

Biotech Daily

Monday September 8, 2025

Daily news on ASX-listed biotechnology companies

- * ASX DOWN, BIOTECH UP: 4D MEDICAL UP 50%; EBR DOWN 5%
- * 4D MEDICAL JUMPS 52% ON 3 LUNG IMAGING DEALS
- * ALTERITY: COMMITMENTS FOR \$20m PLACEMENT
- * SNOW CENTRE OPENS IMMUNE SYSTEM ENROLMENT
- * PHENOMICS, THERAPEUTIC INNOVATION OPEN \$50k ACCELERATOR
- * WOMEN & INFANTS RESEARCH FOUNDATION \$260k PERTH AWARDS
- * MAYNE REBUTS SALISBURY SA CLOSURE MEDIA ARTICLE
- * MEMPHASYS, QATAR'S ITL \$325k FELIX SUPPLY DEAL
- * PROTEOMICS: PROMARKER ESO SENSITIVITY 81% TO 100%
- * ORTHOCELL 49-PATIENT STUDY: 81% REMPLIR SUCCESS RATE
- * S&P DROPS 9 BIOTECHS FROM ALL ORDS, 2 FROM S&P200, 1 FROM S&P300
- * IMAGION BEGINS US MAGSENSE MANUFACTURING
- * CLEVER CULTURE: AZ, BMS, PFIZER PRESENT APAS DATA
- * NOXOPHARM DOSES FINAL PHASE I SOF-SKN COHORT
- * PATRYS 15-TO-1 CONSOLIDATION, 160m REDUNDANCY SHARES AGM
- * NEUROTECH TO RELEASE 10m VOLUNTARY ESCROW SHARES
- * PATRYS DIRECTOR DR ANTON UVAROV TAKES 5.45%
- * DR STEWART, DR PATRIZIA WASHER DILUTED TO 8% OF EMYRIA

MARKET REPORT

The Australian stock market fell 0.24 percent on Monday September 8, 2025, with the ASX200 down 21.6 points to 8,849.6 points. Nineteen of the Biotech Daily Top 40 companies were up, 13 fell, seven traded unchanged and one was untraded.

4D Medical was the best, for the third trading day in a row, up 76.5 cents or 49.5 percent to \$2.31, with 40.4 million shares traded. Dimerix climbed 9.7 percent; Medadvisor rose 8.7 percent, Cynata climbed 7.9 percent; Compumedics and Orthocell were up five percent or more; Immutep, Mesoblast and Proteomics improved more than four percent; Botanix, Imugene, Nova Eye and Starpharma were up more than three percent; CSL, Micro-X and Resonance rose two percent; or more; Cyclopharm, Neuren and Optiscan were up more than one percent; with Cochlear and Pro Medicus up by less than one percent.

EBR led the falls, down 5.5 cents or 4.55 percent to \$1.155, with 1.2 million shares traded. Syntara fell four percent; Actinogen, Clinuvel, Genetic Signatures and Polynovo were down three percent; or more; Paradigm and Telix were down more than one percent; with Avita, Clarity, Emvision, Medical Developments, Nanosonics and Resmed down by less than one percent.

4D MEDICAL

4D Medical climbed as much as 52.1 percent on news that it had deals with the Royal Melbourne Hospital, Spectrum Medical and a "leading global pharmaceutical company".

4D Medical said that, with the unnamed pharmaceutical company, it would launch a screening program in Brazil for lung cancer screening and detecting incidental findings like coronary artery calcification and chronic obstructive pulmonary disease, with the Belo

The company said the deal would cover analysis of up-to 10,000 scans to August 2026, and sought to provide national coverage in Brazil following an initial eight hospitals.

4D Medical said it had a pilot agreement with the Royal Melbourne Hospital (RMH) to

Horizonte, Brazil-based Hospital Madre Teresa being the initial site.

implement its portfolio for advanced lung ventilation analysis and clinical imaging assessment of lung health, including computed tomography lung ventilation analysis software (CT LVAS), X-ray velocimetry (XV) LVAS, lung density analysis—Inspiration (LDAI), functional lung density analysis (LDAF), lung texture analysis and low-dose CT nodule detection as part of the National Lung Cancer Screening Program.

The company said the program would run to December 31, 2025, with the RMH the first Australian public hospital to roll out the 4D Medical platform.

4D Medical said that Sydney's Spectrum Medical Imaging would expand its existing support for its lung health programs to include low-dose CT nodule detection, LDAI, lung map for smoking cessation, lung texture analysis, and LDAF, until June 30, 2027.

The company said Spectrum had been a provider of 4D Medical's technology since July 1, 2025, offering Medicare-funded low-dose computed tomography scans to eligible patients, through Australia's National Lung Cancer Screening Program.

4D Medical chief executive officer Prof Andreas Fouras said "in parallel to our US efforts to bring CT VQ to market, we are pleased to see progress on other products in the portfolio in countries where CT VQ is yet to receive regulatory clearance".

"4D Medical is committed to Australian healthcare, and is excited to support the National Lung Cancer Screening Program [...] this is a key piece of Australian healthcare infrastructure and we believe our suite of products can play a big role," Prof Fouras said. "I am excited to have Royal Melbourne Hospital as the first Australian public hospital and Academic Medical Centre to roll out the 4D Medical suite, further extending the reach of our technology into frontline clinical practice," Mr Fouras said.

"Lastly, in Brazil, our partnership with a global pharmaceutical offers further evidence of the growth of our reputation and a real opportunity to expand our reach to millions in South America," Mr Fouras said.

4D Medical closed up 76.5 cents or 49.5 percent at \$2.31 with 40.4 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has commitments to raise \$20.0 million IN a placement at 1.2 cents a share, a 7.3 percent discount to the 10-day volume weighted average price. Alterity said that with proceeds to go towards non-clinical studies, manufacturing and controls activities, clinical and regulatory activities for ATH434 and working capital. The company said MST Financial Services was the sole manager of the offer. Alterity chief executive officer Dr David Stamler said "we are thankful for the continued interest from the investment community following the robust efficacy we demonstrated in our phase II clinical trial in multiple system atrophy".

"The additional funding allows us to continue advancing our clinical and regulatory strategy for ATH434 with the US FDA and other agencies," Dr Stamler said. Alterity was unchanged at 1.3 cents with 38.95 million shares traded.

SNOW CENTRE FOR IMMUNE HEALTH

The Snow Centre, a partnership between Walter & Eliza Hall Institute and Royal Melbourne Hospital, says it has opened enrollment at its immune disease clinics. A media release from the Snow Centre said it would begin a study at its newly launched research clinics, based at the Royal Melbourne Hospital, to focus on primary immune deficiencies, allergies and asthma, autoimmunity, and kidney transplantation.

The Centre said it was recruiting healthy participants to analyze samples from people with healthy immune systems.

Snow Centre co-director Prof Jo Douglass said "recruiting the first patients into the Snow Research Clinics is a great milestone".

"We're grateful to the patients for giving Snow Centre researchers access to rich data and providing us this opportunity to better understand immune health," Prof Douglass said. "Overall, one-in-five people experience an allergic disease and one-in-10 may develop an auto-immune disease such as rheumatoid arthritis or lupus," Prof Douglass said. "Patients with immune disorders often endure a long diagnostic journey ... in the case of immune deficiencies often lasting up to eight years," Prof Douglass said.

"While symptoms may appear similar across individuals, treatment responses can vary significantly, Prof Douglass said. "This uncertainty can delay effective care, sometimes causing further health complications, and it also takes a heavy emotional and mental toll."

PHENOMICS AUSTRALIA, THERAPEUTIC INNOVATION AUSTRALIA (TIA)

Phenomics Australia says with Therapeutic Innovation Australia(TIA) and others it has developed a pipeline accelerator, a voucher-style scheme for up-to \$50,000. Phenomics said that with TIA, the Australia Nuclear Science and Technology Organisation (ANSTO) and Bioplatforms Australia, the scheme would provide up-to \$50,000 with at least 50 percent matching funding from the applicant.

The organization said that through Federal Government's National Collaborative Research Infrastructure Strategy (NCRIS) it would help academic researchers and small to medium-sized companies access national research infrastructure and Australian translational medical research capabilities.

Phemomics said applications would close on October 31, 2025 at 5:00pm AEST. For more information, go here: https://phenomicsaustralia.org.au/voucher-scheme/

WOMEN AND INFANTS RESEARCH FOUNDATION

Perth's Women and Infants Research Foundation at King Edward Memorial Hospital says it awarded \$260,000 to five women's health research projects, on Friday evening. The Women and Infants Research Foundation said it granted Perth's Curtin University's Dr Yu Yu \$100,000 for her project 'Developing a new treatment for chemotherapy resistant ovarian cancer using bispecific Slit-Robo antibody'; King Edward Hospital's Natalie Williams was awarded \$25,000 for her project 'The CIPNEX study: a hand-foot exercise intervention for chemotherapy-induced peripheral neuropathy in gynecologic oncology'; Perth Children's Hospital's Dr Bradley MacDonald was provided \$45,000 for his project 'Developing an adaptive rare diseases platform trial for therapeutic trial access'; King Edward Hospital's Dr Kelli MacMillan was awarded \$45,000 for her project 'Screening for childbirth related post-traumatic stress disorder at an Australian women's tertiary hospital'; with King Edward Hospital's Dr Gayatri Jape granted \$45,000 for her project 'implementation of a clinical risk score (Check-NEC score) for predicting the risk of NEC in preterm infants'.

MAYNE PHARMA GROUP

Mayne says an article in the Australian media incorrectly said it advised the Foreign Investment Review Board (FIRB) of the closure of its Salisbury site in July. In February, Mayne said the Bridgewater, New Jersey-based Cosette would buy it for \$7.40 a share in cash, valuing the company at \$672 million (BD: Feb 21, 2025). In June, the company said it had received a "purported notice to terminate [the] scheme implantation deed" from Cosette, which it intended to reject as "invalid", reiterating its position that no Mayne material adverse change has been triggered such that there is no lawful basis for Cosette to terminate the [deed]" (BD: Jun 4, 2025).

Today, Mayne Pharma said a recent article referred to an objection from South Australia Premier Peter Malinauskas regarding its scheme transaction with Cosette, saying his objection had been "communicated to the Foreign Investment Review Board" with the article including references, as well as quotes from Premier Malinauskas, related to Cosette's "plans to close" the Salisbury, South Australia site.

The company said the article noted that Mayne had "advised FIRB of the possible closure in July, citing the company's deteriorating financial position".

Mayne Pharma said it was not previously made aware of any dialogue or communications with the Premier Malinauskas, or between his office and Cosette, nor between the premier and the FIRB, and said Cosette was obliged under the scheme implementation deed to make it aware of any such communication.

The company said the article "incorrectly states" it advised the FIRB of the possible site closure and said it had "no intention to close the Salisbury site", with a seven percent increase in full year revenue, as well as an \$18 million Salisbury facility upgrade. Mayne Pharma said it was aware that Cosette had some correspondence with the FIRB in respect of its intentions for the Mayne Pharma business, including possible intentions to close or sell the Salisbury site, following implementation, should Cosette's attempts to terminate or otherwise get out of its obligations fail.

The company said it had had "no direct communications with [the] FIRB or the South Australian government in respect of the scheme transaction" and it would endeavor to obtain "further information" considering what impact the SA Premier's comments" may have had, if any, on the scheme and the FIRB's consideration of the matter, and was considering whether to communicate with the FIRB directly.

Mayne fell 78 cents or 14.8 percent to \$4.50 with 2.3 million shares traded.

MEMPHASYS

Memphasys says it has a \$325,000, five-year deal with the Doha, Qatar-based International Technical Legacy (ITL) for its Felix sperm separation device.

Memphasys said International Technical Legacy would place an initial binding order for Felix catridges valued at \$325,000, to supply 15 countries in the Middle East and North Africa, on it receiving Conformité Européenne (CE) mark approval.

In June, the company said it had submitted a CE mark regulatory dossier for approval to commercialize its Felix sperm separation device in Europe (BD: Jun 30, 2025).

Today, Memphasys the deal had an initial binding order for the first two years, with volume and pricing to be reviewed for the remaining years.

The company said that 10 consoles would be supplied free-of-charge with the initial minimum order, and additional cartridge volumes and consoles might be provided as required to meet higher-than-forecast demand.

The company said it expected CE mark approval "within 12 months".

Memphasys was up 0.1 cents or 25 percent to 0.5 cents with 34.5 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 350-patient study of its Promarker Eso blood test for oesophageal cancer shows sensitivity from 81 percent to 100 percent depending on cancer stage. Proteomics said the study analyzed 350 patients in two independent cohorts, with cohort A comparing 89 healthy controls with oesophageal adenocarcinoma samples of known stages, while cohort B compared 40 negative controls to 48 samples with un-staged oesophageal adeno-carcinoma and 115 Barrett's oesophagus samples.

The company said its test showed 81 percent sensitivity for stage one oesophageal adeno-carcinoma (EAC), 91 percent for stage two EAC, 100 percent for stage three EAC and 100 percent for stage four EAC, as well as 93 percent sensitivity for Barrett's oesophagus with high-grade dysplasia.

Proteomics said Barrett's oesophagus was a pre-malignant condition that was the only known precursor to EAC, although 95 percent of patients never developed EAC, Barrett's oesophagus with high-grade dysplasia was often treated similarly to early stage EAC. The company said current standard screening required a specialist endoscopy, but the invasive procedure could be uncomfortable and costly for patients, and said that despite the testing up to 90 percent of EAC cases went undetected.

Proteomics managing-director Dr Richard Lipscombe said the results had "enormous significance, because if EAC can be detected early it can be more readily treated, whereas late-stage EAC has a very poor prognosis".

"With the increasing numbers of people living with chronic acid reflux, Promarker Eso has the potential to revolutionize how doctors manage the risk of oesophageal cancer ... offering a standard blood test that could reduce reliance on invasive procedures and improve early detection rates," Dr Lipscombe said.

The company said the results, published in Diseases of the Esophagus, would be presented at the Congress for Esophageal Diseases in Brisbane, September 18 to 20, 2025.

Proteomics was up 1.5 cents or 4.9 percent to 32 cents with 1.2 million shares traded.

ORTHOCELL

Orthocell says its Remplir collagen membrane-based nerve repair product showed an 81.1 percent success rate in an analysis of 49 patients, aged 14 to 82 years old. Orthocell said data on 49 patients was included in the interim analysis, with patients undergoing 67 peripheral nerve procedures, 82 percent of which were upper limb and 61.2 percent were nerve reconstruction procedures for acute injury, including nerve transfer and nerve grafting, with 38.8 percent being nerve decompression procedures using Remplir as a protective wrap in patients with chronic nerve injuries.

The company said the interim results included performance data from 43 procedures of the 53 therapeutic targets, or an 81.1 percent success rate following nerve repair procedures, as well as 26 of 32 procedures involving muscles innervated by repaired nerves achieved functional motor recovery and 17 of 19 nerve decompression procedures resulted in significant improvement or complete relief of symptoms.

Orthocell said no post-treatment complications or adverse reactions to Remplir were reported in any patient, and that the results were consistent with previously published clinical trial outcomes.

The company said the study would be used to support US Remplir sales and UK and European Union regulatory submissions, which it expected to submit this year. Orthocell was up six cents or 5.3 percent to \$1.19 with 1.0 million shares traded.

STANDARD AND POOR'S DOW JONES INDICES

Standard & Poor's says it has demoted nine biotechnology companies from the All Ordinaries Index, two from the ASX200 and one from the ASX300.

Standard & Poor's said it had removed 4D Medical, Anteris, Arovella, Avita, Cyclopharm, Imugene, Medadvisor, Opthea and Trajan from the All Ordinaries Index, Clarity and Polynovo from the ASX200 and Opthea from the ASX300.

Previously, Standard & Poor's has told Biotech Daily that inclusion in the indices was based solely on market capitalization.

The Biotech Daily Top 40 Index (BDI-40) is based on quality of science, benefit to human health, board and management, investment potential and market capitalization.

IMAGION BIOSYSTEMS

Imagion says its US contractor has begun manufacturing its Magsense human epidermal growth factor receptor-2 (HER2) agent for its phase II breast cancer trial.

Imagion said manufacturing of the HER2 diagnostic imaging agent was expected to be completed by the end of this month, with analytical testing of the product to be completed shortly thereafter, and the planned trial expected "towards the end of 2025".

Earlier this year, the company said it expected to file a US Food and Drug Administration investigational new drug application (IND) for a phase II trial of Magsense for breast cancer by October (BD: Jul 15, 2025).

Imagion was up 2.1 cents or 131.25 percent to 3.7 cents with 221.8 million shares traded.

CLEVER CULTURE SYSTEMS (FORMERLY LABTECH INNOVATIONS)

Clever Culture says that Astrazeneca, Bristol Myers Squibb and Pfizer will present Automated Plate Assessment System (APAS) Independence data in coming months. Clever Culture said Astrazeneca and Bristol Myers Squibb would present data at the Parenteral Drug Association Pharmaceutical Microbiology Conference in Washington, DC between October 27 to 29, 2025; Astrazeneca would present in Macclesfield, UK between November 20 to 21, 2025; and Pfizer would present data at the Pharmalab Conference in Dusseldorf, Germany from November 24 to 26, 2025.

Clever Culture chief executive officer Brent Barnes said the strategy was engage with the largest pharmaceutical companies and our technology "has been selected for presentation by Astrazeneca, Pfizer and Bristol Myers Squibb at multiple industry leading conferences." Clever Culture was up 0.1 cents or 3.2 percent to 3.2 cents with 1.3 million shares traded.

NOXOPHARM

Noxopharm says it has dosed the fourth and last single-dose cohort in its 16-patient, phase I 'Heracles' trial of SOF-SKN, with the highest dose level "safe and well tolerated". In July, Noxopharm said it dosed the first of 16 patients with its Sofra-based SOF-SKN in the phase I 'Heracles' trial for auto-immune diseases (BD: Jul 16, 2025).

Today, the company said the safety steering committee had "determined the fourth and highest dose level to be safe and well tolerated, with no clinically relevant issues".

Noxopharm chief executive officer Dr Gisela Mautner said: "We are pleased to announce that we have cleared a crucial first hurdle in the development of SOF-SKN, and have shown that these initial doses are safe [...] an achievement that cannot ever be taken for granted in any drug trial".

Noxopharm fell half a cent or 4.8 percent to 10 cents.

PATRYS

Patrys says its annual general meeting will vote on a 15-to-one share consolidation and 278,052,720 redundancy shares to former chief executive officer Dr James Campbell. Patrys said a consolidation would provide a "more appropriate and effective capital structure ... and a share price that is more appealing to a wider range of investors". The company said it currently had 4,583,756,578 shares on issue, which would become 305,583,772 shares on issue if the consolidation was approved.

The company said it would vote to issue Dr Campbell 160,526,930 redundancy shares on a pre-consolidation basis "in connection with the cessation of his employment" as chief executive officer and managing director, and in addition to his current non-executive director salary of \$48,000 a year.

In June, the company said it had appointed Peter Christie chair and Dr Anton Uvarov a director, with Dr Campbell continuing as a director and the chief executive officer role made redundant, to be managed by the board (BD: Jun 11, 2025).

Today, Patrys said the meeting would vote on the remuneration report, a conditional spill resolution, elect directors Peter Christie, Dr Uvarov and Dr Campbell, approve the placement capacity, renew constitutional proportional takeover provisions, ratify placement shares and options and approve director participation in the placement. Patrys was up 0.1 cents or 100 percent to 0.2 cents with 5.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it will release 10,000,000 shares from voluntary escrow on September 17. According to its most recent notice, Neurotech had 1,049,621,921 shares on issue. Neurotech was up 0.1 cents or 7.1 percent to 1.5 cents with 4.9 million shares traded.

PATRYS

Patrys director Dr Anton Uvarov says he has become a substantial shareholder in the company with 250,000,000 shares or 5.45 percent.

Dr Uvarov said he acquired 200,000,000 shares for \$200,000 on September 4, 2025, and 50,000,000 shares as free attaching shares.

In June, Patrys said it had "commitments" to raise \$308,362 at 0.1 cents a share in a placement, along with \$50,000 from Dr Uvarov, subject to approval (BD: Jun 11, 2025).

EMYRIA

Perth's Dr Stewart Washer and Dr Patrizia Washer say they have been diluted in Emyria from 54,788,694 shares (14.25%) to 54,788,694 shares (8.25%).

Dr Stewart Washer said they were diluted on through the issue of entitlement shares. Emyria fell half a cent or 10.2 percent to 4.4 cents with 7.9 million shares traded.