Biotech Daily

Thursday May 15, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: AMPLIA UP 27%; ACTINOGEN, CYNATA DOWN 8%**

*** AMPLIA: 'AMP945, CHEMO BEATS PANCREATIC CANCER CHEMO ALONE'**

*** IMMUTEP: 'EFTI 60% RESPONSE, 90% CONTROL IN LUNG CANCER'**

*** CHIMERIC: '2 OF 3 BLOOD CANCER PATIENTS COMPLETE RESPONSE'**

*** MESOBLAST: FDA 7-YEAR RYONCIL ORPHAN EXCLUSIVITY**

*** MEDADVISOR SHARE PLAN RAISES $2.7m; TOTAL $7.7m**

*** IMEX $1m SHARE PLAN RAISES $103k; TOTAL $2.6m**

*** PARADIGM US PHASE III KNEE OSTEOARTHRITIS ETHICS APPROVAL**

*** RHYTHM, MELBOURNE UNI 12-MONTH GENETYPE STUDY**

*** EPSILON 6-WEEK LOAN NOTES RAISE $335k OF $1m**

*** PROTEOMICS OXIDX CHINA PATENT**

*** MAYNE PLEADS 'SCHULTZ, FDA LETTER' TO ASX 12% PRICE FALL QUERY**

*** COURT APPROVES MAYNE, COSETTE SCHEME MEETING**

*** HERAMED REQUESTS 'MATERIAL UPDATE, US STRATEGY' TRADING HALT**

*** UNISUPER INCREASES, DILUTED BELOW 5% OF BOTANIX**

MARKET REPORT

The Australian stock market was up 0.22 percent on Thursday May 15, 2025, with the ASX200 up 17.9 points to 8,297.5 points. Fifteen of the Biotech Daily Top 40 companies were up, 18 fell, six traded unchanged and one was untraded.

Amplia was the best, up 1.5 cents or 27.3 percent to seven cents, with 88.1 million shares traded. Immutep improved 7.1 percent; Impedimed was up 6.45 percent; Nova Eye and Optiscan were up four percent or more; Cyclopharm climbed 3.5 percent; Proteomics and Universal Biosensors rose more than two percent; Aroa, Clarity, Mesoblast and Micro-X were up more than one percent; with Clinuvel, Cochlear, Emvision, Nanosonics, Pro Medicus and Resmed up by less than one percent.

Actinogen and Cynata led the falls, both down 7.7 percent to 2.4 cents and 18 cents, respectively, with 28.1 million shares traded and 653,284 shares traded, respectively. Paradigm lost seven percent; 4D Medical, Botanix and Medadvisor were down five percent or more; Avita, Dimerix and Orthocell fell more than four percent; Curvebeam and EBR were down more than three percent; Prescient and Resonance shed two percent or more; Compumedics, Medical Developments, Neuren, Polynovo and Telix were down more than one percent; with CSL down by 0.6 percent.

AMPLIA THERAPEUTICS

Amplia says its 55-patient, phase Ib/IIa trial shows narmafotinib, or AMP945, with chemotherapy “is superior to chemotherapy alone”, with 15 partial responses.
Amplia managing-director Dr Chris Burns told Biotech Daily that the company’s statistician had nominated 15 partial responses of the 55 patients (27.3%) as the benchmark compared to the historical 23 percent rate for the single-arm trial.
Dr Burns said that there were more than 10 patients on the trial at an early stage and yet to be assessed for partial responses.
In April, the company said 11 of 29 advanced pancreatic cancer patients had partial responses following narmafotinib and chemotherapy therapy (BD: Apr 29, 2025).
Today, Amplia said a confirmed partial response was where tumor shrinkage greater than 30 percent was recorded and sustained for two or more months, with no new cancerous lesions detected.
The company said “at the outset of the study a statistical analysis was performed which identified that … 50 patients would be sufficient to allow the efficacy of our combination to be ascertained with reasonable confidence if 15 or more responders were recorded”.
Amplia said 55 advanced pancreatic cancer patients had been enrolled in the study, with 21 patients still on the study at this time.
The company said narmafotinib continued to be well-tolerated, with adverse events similar for the combination and chemotherapy monotherapy.
Dr Burns said the company was “extremely excited to have now recorded 15 confirmed partial responses in the ‘Accent’ trial, demonstrating the benefit of adding narmafotinib to standard-of-care chemotherapy”.
Amplia was up 1.5 cents or 27.3 percent to seven cents with 88.1 million shares traded.

IMMUTEP

Immutep says its 51-patient, phase I trial of efti, Keytruda and chemotherapy shows a 60.8 percent response rate and 90.2 percent disease control rate for lung cancer.
In January, Immutep said it had enrolled its 50-patient, phase I trial of subcutaneous eftilagimod alpha, or ‘efti’, with Keytruda and chemotherapy for non-small cell lung cancer, with data expected “in 2025” (BD: Jan 19, 2025).
Today, the company said 31 patients had a recorded response, which was “a substantial improvement compared to historical control of 48.0 percent”.
Immutep said 46 patients (90.2%), had disease control and that efti continued to have favorable safety for lung cancer, with “no new safety signals”.
The company said 47 of the 51 evaluable patients (92.2%) had a programmed death-ligand-1 (PD-L1) tumor proportion score (TPS) of less than 50 percent, including 22 patients with PD-L1 below one, demonstrating a “high unmet need” and representing more than two-thirds of first-line non-small cell lung cancer patients.
Immutep said the trial showed “significant improvement of overall response rate … across all levels of PD-L1 expression compared to historical control” including 75 percent objective response rate compared to 62.1 percent in historical controls.
The company said objective response rate was 64.0 percent with the efti combination compared to 49.2 percent historically in patients with low PD-L1 expression and 54.5 percent compared to a historical 32.3 percent in patients with negative PD-L1 expression.
Immutep said the results from an investigator-led Insight-003 trial by the Frankfurt Institute of Clinical Cancer Research and other centres was the third arm of its phase I trial, with further data expected to be presented at a conference late this year.
Immutep was up two cents or 7.1 percent to 30 cents with 8.2 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric says two of three evaluable blood cancer patients in its phase Ib trial of its core natural killer (Core NK) cells have had a complete response with remission.
Last year, Chimeric said it had dosed the first patient in its up-to 20-patient, phase Ib trial of its CHM0201 natural killer (NK)-cells therapy in combination with standard-of-care azacitidine and venetoclax for acute myeloid leukaemia (AML); and later, said it had dosed the first cohort of three patients (BD: Feb 8, Jun 5, 2024).
Later, the company said it had opened its 20-patient, phase Ib trial of CHM0201 to enrol 12 patients with newly diagnosed AML (BD: Dec 16, 2024).
Today, Chimeric said the results were from three patients in the cohort of newly diagnosed acute myeloid leukaemia patients who were ineligible for transplantation and had not been previously treated for the disease; and the third patient had “achieved stable disease, whereby the cancer is neither increasing nor decreasing in extent or severity”.
The company said trial completion was “subject to satisfactory enrolment of sufficient eligible patients”, which it expected by 2026.
Chimeric chief executive officer Dr Rebecca McQualter said the results were “great news for newly diagnosed AML patients who may benefit from our Core NK cells as their initial AML therapy”.
Chimeric was up 0.3 cents or 60 percent to 0.8 cents with 184.9 million shares traded.

MESOBLAST

Mesoblast says it has an exclusive, seven-year orphan drug approval from the US Food and Drug Administration for Ryoncil for acute graft versus host disease.
Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil, or remestemcel-L, for steroid-refractory acute graft versus host disease (GvHD) in children aged two months and older (BD: Dec 19, 2024).
In February, the company said Ryoncil would cost $US194,000 ($A308,616) wholesale per intra-venous infusion (BD: Feb 27, 2025).
At that time, Mesoblast said that 375 US children were diagnosed with GvHD a year and that it cost about $US2.5 million to treat a child who died of GvHD within a year of transplant and a further $US1.8 million for those who remained alive.
Today, the company said the exclusivity period meant that the FDA would not approve another mesenchymal stromal or stem cell product for the indication for seven years.
Mesoblast said that it separately had biologic exclusivity preventing another sponsor from referencing the Ryoncil biologic licence application until December 2036, 12 years from its first approval, which would prevent market entry by a similar product.
Mesoblast was up two cents or 1.1 percent to $1.80 with 12.7 million shares traded.

MEDADVISOR

Medadvisor says it has raised $2,668,000 in a share plan at 10 cents a share, taking the total raised with its $5 million institutional placement to $7.7 million.
Last month, Medadvisor said it raised $5 million at 10 cents a share and hoped to raise $2 million from a share plan, with funds to be used to “continue executing the strategic and cost optimization initiatives and working capital” (BD: Apr 1, 2025).
Today the company said that it had accepted oversubscriptions in the share purchase plan and that the placement included $375,000 from its directors, subject to shareholder approval at an extraordinary general meeting on June 27, 2025.
Medadvisor fell half a cent or 5.15 percent to 9.2 cents with 1.4 million shares traded.

IMEX HEALTH SERVICES

Imex says it has raised $103,000 of a hoped-for $1.0 million in a share purchase plan at 3.5 cents a share, taking the total with its $2.5 million placement to $2.6 million.
Last month, Imex said it had raised $1.5 million at 35 cents a share in a placement and a further $1.0 million in a conditional placement to its directors, with an up-to $1.0 million, non-underwritten share purchase plan to follow (BD: Apr 3, 2025).
Imex fell half a cent or 1.5 percent to 33 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has US ethics approval for a 446-patient, phase III trial of injectable pentosan polysulfate sodium (PPS) for moderate to severe knee osteo-arthritis pain.
Last year, Paradigm said the US Food and Drug Administration approved its open-label, randomized, double-blind phase III trial of PPS for knee osteo-arthritis, focusing on pain reduction and functional improvement (BD: Nov 28, 2024).
Today, the company said it expected to conduct the trial at up-to 55 sites in the US, “with many sites already selected and preparing for trial start-up”.
Paradigm said it expected to enrol the first US patient by October 2025.
The company said the primary endpoint was a change from baseline in average daily pain score at day 112.
Paradigm managing-director Paul Rennie said US ethics approval was “a major step forward for Paradigm as we expand our global phase III program”.
“With clinical sites across the US now preparing to activate, we are entering a pivotal phase of clinical development that brings us closer to delivering a first-in-class treatment for the millions affected by knee osteoarthritis,” Mr Rennie said.
Paradigm fell 2.5 cents or seven percent to 33 cents with 4.4 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says its recently acquired subsidiary Genetype has a 12-month deal to provide its breast cancer risk assessment for a study with the University of Melbourne.
Last year, Rhythm said it would acquire Genetic Technologies’ Genetype risk assessment test for various diseases for $625,000 in cash; and later, said it had its first commercial sale for an undisclosed price (BD: Jan 19, Mar 19, 2025).
Today, the company said the University of Melbourne would conduct a study in Australian women aged 40-to-59 years old, with an aim to improve breast cancer screening, incorporating major risk factors like family history, mammographic breast density and a polygenic risk score.
Rhythm said the study would “evaluate attitudes and willingness to engage in this risk-stratified screening, while qualitative interviews will provide insights into participants' understanding and acceptance of the intervention that will personalize screening recommendations according to their risk”.
The company said the study would cover the costs of any additional imaging required due to any identified risks.
Rhythm director of clinical and scientific affairs Dr Erika Spaeth said the study continued “to strengthen the business case supporting the Genetype acquisition”.
Rhythm fell 0.1 cents or 1.6 percent to 6.3 cents.

EPSILON HEALTHCARE

Epsilon says it has issued 16,750,000, six-week, loan notes at 2.0 cents per note, raising $335,000, with the potential to raise up to $1,000,000.
Epsilon said that the 50,000,000 maximum number of loan notes had an interest rate of 10 percent per annum and a redemption date of June 30,2025.
The company said the notes “complemented … recent cost-reduction initiatives”.
Epsilon chair Alan Beasley said “the funds raised will allow [the company] to continue the ongoing work of investing in the business and undertake activities necessary to lift the suspension of trading of the company’s shares”.
“The structure of the loan note raising is intended to provide minimal dilution to existing shareholders and reflects our commitment to protecting shareholder value,” Mr Beasley said.
Epsilon said that, subject to shareholder approval, the notes could be converted into shares at the election of the noteholder, in lieu of being redeemed by the company.
Epsilon was in a suspension and last traded at 2.4 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has been granted a patent in China protecting its Oxidx finger-prick blood test for measuring oxidative stress.
Proteomics said the patent, titled ‘Methods for measuring relative oxidation levels of a protein’, would protect its intellectual property in China until March 2039.
The company said it had original patents protecting Oxidx in Australia and the US, which were valid until 2026 and 2028, respectively, with a second-generation patent pending in the US, Singapore and India.
Proteomics was up 0.75 cents or 2.1 percent to 36.75 cents.

MAYNE PHARMA

Mayne Pharma has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said that the company’s share price dropped 12.1 percent from $6.79 a share at the close of trading on May 13, 2025 to a low of $5.97 yesterday, and noted a significant increase in the volume of shares traded.
Mayne said it was aware that “on May 12, 2025 US time the US Food and Drug Administration published on its website an ‘untitled letter’ received by Mayne Pharma on April 28, 2025 US time, related to certain promotional claims used in a speaker presentation for Nextstellis”.
The company said it could “only assume that the recent trading is due to market speculation about the perceived implications of the FDA untitled letter”.
Mayne said its view was that “in and of itself, the FDA untitled letter is not materially price sensitive” and confirmed that it had a near finalized response to the letter which it proposed to provide to the FDA within the prescribed timeframe.
Separately, the company said it had withdrawn a speaker presentation related to its Nextstellis contraceptive, following the FDA letter which related to promotional claims for its Nextstellis, or drospirone and estetrol, tablet.
Mayne said the untitled FDA letter did not impact its ability to sell and distribute Nextstellis in the US.
Mayne Pharma was up 47 cents or 8.2 percent to $6.20 with 4.8 million shares traded.

MAYNE PHARMA GROUP

Mayne Pharma says it has Supreme Court of New South Wales approval to convene a shareholder meeting to vote on its proposed acquisition by Cosette Pharmaceuticals.
Earlier this year, Mayne said that the Bridgewater, New Jersey-based Cosette Pharmaceuticals Inc would buy it for $7.40 a share in cash, valuing the company at $672 million (BD: Feb 21, 2025).
The meeting will be held at 495 Collins Street, Melbourne on June 18, 2025 at 10am (AEST).

HERAMED

Heramed has requested a trading halt to announce “a material customer update and its go-to-market strategy in the US due to changes in the business environment”.
Trading will resume on May 19, 2025, or on an earlier announcement.
Heramed last traded at 1.9 cents.

BOTANIX PHARMACEUTICALS

Melbourne’s Unisuper says it has increased and been diluted below the five percent substantial threshold in Botanix, following a capital raising.
Unisuper said that on May 9, 2025 it bought 16,672,242 shares, which increased its holding from 80,730,536 shares (5.14%) to 97,402,778 shares, but did not disclose the consideration given for the shares as required under the Corporations Act (2001).
Earlier this month, Unisuper said it became substantial in shareholder in Botanix with 100,455,466 shares, or 5.14 percent (BD: May 2, 2025).
According to its latest filing, Botanix had 1,953,940,463 shares on offer, with Biotech Daily calculating Unisuper retained 4.985 percent of the company.
Earlier this year, Botanix said it had “firm commitments” to raise $40 million at 33.0 cents a share, a 7.0 percent discount to its last traded price, in a non-underwritten institutional placement (BD: Apr 15, 2025).
Botanix fell two cents or five percent to 38 cents with 6.9 million shares traded.