has suspended enrolment in its trial of its Strepsure test for Group B streptococcus for women in labour at Melbourne's Northern Health in Epping.

Nexsen said that the study, included a pre-defined interim review to assess early-stage performance, allowing the company "to refine the program before committing to a larger US regulatory study".

The company said that the suspension had delayed US Food and Drug Administration submission by about three months.

Nexsen said that the review had taken place and enrolment was suspended, but there were no adverse safety signals or events.

Last year, Nexsen said it had begun its 2,400 patient, pivotal trial of its Strepsure group B streptococcus (GBS) Rapid Sensor at Melbourne's Northern Hospital (BD: Oct 21, 2025).

The company said last year the trial would provide clinical validation of the vaginal-rectal swab-based GBS Rapid Sensor, comparing its accuracy to that of laboratory testing.

Today, Nexsen said that following a review of the interim data, together with ongoing scientific and regulatory assessment, the assessment of Strepsure in its current form had ceased and it identified a targeted set of enhancements to strengthen Strepsure ahead of its US Food and Drug Administration submission.

The company said that the real-world clinical evidence was that Strepsure could be optimized "before substantially greater time and capital are committed to the US regulatory pathway".

Nexsen said that the planned enhancements were "targeted improvements to the existing Strepsure platform rather than a fundamental redesign, and [were] not expected to require material additional development expenditure".

Nexsen managing-director Mark Muzzin said: "We have made the decision not to submit the current configuration to the FDA and instead use what we have learned to make Strepsure stronger."

"Making this decision now avoids committing substantially more capital to the current configuration and reduces the risk of having to repeat clinical and regulatory work at a later, more expensive stage," Mr Muzzin said. "Our Asia-Pacific strategy continues, our other diagnostic programs continue to progress, and the capabilities we are building through Strepsure have application across the broader Nexsen platform."

Nexsen said the interim data provided "clear evidence of Strepsure's ability to detect GBS in the intended clinical setting and identified clear opportunities to further strengthen performance before progressing to a larger US regulatory program".

The company said the review identified that GBS prevalence at the trial site was about 11 percent, materially below the 18-25 percent prevalence seen at many US study sites.

Nexsen said that this resulted in fewer GBS-positive cases being captured through the study and it has clarified what Strepsure needs to achieve in lower-prevalence settings.

The company said that "where GBS is less common, a test must be especially good at avoiding false positives for a positive result to be reliable ... a recognized feature of all diagnostic testing, not something unique to Strepsure or to lateral-flow technology".

Nexsen said that in the next phase, it would "concentrate more GBS from each sample, read the signal more clearly through quantitative electronic measurement and confirm it through stronger biological recognition".

The company said that alongside Strepsure, it was advancing diagnostics across kidney disease, traumatic brain injury, neonatal sepsis and biosecurity.

Nexsen said it requested a voluntary suspension following Tuesday's trading halt for "an announcement regarding ... a contract regarding an additional device".

Nexsen last traded at 16.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that following yesterday's trial halt it will return \$US2 million (\$A2.8 million) to Obsidian Global GP and cancel the 2,000,000 convertible notes issued.

Yesterday, Paradigm said it halted its phase III pentosan polysulfate sodium trial for knee osteoarthritis after the independent data safety monitoring board confirmed the interim efficacy result "did not reach the pre-specified threshold required" (BD: Sep 23, 2026).

Today, the company said that "no premium, redemption amount, fee or other additional payment is payable ... in connection with this arrangement".

Paradigm said that the drawdown "was intended to support ongoing phase III clinical trial activities, including clinical operations, data management and regulatory activities".

The company said it "continues to assess the implications of the interim analysis".

Paradigm was in a voluntary suspension and last traded at 24.5 cents.

CLEO DIAGNOSTICS

Cleo says it has begun prototype development of its multi-biomarker screening blood test for early-stage ovarian cancers in asymptomatic women.

Cleo said its pre-surgical ovarian cancer test was its "primary commercial product"

progressing towards US Food and Drug Administration 510(k) submission by July, 2027.

The company said initial proof-of-concept screening test data was expected in the coming three months, with finalization of test panel architecture by the end of this year.

Cleo said it was targeting a "larger addressable market while leveraging the company's existing biomarker technology, clinical datasets and development infrastructure".

The company said the development work was "a separate workstream and does not alter ... [its] regulatory and commercial focus on advancing its pre-surgical ovarian cancer test".

Cleo said that ovarian cancer screening had "different performance requirements to pre-surgical triage due principally to the significantly lower prevalence of ovarian cancer within asymptomatic populations".

The company said it would pursue the following minimum performance requirements, based on best-practice screening literature.

Cleo said that for high-risk screening, the minimum sensitivity was 90.0 percent and minimum specificity was 90.0 percent.

The company said that for general population screening, the minimum sensitivity was 75.0 percent and minimum specificity was 99.6 percent.

According to the Australian Government ovarian cancer website: "There is currently no recommended screening test for ovarian cancer, even for high-risk individuals, as no existing test can accurately detect early-stage disease."

Ovarian cancer screening or surveillance is not currently recommended, even for women at high or potentially high risk of ovarian cancer," the Federal Government website said.

"This is because there is no test that can accurately detect early ovarian cancer."

According to the Cancer Council of Victoria the incidence of ovarian cancer in the general population was 12 per 100,000 females, or 0.012 percent.

Cleo said the minimum performance requirements were "set according to calculated predictive probabilities required for clinical use, accounting for both negative and positive predictive values (NPV and PPV) appropriate to a low prevalence disease".

The company said that "a high specificity bar is required for general population screening, where false positive results carry significant downstream cost and patient impact".

Cleo said that the targets were "intended to support both clinical credibility and regulatory positioning as the program progresses".

Cleo fell one cent or 3.3 percent to 29.5 cents.

MESOBLAST

Mesoblast says it has US Food and Drug Administration approval for its T-cell Proliferation Inhibition Bio-Assay for potency monitoring commercial lots of Ryoncil.

In 2024, Mesoblast said the FDA had approved Ryoncil (remestemcel-L-rknd, previously known as MSC-100-IV) for children aged two months and older for graft versus host disease (GvHD) (BD: Dec 19, 2024)

Today, the company said that its T-cell Proliferation Inhibition Bio-Assay (Tiba) would “ensure sufficient sensitivity to detect any shifts in potency of the commercial product that could arise during changes in manufacturing processes or production in new facilities”.

Mesoblast said that the assay would be used as part of a matrix to release each commercial batch of Ryoncil, in conjunction with the existing potency assays which determine interleukin-2 receptor alpha (IL-2R α) inhibition and cell adhesion and proliferation, as per the product's biologics licence.

The company said that together the assays ensured that the Ryoncil product was “consistent, potent, and clinically effective”.

Mesoblast said that Ryoncil was the first industrially-manufactured allogeneic mesenchymal stem cell (MSC) product approved by the FDA for any indication, and the only MSCs approved for patients with steroid-refractory acute graft versus host disease.

The company said it was working closely with the FDA “to ensure alignment on continued advancements to the product's manufacturing processes and implementation of assays measuring the product's ongoing quality control”.

Mesoblast was up one cent or 0.5 percent to \$2.19 with 5.4 million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says its researchers are testing the Nanoam anti-microbial coating made from Queensland agricultural waste.

The University of Queensland said the tests included performance of safety as part of the critical care research group's intensive care unit of the future at Brisbane's Prince Charles Hospital, funded by The Prince Charles Hospital Foundation.

The University said the anti-microbial coating for hospital surfaces and equipment “could prevent healthcare-associated infections such as ‘golden staph’ [Staphylococcus aureus] which cost Australia's health system \$1 billion every year”.

The University of Queensland said that Nanoam lead developer Prof Nasim Amiralian of its Australian Institute for Bioengineering and Nanotechnology, said the coating was designed to improve patient safety and protect hospital staff from microbes in hospital environments, which include bacteria and viruses.

“The technology works by converting green waste, including sugarcane, banana and hemp, into long-lasting, hospital-grade surface protection,” Dr Amiralian said.

“Acting as a sustainable, self-cleansing and non-toxic shield, the coating kills pathogens and prevents microbial build-up - in turn reducing hospital-acquired infections in vulnerable patients and prolonged hospital stays,” Dr Amiralian said.

The University said that healthcare-associated infections were “a major financial burden on Australia's healthcare system, with infections responsible for 38 percent of all hospital-acquired complications and contributing to 7,000 deaths each year”.

Dr Amiralian said Queensland hospitals relied on chlorine or bleach-based disinfectants to address infection risk.

“These existing hospital approaches are short-lived - damaging surfaces, fueling antimicrobial resistance, releasing toxic materials - while generating tonnes of chemical and hazardous healthcare waste across the state every year,” Dr Amiralian said.

4D MEDICAL

4D Medical says investors will vote to grant four directors 1,719,853 restricted stock units and 957,130 options, and increase the directors fee pool 60 percent to \$1.2 million.

4D Medical said the annual general meeting would vote to issue managing-director Prof Andreas Fouras 1,697,041 restricted stock units exercisable at no cost and 945,724 options exercisable at \$3.98931 each within four years.

The company said that 11,406 options for executive director John Livingston were exercisable at no cost as were the 11,406 restricted stock units to be issued to each of directors Dr Robert Figlin and Dr Geraldine McGinty.

4D Medical said shareholders would vote to increase the maximum aggregate directors fee pool by \$450,000 or 60 percent, from \$750,000 to \$1,200,000.

The company said the meeting would vote on the remuneration report, the renewal of the incentive plan, the ratification of the prior issue of shares and options, a constitution amendment and the re-election of director Dr Geraldine McGinty.

The meeting will be held at the Forum Rooms 2 and 3, Melbourne Connect, Mezzanine, 700 Swanston Street, Carlton, on October 28, 2026 at 10am (AEDT).

4D Medical was up two cents or 0.5 percent to \$4.10 with 2.8 million shares traded.

4D MEDICAL

4D says Prof Christine Jenkins has been appointed a director, Chris Cox chief financial officer, Beth Plunkett general counsel and Julian Sutton will replace chair Lil Bianchi.

4D Medical said that Prof Jenkins was “one of Australia's most influential figures in respiratory medicine ... [combining] combined clinical practice, research, education and policy leadership at the highest levels of the profession”.

The company said that Prof Jenkins was a senior staff specialist in respiratory medicine at Sydney's Concord Repatriation General Hospital for 40 years, led more than 34 trials as principal investigator and authored more than 320 publications, with her work focused on improving diagnostic pathways and outcomes for patients with respiratory disease, particularly those presenting with breathlessness, chronic obstructive pulmonary disease (COPD) and asthma.

4D Medical said that Prof Jenkins had been the chair of Lung Foundation Australia, the Thoracic Society of Australia and New Zealand and the National Asthma Council.

The company said that Mr Sutton would become the executive chair, effective immediately following the 2026 annual general meeting when Lil Bianchi retired.

4D Medical said that Mr Sutton was “an early investor ... and served as a non-executive director from September 2017 before being appointed chief financial officer and executive director in January 2026”.

The company said that following the 2026 annual general meeting the Board would be Julian Sutton, managing-director Dr Andreas Fouras, John Livingston, Dr Robert Figlin, Dr Geraldine McGinty and Prof Christine Jenkins.

4D Medical said that former financial controller and interim chief financial officer Chris Cox had been appointed chief financial officer from the close of the annual general meeting; had worked for Invetech and Medadvisor, and held a Bachelor of Commerce.

The company said that its legal head Beth Plunkett had been appointed general counsel, effective immediately.

4D Medical said Dr Plunkett had worked for Smile Solutions and held a Juris Doctor from the University of Melbourne.

ANTERIS TECHNOLOGIES

Anteris says that its Aus Operations Pty Ltd subsidiary and Harvey Industries Group Pty Ltd have extended their supply and quality agreement.

Anteris said the extension was to “the earlier of December 31, 2026 and the date of execution of a separate supply and quality agreement between the parties”.

Anteris fell 47 cents or 4.2 percent to \$10.73.

RESONANCE HEALTH

Resonance director Simon Panton says he has increased and been diluted in the company from 72,546,350 (18.02%) to 80,137,174 shares (16.8%).

The Perth-based Mr Panton said that through Southam Investments and Design Council, he and Karen Panton bought shares between February 5, 2019 and July 13, 2026 with the most recent purchase 1,640,824 shares for \$73,837, or 4.5 cents a share.

According to Commsec data, Resonance has not raised dilutive capital in the past 12 months.

Resonance was up 0.1 cents or 1.5 percent to 6.6 cents.

SALUDA MEDICAL

Saluda says it has appointed chief executive officer Mike Mathias, as a director of the company, effective immediately.

Earlier this month, Saluda said that chief commercial officer Mike Mathias had been promoted to replace chief executive officer Barry Regan. (BD: Sep 7, 2026).

Saluda was unchanged at 39 cents.