Biotech Daily

Tuesday June 17, 2025

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: AMPLIA UP 15%; IMUGENE DOWN 7%**

*** CSL: FDA APPROVES ANDEMBRY FOR HEREDITARY ANGIOEDEMA**

*** MICRO-X $2.3m FULL-BODY CT, BAGGAGE CT MILESTONE PAYMENTS**

*** FLINDERS UNI LINKS SLEEP APNOEA, CLIMATE CHANGE**

*** 4D MEDICAL, STANFORD UNI EXTEND CT LVAS CONTRACT**

*** CLARITY, SPECTRONRX PRODUCE CU-64 SAR-BIS-PSMA**

*** RACE 'TERMINATES' CITY OF HOPE BISANTRENE LICENCE**

*** LUMOS FEBRIDX IN WOLLONGONG UNI TRIAL**

*** RECCE TAKES UP-TO $30m AVENUE CAPITAL DRAW-DOWN FACILITY**

*** CHIMERIC 4 PHASE I/II PATIENTS EXPANDED CAR-T CELLS AT 1 MONTH**

*** REGAL TAKES 9% OF GENETIC SIGNATURES**

*** REGAL INCREASES, DILUTED TO 7% OF RADIOPHARM**

*** WASHINGTON H SOUL PATTINSON, BRICKWORKS DILUTED TO 5% OF ENLITIC**

*** OPYL APPOINTS MATT HALLAM CHIEF REVENUE OFFICER**

*** PATRYS $536k M-D DR JAMES CAMPBELL REDUNDANCY**

MARKET REPORT

The Australian stock market slipped 0.08 percent on Tuesday June 17, 2025, with the ASX200 down 7.1 points to 8,541.3 points. Sixteen of the Biotech Daily Top 40 companies were up, 14 fell and 10 traded unchanged.

Amplia was the best for the second day in a row, up one cent or 15.15 percent to 7.6 cents, with 8.1 million shares traded. Micro-X climbed seven percent; Paradigm was up 6.9 percent; Aroa, Nova Eye, Prescient and Proteomics improved four percent or more; Genetic Signatures was up 3.6 percent; Alcidion, EBR and Immutep rose two percent or more; Medadvisor, Orthocell and Syntara were up more than one percent; with Clarity, CSL and Cyclopharm up by less than one percent.

Imugene led the falls, down 0.1 cents or 6.7 percent to 1.4 cents, with 29.8 million shares traded. Atomo fell 5.9 percent; Compumedics and Cynata lost three percent or more; Nanosonics and Starpharma shed more than two percent; Avita, Cochlear, Curvebeam, Dimerix and Mesoblast were down one percent or more; with Clinuvel, Emvision, Neuren, Pro Medicus, Resmed and Telix down by less than one percent.

CSL

CSL says the US Food and Drug Administration has approved its factor XIIa inhibitor Andembry for preventing hereditary angioedema (HAE) attacks.

Earlier this year, CSL said it had Australian Therapeutic Goods Administration approval for Andembry, or garadacimab, and formerly CSL312, for the prevention of recurrent hereditary angioedema (BD: Jan 28, 2025).

Today, the company said Andembry was "the first and only treatment targeting factor XIIa for prophylactic use to provide sustained protection from attacks of [hereditary angioedema] in adult and pediatric patients aged 12 years and older".

In 2017, CSL said the FDA had approved Haegarda, or human C1 esterase inhibitor, for hereditary angioedema, a rare, genetic and life-threatening condition that causes painful, debilitating and unpredictable episodes of swelling on the body, including the abdomen, face, larynx, and extremities (BD: Jun 23, 2017).

At that time, the company said Haegarda was approved to prevent hereditary angioedema attacks and was self-administered subcutaneously twice weekly.

Today, CSL said Andembry was "the only treatment to offer once-monthly dosing from the start for all patients and is administered via an auto-injector".

In its 2022 research and development briefing, the company said garadacimab was "discovered and optimized by scientists at CSL's Bio21-based research site".

At that time, CSL said it had enrolled its double-blind, placebo-controlled, randomized phase III trial of garadacimab for hereditary angioedema and had begun a phase II study of the drug for fibrosing interstitial lung disease and idiopathic pulmonary fibrosis.

Today, the company said its 64-patient, 'Vanguard' phase III trial showed 400mg followed by 200mg of Andembry monthly "reduced the median number of [hereditary angioedema] attacks by more than 99 percent and a 'least squares mean' of 89.2 percent, compared to placebo" at six-months of treatment.

CSL said it was conducting a 160-patient, two-year, open-label extension of the phase III study which was evaluating the long-term safety and efficacy of a 200mg monthly dose of garadacimab for the prophylactic treatment of hereditary angioedema attacks.

The company said the drug was approved in the UK, the EU, Japan, Switzerland and the United Arab Emirates; with US commercialization to begin immediately.

CSL was up 19 cents or 0.1 percent to $239.29 with 576,209 shares traded.

MICRO-X

Micro-X says it has received $1,400,000 and $900,000 in milestone payments from its full-body CT and baggage and parcel CT scanner development contracts, respectively.

Last year, Micro-X said it had won $US8.15 million ($A12.75 million) from the US Advanced Research Projects Agency for Health to develop a lightweight, portable full-body computed tomography (CT) scanner over two years (BD: Dec 4, 2024).

In February, Micro-X said it would develop a baggage and parcel scanner for Billion Prima for $3.2 million using its Nex technology, x-ray tubes and generators (BD: Feb 6, 2025).

Today, Micro-X said the US Agency paid $1.4 million for submitting a technical dossier including design and architecture work for the full-body CT device "on time and in budget'.

The company said it had triggered a $900,000 payment from Billion Prima for the second milestone, which was expected to be completed in 2025.

Micro-X said it continued to progress its US Department of Homeland Security-funded project "on time and in budget", with the first self-screening checkpoint delivered to a test laboratory in May 2025 (BD: Feb 13, 2025).

Micro-X was up 0.3 cents or seven percent to 4.6 cents with 2.0 million shares traded.

FLINDERS UNIVERSITY

Flinders University says sleep apnoea will become more common and severe due to climate change because “rising temperatures increase the severity” of the disease.

Adelaide’s Flinders University said that a study showed “under the most likely climate change scenarios, the societal burden of [obstructive sleep apnoea] is expected to double in most countries over the next 75 years”.

The University said sleep apnoea disturbed breathing during sleep which affected about one billion people and, if untreated or severe, increased the risk of dementia and Parkinson’s disease, hypertension, cardiovascular disease, anxiety and depression, traffic accidents and all-cause mortality.

Flinders University said its study analyzed sleep data from more than 116,000 people using a US Food and Drug Administration-cleared, under-mattress sensor to estimate the severity of obstructive sleep apnoea.

The University said the sensor recorded about 500 separate nights of data for each user and its researchers matched the data with 24-hour temperature information sourced from climate models.

Flinders University said the study used economic modelling that measured “the wellbeing and societal burden due to increased prevalence of [obstructive sleep apnoea] from rising temperatures under several projected climate scenarios”.

The University said the study provided “further evidence of the major threat of climate change to human health and wellbeing [and] ... highlights the importance of developing effective interventions to diagnose and manage [obstructive sleep apnoea]”.

Flinders University said the research was supported by the Federal Government’s National Health and Medical Research Council (NHMRC) of Australia Fellowships.

The University said the article, titled ‘Global warming may increase the burden of obstructive sleep apnoea’ was published in the journal Nature Communications, with the full article available at: https://www.nature.com/articles/s41467-025-60218-1.

Study lead author Dr Bastien Lechat said it was “the first study of its kind to outline how global warming is expected to affect breathing during sleep and impact the world’s health, wellbeing and economy”.

“This study helps us to understand how environmental factors like climate might affect health by investigating whether ambient temperatures influence the severity of [obstructive sleep apnoea],” Dr Lechat said.

“Overall, we were surprised by the magnitude of the association between ambient temperature and [obstructive sleep apnoea] severity,” Dr Lechat said.

“Higher temperatures were associated with a 45 per cent increased likelihood of a sleeper experiencing [obstructive sleep apnoea] on a given night,” Dr Lechat said.

“Importantly, these findings varied by region, with people in European countries seeing higher rates of [obstructive sleep apnoea] when temperatures rise than those in Australia and the US, perhaps due to different rates of air conditioning usage,” Dr Lechat said.

“Using our modelling, we can estimate how burdensome the increase in [obstructive sleep apnoea] prevalence due to rising temperature is to society in terms of wellbeing and economic loss,” Dr Lechat said.

“The increase in [obstructive sleep apnoea] prevalence in 2023 due to global warming was associated with a loss of approximately 800,000 healthy life years across the 29 countries studied,” Dr Lechat said. “This number is similar to other medical conditions, such as bipolar disorder, Parkinson’s disease or chronic kidney diseases.”

“Our findings highlight that without greater policy action to slow global warming, [obstructive sleep apnoea] burden may double by 2100 due to rising temperatures,” Dr Lechat said.

4D MEDICAL

4D Medical says it has a one-year contract extension with California's Stanford University for its computed tomography (CT) lung ventilation analysis software (LVAS).

4D Medical managing-director Prof Andreas Fouras told Biotech Daily that the Stanford University contract was acquired through its 2023 purchase of the Minneapolis, Minnesotta-based Imbio imaging company (BD: Dec 11, 18, 2023).

The company said that under the renewed, one-year subscription agreement, Stanford University had licenced its image analysis products including up-to 20,000 CT scan analyses a year.

4D Medical said Stanford University had expanded the agreement to include its CT LVAS, IQ-UIP artificial intelligence-based software for detecting usual interstitial pneumonia patterns to aid in diagnosing fibrotic interstitial lung diseases and CT ventilation perfusion (VQ) contrast-free ventilation perfusion product.

The company said the products would be used at Stanford University's three-dimensional quantitative imaging laboratory, which was "recognized for its role in evaluating, validating and operationalizing next-generation imaging technologies across clinical research and patient care".

4D Medical said the agreement validated its "strategic focus on delivering next-generation pulmonary imaging capabilities to meet urgent healthcare needs".

The company did not disclose the commercial terms of the agreement.

4D Medical managing-director Prof Andreas Fouras said Stanford's 3D quantitative imaging laboratory was "one of the most influential medical imaging research centres in the world, and the renewal and expansion of their contract shows the value they see in 4D Medical's technology".

"In addition, their decision to also include our CT VQ technology in the contract, ahead of FDA clearance, is an extraordinary validation of the strength of the interest in this revolutionary product," Prof Fouras said.

"CT VQ's inclusion at Stanford will accelerate both clinical insight and market momentum, as we move closer to FDA clearance and large-scale US deployment," Prof Fouras said.

4D Medical was unchanged at 26.5 cents with 2.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says the Indianapolis, Indiana-based Spectronrx will manufacture copper-64 Sar-Bis-prostate specific membrane antigen (PSMA) for its prostate cancer diagnostic.

Last year, Clarity said Spectronrx would produce copper-64 isotope and copper-64 Sar-Bis-PSMA for its phase III trial (BD: Nov 30, 2023; Oct 8, 2024).

Today, the company said its additional commercial manufacturing agreement would provide "on-demand commercial-scale manufacturing of both copper-64 and copper-64 Sar-Bis-PSMA under one roof and enable distribution to all 50 [US] states".

Clarity said Spectronrx could produce up-to 400,000 patient-ready doses yearly from one facility and that with its existing supply and manufacturing deals the deal "substantially bolsters reliable, universal access to copper-64 Sar-Bis-PSMA in the US for a commercial rollout", subject to phase III trial success and regulatory approval.

The company said the five-year contract included options to expand production to additional US sites and was effective from June 17, 2025, with cancellation and extension provisions "aligned with industry standard rates".

Clarity was up one cent or 0.45 percent to $2.24 with 3.2 million shares traded.

RACE PHARMACEUTICALS

Race says it has terminated its exclusive licence of the City of Hope's intellectual property relating to bisantrene following legal and intellectual property advice.
In 2023, Race said it would pay up-to $US23,050,000 ($A34,470,580) for access to the Los Angeles-based City of Hope cancer centre's bisantrene patent application and associated information identifying bisantrene as a "potent inhibitor" of the human fat mass and obesity-associated protein (FTO) (BD: Jul 10, 2023).
Today, the company said it had "determined with senior expert legal and intellectual property advice that the City of Hope licence is no longer of value to its shareholders given the future costs required to maintain the licence".
Race said it had full freedom to operate and to utilize bisantrene in clinical and non-clinical applications, including those related to the epigenetic regulation of messenger RNA.
Race managing-director Dr Daniel Tillett said the 2023 licence agreement no longer met the needs of the company and "based on the … advice we have received we are comfortable that our intellectual property strategy affords strong … protection of RC220".
Race was up six cents or 5.3 percent to $1.19.

LUMOS DIAGNOSTICS

Lumos says its Febridx finger-prick blood test will be included in a University of Wollongong study for reducing the inappropriate prescription of antibiotics.
Lumos said Febridx was a "point-of-care test that differentiates between viral and bacterial acute respiratory infections, allowing clinicians to make more informed prescribing decisions … this will be the first time Febridx is formally evaluated in an Australian primary care setting".
Lumos said the trial was funded by a $2.7 million grant from the Federal Government's Medical Research Future Fund and would study the use of "a suite of interventions" for supporting the prescription of antibiotics in acute respiratory infection cases.
The company said it would provide 2,000 Febridx tests at a reduced cost.
Lumos managing-director Doug Ward said the company was "pleased to support an initiative aimed at reducing inappropriate antibiotic use and combating antimicrobial resistance".
Lumos fell 0.1 cents or 3.6 percent to 2.7 cents.

RECCE PHARMACEUTICALS

Recce says it has taken a $US20 million ($A30 million) draw-down debt facility at 12.75 percent annual interest with New York's Avenue Capital Group.
Recce said Avenue had committed $US12.5 million through an initial $US7.5 million and further $US5.0 million available from April 1 to September 30, 2026, subject to conditions.
The company said a $US7.5 million tranche was available from January 1 to December 31, 2027, subject to commercial traction for R327, clinical progress and approval.
Recce said the funds would be used for its two phase III registrational studies and submitting marketing authorization, as well as commercialization.
The company said it would issue Avenue Capital $US1.0 million in warrants, exercisable at the lower of the five-day volume weighted average price prior to April 8 or June 16, 2025 and the effective price of any bona fide equity raise prior to December 31, 2025 within five years from the close of the agreement; the facility had an interest only period of two years and was repayable within three years.
Recce was up two cents or 6.6 percent to 32.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says four patients receiving the first dose in its phase I/II trial show “expansion and persistence of CHM CDH17 CAR-T cells up-to 28 days”.
Last year, Chimeric said its 15-patient, phase I/II trial of CHM CDH17 chimeric antigen receptor (CAR)-T cells had advanced to its second dose level of 150 million cells, with no safety concerns at the first 50 million cell dose (BD: May 21, 2025).
Today, the company said CHM CDH17 CAR-T cells target cadherin 17, a cell surface protein that is dysregulated and overexpressed in gastro-intestinal tumors.
Chimeric said immuno-histo-chemistry data of the four subjects at dose level one confirmed “the presence of the target, cadherin 17, on the surface of the tumor cells of all the study subjects”.
Chimeric chief executive officer Dr Rebecca McQualter said “although this translational dataset represents only a small number of clinical trial subjects, CAR-T expansion and persistence is highly validating for CHM CDH17 and increases our confidence as we advance through clinical dose finding”.
Chimeric was unchanged at 0.4 cents with 1.1 million shares traded.

GENETIC SIGNATURES

Regal Funds Management Pty Ltd says it has increased its substantial shareholding in Genetic Signatures from 14,529,831 shares (6.75%) to 20,138,177 shares (8.87%).
The Sydney-based Regal said that it bought and sold shares between July 3, 2024 and June 12, 2025, with the single largest purchase 2,712,667 shares on June 12, 2025 for $976,560, or 36 cents a share.
Genetic Signatures was up 1.5 cents or 3.6 percent to 43 cents.

RADIOPHARM THERANOSTICS

Regal Funds Management says it has increased and been diluted in Radiopharm from 160,080,333 shares (8.30%) to 172,634,988 equivalent shares (7.30%).
The Sydney-based Regal Funds said that it bought, sold and disposed of shares between December 9, 2024 and May 6, 2025, with the single largest purchase 40,000,000 shares on March 31 for $1,080,000, or 2.7 cents a share and was diluted on June 12, 2025 due to the issue of shares.
Earlier this year, Radiopharm said it raised $US5.0 million ($A8.0 million) in a placement at six cents a share to Lantheus Holdings (BD: Jan 19, 2025).
Radiopharm fell 0.1 cents or 3.85 percent to 2.5 cents with 2.3 million shares traded.

ENLITIC

Sydney’s Washington H Soul Pattinson says its shareholding in Enlitic was diluted to 4.90 percent through its more than 20 percent holding in Pengana Capital Group.
Yesterday, Sydney’s Pengana said its 40,474,040 share-holding in Enlitic was diluted from 5.61 percent to 4.90 percent due to the issue of shares (BD: Jun 16, 2025).
Enlitic fell 0.4 cents or 14.8 percent to 2.3 cents with 4.6 million shares traded.

ENLITIC

Sydney’s Brickworks Ltd says its substantial shareholding in Enlitic was diluted to 4.90 percent through its 25.7 percent holding in Washington H. Soul Pattinson (see above).

OPYL

Opyl says it has appointed Matt Hallam as chief revenue officer, effective immediately.
Opyl said Mr Hallam had more than 25 years of experience and had worked for Johnson & Johnson, Medtronic and Citeline.
According to his Linkedin profile, Mr Hallam held a Bachelor of Science from England's University College Worcester.
The company said Mr Hallam would "lead strategic market expansion initiatives, forge partnerships with top-tier contract research organizations, pharmaceutical companies, and convert high-value opportunities into revenue".
Opyl was up 0.1 cents or 5.3 percent to two cents.

PATRYS

Patrys says it will pay managing-director Dr James Campbell about $535,877 under the terms of his redundancy, effective from July 1, 2025.
Last week, Patrys said it had appointed two directors, its chair and a director had resigned, and Dr Campbell would remain as director, with the chief executive officer role made redundant (BD: Jun 11, 2025).
Today, the company said Dr Campbell would take leave without pay from June 17 to 30, 2025 and was entitled to his accrued leave, unpaid salary, redundancy payments and termination payments equalling about $535,877.
Patrys said to conserve cash Dr Campbell had requested that about 43 percent of his entitlements, or $231,748, be paid through the issue of shares at 0.1 cents a share, subject to shareholder approval.
Patrys fell 0.05 cents or 33.3 percent to 0.1 cents with 3.6 million shares traded.