Biotech Daily

Monday September 15, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMMUTEP UP 13%; ATOMO DOWN 4.55%**

*** ONCOLOGY ONE, PFIZER PHASE III PF-07248144 BREAST CANCER TRIAL**

*** CE MARK FOR AVITA RECELL GO**

*** ADHERIUM CLAIMS COPD, ASTHMA SMARTINHALER ADHERENCE**

*** PACIFIC EDGE: NOVITAS PANEL TO REVIEW CXBLADDER COVERAGE**

*** BIOXYNE: GERMANY BUYS $5.1m, 1.6t MARIJUANA FLOWERS**

*** ACTINOGEN: FDA WANTS PIVOTAL XANAMEM ALZHEIMER'S TRIAL**

*** CLEO, FDA 2nd MEETING FOR OVARIAN CANCER TEST**

*** EMVISION REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** EMYRIA SELLS 9m SHARE FACILITY**

*** COGSTATE 592k CEO BRAD O'CONNOR RIGHTS AGM**

MARKET REPORT

The Australian stock market fell 0.13 percent on Monday September 15, 2025, with the ASX200 down 11.9 points to 8,853.0 points. Twenty-two of the Biotech Daily Top 40 companies were up, 11 fell, six traded unchanged and one was untraded.

Immutep was the best, up three cents or 13.0 percent to 26 cents, with 5.85 million shares traded. Avita climbed 10.1 percent; EBR, Imugene, Mesoblast, Nova Eye and Polynovo improved five percent or more, Dimerix, Medadvisor, Nanosonics and Starpharma were up more than four percent; Actinogen was up 3.7 percent; Cynata, Impedimed and Telix rose more than two percent; 4D Medical, Clinuvel, Cochlear, Compumedics and Medical Developments were up one percent or more; with Cyclopharm, Neuren and SDI up by less than one percent.

Friday's 22.2 percent best, Atomo, led today's falls, down 0.1 cents or 4.55 percent to 2.1 cents, with 4.8 million shares traded. Curvebeam lost 3.85 percent; Imricor, Prescient and Proteomics shed more than two percent; Alcidion, Aroa, CSL, Micro-X, Orthocell, Pro Medicus and Resmed were down more than one percent; with Clarity and Genetic Signatures down by less than one percent.

ONCOLOGY ONE PTY LTD (FORMERLY CTXONE)

Melbourne's Oncology One says Pfizer has begun an up to 400-patient, phase III trial of PF-07248144, licenced from its KAT6 inhibitor program, for breast cancer.

Oncology One said the Pfizer phase III 'Katsis-1' trial would study PF-07248144 in combination with fulvestrant in patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative, advanced or metastatic breast cancer who had progressed after a prior line of treatment.

The company said that PF-07248144 was a selective catalytic inhibitor of lysine acetyl-transferase 6 (KAT6), which was involved in the regulation of gene expression, with dysregulated KAT6 gene activity promoting cancer cell growth in "certain cancers".

Oncology One said PF-07248144 suppressed this abnormal gene activity, thereby suppressing cancer growth, with previous trials showing "promise for treating advanced or metastatic hormone receptor positive, HER2-negative breast cancer".

The company said that, in 2009, the KAT6 project was licenced to Melbourne's Cancer Therapeutics Cooperative Research Centre (CTx), a cooperative network funded by the Federal Government and participating organizations, and was further developed by CTx and later licenced to Pfizer in 2018 by Oncology One (formerly CTx One Pty Ltd).

In 2021, Oncology One said it was "the original management company and then a commercialization partner of the CRC] for Cancer Therapeutics, a 2007 collaboration of research institutes, universities and companies (BD: Jul 27, 2021).

At the time, the company said it had licenced technology "related to a class of cancer drugs" to Pfizer in 2018, in a deal worth up to $US475 million ($A713 million) in development milestones, with additional royalties on sales if the technology was successful, and that PF-07248144 began phase I clinical trials in 2020 for the potential treatment of patients with advanced or metastatic breast, prostate or lung cancer.

Today, Oncology One said early detection had improved the overall survival rate of breast cancer, but that an estimated 10,000 to 12,000 Australians were living with metastatic disease, with the most common cancer type, HR+ HER2- metastatic breast cancer, responsible for about 2,500 deaths each year, or six Australians a day, indicting a clear need for better treatment of this disease.

Oncology One scientific advisory board chair Prof Ian Street said that "in the early 2000s at Walter and Eliza Hall Institute (WEHI), Prof Anne Voss and Prof Tim Thomas made foundational discoveries about KAT6A, a protein that is important for controlling gene expression during development and growth of some blood cancers".

"Many CTx research and industry partners - Monash Institute of Pharmaceutical Sciences, Synthesis Med Chem, Peter MacCallum Cancer Centre, WEHI, CSIRO, Griffith University, St Vincent's Institute of Medical Research, and the Children's Cancer Institute, along with Pfizer, have worked together to develop a new drug that targets KAT6," Prof Street said.

"This is a deeply inspiring story of collaboration in Australia's medical research sector," Prof Street said.

"I would like to congratulate the visionary and talented Australian scientists and clinicians who contributed to the discovery and development of PF-07248144 - and of course, share our sincere gratitude to Pfizer for backing this potential cancer therapeutic so quickly into a phase III clinical trial," Prof Street said.

Oncology One said that "if successful, PF-07248144 is on track to become a therapeutic in a completely new class of drugs, which essentially turns off cancer cells and stops them from multiplying".

The company said the Pfizer Katsis-1 trial was published on clinicaltrials.gov with the reference NCT07062965.

Oncology One is a private company.

AVITA MEDICAL

Avita says it has Conformité Européenne (CE) mark certification to sell its Recell Go spray-on-skin in the European Union.

Avita said it would begin commercialization of Recell Go in Germany, Italy and the UK, in collaboration with burn centers and clinical partners.

Avita chief executive officer Jim Corbett said that CE mark for Recell Go was “an important milestone for Avita Medical and for patients”.

“It enables us to bring this option to burn centers and clinicians in Europe to support their treatment of patients with acute wound injuries,” Mr Corbett said.

Avita said that Recell Go was a point-of-care device used by healthcare professionals to prepare a suspension of a patient’s own skin cells from a small sample of healthy skin.

The company said that the cells were applied to promote healing in burns and traumatic or surgical wounds.

Avita said that Recell Go built on the Recell spray-on skin system in use across Europe.

Avita was up 13.5 cents or 10.1 percent to $1.475 with 1.5 million shares traded.

ADHERIUM

Adherium says a study of 850 patients shows that chronic obstructive pulmonary disease and asthma patients used its Smartinhaler “far more” than typical inhaler use.

Adherium said the published norms for inhaler adherence were 20 to 40 percent, with its study showing the average two-week baseline adherence for its Smartinhaler was 62 percent, with about 40 percent of patients reaching the critical threshold of more than 80 percent adherence, which was associated with “50 percent fewer respiratory attacks”.

The company said a separate analysis of about 700 patients showed “clinically meaningful improvements” in multiple respiratory care dimensions, including reduction in inpatient admission, 30-day readmissions, average length of stay and lower reliance on rescue medications, resulting in decreases in the overall cost of care.

Adherium said the study also showed “strong persistence” of its Carecentra remote patient monitoring platform, with more than half of its active users staying engaged for more than a year, outpacing expectations typically reported in such programs, with engagement highest in elderly, high risk patients, including those with depression.

In 2015, Adherium listed on the ASX to develop "technologies that address suboptimal medication use and remote patient management in chronic disease” (BD: Aug 27, 2015).

At the time, the company said clinical data had shown the Smartinhaler could improve adherence by up to 59 percent in adults and 180 percent in children with asthma, with severe episodes reduced by 60 percent in adults with asthma.

In October 2015, Adherium said data from three UK studies showed the efficacy of its Smartinhaler platform in paediatric asthma management (BD: Oct 1, 2015).

Today, Adherium chief executive officer Dawn Blitz said “these interim results prove that digital health can deliver both measurable patient impact and health system value at scale. By combining innovative connected inhaler technology with Carecentra’s [artificial intelligence]-driven behavioral engagement, we are not only improving adherence but also validating a sustainable, value-based care model”.

“At the same time, outpatient encounters are increasing, reflecting earlier, proactive interventions that prevent costly crisis-level exacerbations,” Ms Blitz said.

“Together, these shifts demonstrate I-Care’s potential to fundamentally bend the cost curve in respiratory disease management … an outcome highly aligned with payer priorities in both US and Australian markets,” Ms Blitz said.

Adherium was unchanged at half a cent with 30.4 million shares traded.

PACIFIC EDGE

Pacific Edge says its Medicare administrative contractor (MAC) Novitas intends to convene a panel to consider coverage for tests including its Cxbladder triage.

In April, Pacific Edge said local coverage determination changes by its US Medicare administrative contractor Novitas halted coverage of its Cxbladder urine test, and later said the US Centers for Medicare and Medicaid Services proposed a draft 'gap-fill' price for its Cxbladder Triage Plus of $US1,018 (BD: Apr 28, 29, 2025).

Today, the company said the panel was likely be convened in early 2026 to consider coverage for tests mentioned in the 2025 update to the American Urological Association micro-haematuria guideline and work on aligning Medicare policy with the new guidelines.

Pacific Edge said the contractor advisory committee meetings "generally precede the draft issuance of a new or substantially revised local coverage determination".

Pacific Edge chief executive Dr Peter Meintjes said the company was "pleased that Novitas has acknowledged the importance of the [American Urological Association] micro-haematuria guideline and is taking a robust and credible approach to policy development by convening a panel of urologists who understand the latest update to the guideline".

Pacific Edge was up 4.5 cents or 32.1 percent to 18.5 cents.

BIOXYNE

Bioxyne says its German local partner has received import authorization from the German Government for 1,550kg of medical marijuana flower products.

In June, Bioxyne said it had an EUR3,200,000 ($A5,637,490) marijuana manufacturing and supply deal with the Koblenz, Germany-based Adrex Pharmaceuticals GmbH and the Bohova, Slovenia-based Farmakem d.o.o., with the deal committing the companies to buy and distribute a minimum 1,600 kilograms of its medical marijuana flower and finished product, which it expected to generate a minimum of $5.6 million revenue for the year to June 30, 2026 (BD: Jun 18, 2025).

Today, the company said it received $5.1 million in purchase orders from German clients, with exports to Germany planned for the end of September or early October.

Bioxyne was up 0.2 cents or five percent to 4.2 cents with 4.9 million shares traded.

ACTINOGEN MEDICAL

Actinogen says the US Food and Drug Administration has requested further clinical data to market Xanamem for Alzheimer's disease, including a phase III trial.

Actinogen said it had reached an understanding with the FDA following a type-C meeting that included the "regulatory starting materials" required to commercially manufacture Xanamem, or 'emestedastat', as well as general design of the interim analysis for its 'Xanamia', 220-patient, phase IIb/III trial of Xanamem for Alzheimer's disease.

The company said it had also agreed to the design of one additional, controlled phase III trial to support a "positive Xanamia pivotal trial", including a single dose design of 10mg compared to placebo, as well as the number of people to be treated with Xanamem to be described in the new drug application.

Actinogen said it would conduct a "small number" of ancillary clinical pharmacology trials and that non-clinical studies were required to "further characterize the metabolism and excretion pathways of Xanamem".

The company said the outcome from the meeting was a "major milestone" as it prepared for a new drug application in the US and submissions to other regulators.

Actinogen was up 0.1 cents or 3.7 percent to 2.8 cents with 12.6 million shares traded.

CLEO DIAGNOSTICS

Cleo says it has “positive feedback” from a second 510(k) pre-submission meeting with the US Food and Drug Administration for its ovarian cancer pre-surgical triage test.
Last year, Cleo said it had “constructive and positive feedback” from the FDA on the approval process for its ovarian cancer detection blood test, with an initial pre-submission meeting with the FDA “designed to permit Cleo to receive early guidance from FDA review teams prior to an eventual application submission” (BD: Jun 26, 2024).
Today, the company said that, in a second pre-submission meeting, the FDA offered “positive and detailed feedback” that reinforced its clinical trial and “broader strategic direction”, and that enabled it to further strengthen data collection to support its submission.
Cleo said it discussed trial design, sample stability, the use of bio-bank samples and clinical specificity of the test with the FDA, as well as the test’s use and clinical workflow.
Cleo chief executive officer Dr Richard Allman said “this second round of positive feedback from the FDA marks another important milestone in our regulatory journey”.
“The FDA’s guidance enables us to strengthen our trial design and move forward with greater confidence in our 510(k) strategy,” Dr Allman said.
“It supports our approach and underscores the opportunity Cleo has to deliver a clinically meaningful and accessible solution to support more appropriate surgical triage for ovarian cancer,” Dr Allman said.
Cleo was up three cents or eight percent to 40.5 cents with 1.5 million shares traded.

EMVISION MEDICAL DEVICES

Emvision has requested a trading halt pending an announcement “regarding a capital raising”.
Trading will resume on September 17, 2025 or an earlier announcement.
Emvision last traded at $2.32.

EMYRIA

Emyria says it has sold 9,124,870 shares at five cents a share through its un marketable parcels facility to a “consortium of specialist life sciences investors”.
In July, Emyria said it had an unmarketable parcels facility for holders of shares worth less than $500, or 2.9 cents a share, at the record date of July 15, 2025 (BD: Jul 18, 2025).
At the time, the company said that an unmarketable parcel was 17,241 shares or fewer and that the shares would “be sold on-market or as otherwise determined by the directors after the closing date at or above the prevailing market price”.
Today, Emyria said the proceeds would be distributed to eligible shareholders as soon as practicable, with the facility conducted to “allow smaller shareholders the opportunity to sell their shares without having to use a broker or pay brokerage”, providing an opportunity to dispose of shares in a cost-effective manner.
The company said the acquisition of the shares by the consortium at a 6.38 percent premium to its last traded price of 4.7 cents on September 12, 2025 was a “strong validation” of its growth trajectory and its expansion to a “national network of third-party funded mental health treatment clinics”.
Emyria said the consortium investors were introduced by GBA Capital Pty Ltd.
Emyria was up 0.2 cents or 4.3 percent to 4.9 cents with 1.5 million shares traded.

COGSTATE

Cogstate says its annual general meeting will vote to issue 591,822 performance rights to chief executive officer Bradley O'Conno, pending performance hurdles.

Cogstate said the rights were part of Mr O'Connor's long term incentive remuneration, and were in addition to his $US457,000 annual salary, as well as up-to $US228,500 in short term incentives.

The company said shareholders would also vote to adopt its remuneration report, re-elect Martyn Myer and Ingrid Player as directors, and renew the employee equity plan.

The meeting will be held on-line and at Pitcher Partners, Level 13, 664 Collins Street, Docklands on October 16, 2025 at 11am (AEDT).

Cogstate was up 15 cents or 8.5 percent to $1.91.