Biotech Daily

Tuesday June 3, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: EMVISION UP 7%; UNIVERSAL BIO DOWN 24%**

*** RMIT 'INSECT PROTEIN BLOCKS BACTERIA'**

*** TGA TAKES PHILIPS TO COURT OVER APNOEA, OTHER DEVICES**

*** COCHLEAR TO RELEASE BAHA 7 HEARING AID**

*** RECCE $7.4m RIGHTS SHORTFALL, TOTAL $15.8m**

*** PACIFIC EDGE RAISES $15m**

*** ADALTA RIGHTS RAISE $1.1m; SHORTFALL $200k**

*** EMVISION TO OPEN 2 MORE EMU BRAIN SCANNER TRIAL SITES**

*** PARADIGM RECRUITS 1st PHASE III PPS OSTEO-ARTHRITIS PATIENT**

*** INHALERX INCREASES PHASE II MARIJAUNA IRX-211 PATIENTS**

*** ARAVAX APPOINTS LOUISE PEACOCK CHIEF REGULATORY OFFICER**

*** PATRYS TAKES 'OPERATIONS UPDATE' HALT TO SUSPENSION**

*** MARK AZZI TAKES 11% OF NYRADA**

*** MWP PARTNERS REDUCES TO 8% OF ISLAND**

MARKET REPORT

The Australian stock market was up 0.63 percent on Tuesday June 3, 2025, with the ASX200 up 52.6 points to 8,466.7 points. Fifteen of the Biotech Daily Top 40 companies were up, 20 fell and five traded unchanged. The four Big Caps were mixed.

Emvision was the best, up 12 cents or 7.3 percent to $1.765, with 28,533 shares traded. Clarity climbed 5.5 percent; Curvebeam was up 4.8 percent; Avita and Cynata were up three percent or more; Alcidion rose 2.35 percent; Compumedics, Dimerix, EBR, Mesoblast, Neuren, SDI and Starpharma were up one percent or more; with Polynovo, Pro Medicus, Resmed and Telix up by less than one percent.

Universal Biosensors led the falls, down one cent or 23.8 percent to 3.2 cents, with 936,330 shares traded. Medical Developments lost 11.2 percent; Resonance retreated 9.1 percent; Nova Eye shed eight percent; Genetic Signatures fell 7.2 percent; Imugene and Medadvisor were down more than six percent; Micro-X lost 5.45 percent; Proteomics fell 4.8 percent; 4D Medical, Aroa, Clinuvel, Impedimed and Optiscan were down three percent or more; Botanix, Nanosonics and Prescient shed more than two percent; with Cochlear, CSL, Cyclopharm, Immutep and Orthocell down by one percent or more.

ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

RMIT says the resilin-mimetic proteins found in insects have potential as anti-bacterial coatings to block bacteria from attaching to surfaces.

RMIT said a study led by its researchers was “the first reported use of anti-bacterial coatings made from resilin-mimetic proteins to fully block bacteria” and could be used as spray coatings for surgical tools, medical implants, catheters and wound dressings.

The Institute said bacteria was “often found on implants following surgery, despite sterilization and infection controls” and could lead to infections requiring antibiotics.

RMIT said with antibiotic resistance becoming more common, further preventative measures were needed.

The Institute said resilin protein was “known for its remarkable elasticity, it enables fleas to jump more than a hundred times their own height in microseconds, but it’s also extremely resilient and biocompatible … [it was] “highly responsive to stimuli and changes in its environment, making it potentially tunable for many functions.

The Institute said its researchers developed several forms of coating from altered forms of resilin, then tested their interactions with Escherichia coli bacteria and human skin cells in laboratory conditions.

RMIT said the study showed “how the altered proteins in nano droplet form known as coacervates were 100 percent effective at repelling the bacteria, while still integrating well with healthy human cells, a critical part of medical implant success”.

The Institute said transitioning from laboratory to clinical use would “require ensuring the formula’s stability and scalability, conducting extensive safety and efficacy trials, while developing affordable production methods for widespread distribution”.

RMIT said the early results were promising to help improve infection control in hospitals and other medical settings, but more testing was needed to see how these coatings work against a wider range of harmful bacteria.

The Institute said the study was conducted with the Australian Research Council Centre of Excellence and the Australian Nuclear Science and Technology Organisation.

RMIT said the study was funded by the Australia India Strategic Research Fund, Australian Institute of Nuclear Science and Engineering top-up post-graduate research award and supported by the Australian Research Council.

The Institute said the study, titled ‘Nano-structured antibiofilm coatings based on recombinant resilin’ was published in Advances in Colloid and Interface Science, with the full article available at: https://bit.ly/3ZfzZRT.

RMIT study lead author Prof Namita Roy Choudhury said the finding was “a critical step towards their goal of creating smart surfaces that stop dangerous bacteria, especially antibiotic-resistant ones like [methicillin-resistant staphylococcus aureus], from growing on medical implants”.

“This work shows how these coatings can be adjusted to effectively fight bacteria, not just in the short term, but possibly over a long period,” Prof Choudhury said.

“Antibiotic resistance has prompted greater interest in the area of self-sterilizing materials and easy preparation of antibacterial surfaces,” Prof Choudhury said.

“Therefore, we designed this surface to completely prevent the initial attachment of the bacteria and biofilm formation to decrease the infection rates,” Prof Choudhury said.

"These exceptional properties and non-toxic nature make resilin and resilin-mimetic proteins ideal for many applications requiring flexible, durable materials and coatings,” Prof Choudhury said.

“These applications range from tissue engineering and drug delivery to flexible electronics and sports equipment, but this is the first work published on its performance as an antibacterial coating,” Prof Choudhury said

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration says it has begun proceedings against Philips Electronics Australia in the Federal Court over sleep apnoea and other devices.
The TGA said the proceedings “alleged unlawful supply of medical devices that did not meet Australian safety and performance requirements”, including at-home devices for sleep apnoea and devices used by patients who need help breathing.
The Administration said the devices contained a polyester-based polyurethane (PE-PUR) foam used for noise suppression and that there “was a real risk of the PE-PUR foam degrading and then particulates being inhaled or ingested by the patient”.
The TGA said that the devices were recalled in 2021.
The Administration said the “potential harm from short and intermediate exposure included skin, eye and respiratory tract irritation, inflammatory response, headache, asthma, effects on the user’s reproductive system and neoplasia … [and] potential harm from long term exposure included cytotoxic, genotoxic and carcinogenic effects”.
The Administration said a particular model, the Trilogy 100, used a silicone foam as a replacement for devices containing the PE-PUR foam and that there “was a real risk of the silicone foam dislodging from its position and blocking the air pathway”.
The TGA said the silicone foam could “stop the device from working, resulting in ventilation failure or underventilation … [which] could then result in hypoventilation, hypoxemia, hypercapnia and asphyxia”.
The TGA alleged “that, due to the risk of the PE-PUR foam degrading and silicone foam dislodging, the devices supplied from June 2, 2019 to October 13, 2022, depending on the device, were unsafe, did not perform as intended, and were therefore unlawfully supplied” with more than 44,000 instances of unlawful supply of devices in that period.

COCHLEAR

Cochlear says it will release its bone-anchored hearing aid Baha 7 sound processor and the non-surgical Baha sound band products for mixed hearing loss in the US.
In an announcement not released on the ASX, Cochlear said its bone conduction hearing products were “designed to improve hearing outcomes for children and adults with conductive hearing loss, mixed hearing loss and single-sided deafness”.
The company said the Baha 7 sound processor was the seventh generation of the product and had 55 decibel hearing level fitting range “in a small form factor, offering powerful hearing without compromising on discretion”.
Cochlear said its Baha 7 sound processor had Bluetooth audio and Auracast broadcast audio compatibility, meaning users could “access audio streams in places like theatres, concert halls, lecture halls and airports, through a … smartphone”.
The company said its Baha 7 sound processor could stream directly from any compatible Apple and Android device as well as a range of wireless accessories.
Cochlear said its next-generation non-surgical Baha portfolio of products included Baha Start, which was “designed to help babies and young children experience the fullness of clear, rich and natural sound as early as possible”.
The company said its next-generation sound band product featured “a slimmer band with improved adjustability, a lower profile, moveable connector discs and more color options to help young children be as comfortable and confident as possible”.
Cochlear said it had released additional features on its Baha application and fitting software to help parents and clinicians treat children for the best possible outcomes.
The company said the products would be available in the US “in late Summer 2025”.
Cochlear fell $3.38 or 1.2 percent to $268.35 with 146,056 shares traded.

RECCE PHARMACEUTICALS

Recce says it has “firm commitments” to raise the $7.4 million shortfall from its one-for-six entitlement offer at 28 cents a share, taking the total raised to $15.8 million.
Last month, Recce said it raised $3,436,449 at 28 cents a share of a hoped-for $10,820,208 in a one-for-six rights offer, taking the total to $8,436,449 with the $5,000,000 placement to an unnamed “Australian-based private investor” and leaving a $7,383,759 rights offer shortfall (BD: May 16, 2025).
Today, the company said the shortfall was raised from “existing institutional and sophisticated investors”.
Recce said the “funds raised under the capital raising will be used to support significant phase III clinical trials for topical treatments in Indonesia and Australia, which will progress Recce through to commercialization, and an investigational new drug application to the US [Food and Drug Administration]”.
The company said Ord Minnett and Spark Plus were co-lead managers to the placement.
Recce fell two cents or 5.8 percent to 32.5 cents.

PACIFIC EDGE

Pacific Edge says it has raised $NZ16 million ($A14.9 million) in a placement at 10 NZ cents a share (9.3 Australian cents), $NZ1 million ($A930,000) more than expected
Last week, Pacific Edge said it hoped to raise $NZ15 million in a placement at 10 NZ cents a share, a 22 percent premium to the last closing price, and $NZ5 million in a share plan (BD: May 30, 2025).
Today, the company said its directors had resolved to accept over subscriptions and that the raise was “well supported by existing shareholders”.
Pacific Edge said the placement was subject to shareholder approval at a meeting “planned for late July or early August 2025”.
The company said the funds raised would be used for “additional resources and capacity to capitalize on its recent clinical and commercial milestones, grow in non-Medicare channels and regain Medicare coverage of its tests”.
Pacific Edge said Cameron Partners, Harmos Horton Lusk and the Project were advisers to the raise.
Pacific Edge was up half a cent or 6.7 percent to eight cents.

ADALTA

Adalta says it has raised $1,090,452 of a hoped for $1,300,000 at 0.3 cents a share in a two-for-three, partly-underwritten rights offer, leaving a $209,548 shortfall.
Last month, Adalta said hoped to raise up-to $1.3 million at 0.3 cents a share in a two-for-three, partially underwritten rights offer, with one option for every share issued, exercisable at one cent each within three years (BD: May 1, 2025).
At that time, the company said the issue price was a 50.8 percent discount to the 15-day volume weighted average price and a 50.0 percent discount to the last closing price.
Today, Adalta said the rights offer raised $191,452 from investors and $899,000 from the underwriters of the shortfall and that it reserved the right to place the remaining shortfall within three months of the closing date.
The company said the funds would be used for its first chimeric antigen receptor (CAR) T-cell product licencing transaction, advancing business development for its AD-214 and WD-34 products and evaluating other options, as well as general working capital.
Adalta was unchanged at 0.2 cents.

EMVISION MEDICAL DEVICES

Emvision says it will open its 'Emu' bedside brain scanner validation trial for stroke diagnosis at New York's Mount Sinai Stroke Centre and Sydney's Liverpool Hospital.
Last year, Emvision said it had "positive engagement" from the US Food and Drug Administration for a 300-patient validation trial of its brain scanner; and later, said it had US ethics approval to begin the trial (BD: Oct 29, 2024; Feb 12, 2025).
Earlier this year, the company said it began the trial at the Royal Melbourne Hospital and Houston's University of Texas; and later, said it had opened the opened its second US site at Jacksonville, Florida's Mayo Clinic (BD: Mar 27, Apr 28, 2025).
Today, Emvision said site initiation visit and device training at Liverpool Hospital, the second Australian site, was in progress this week, with activation of the third US site, Mount Sinai, scheduled for this month.
The company said Liverpool Hospital had "comprehensive stroke care services, including acute stroke care, endovascular clot retrieval, and ongoing rehabilitation" and had conducted a previous pre-validation trial of its 'Emu' device.
Emvision said Mount Sinai was "recognized as a leader in stroke research and treatment".
The company said the total number of sites activated for the trial was five, including the two additional sites "with a sixth to be activated shortly thereafter".
Emvision said the study would be used to support US Food and Drug Administration de novo clearance for the 'Emu' bedside brain scanner for stroke diagnosis.
Emvision managing-director Scott Kirkland said it was "a pleasure to work with so many highly engaged clinical research teams across our trial sites".
"We're proud to collaborate with these luminary sites, with excellent track records in driving innovation in stroke care," Mr Kirkland said.
Emvision was up 12 cents or 7.3 percent to $1.765.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has opened the first Australian site and enrolled the first of up-to 466-patients in its phase III trial of pentosan polysulfate sodium for knee osteoarthritis.
Last year, Paradigm said it had US Food and Drug Administration approval for its open-label, randomized, double-blind phase III trial of injectable pentosan polysulfate sodium (PPS) for knee osteo-arthritis; and last month, said it had US ethics approval for the trial (BD: Nov 28, 2024; May 15, 2025).
Today, the company said the first site was opened at Melbourne's Sportsmed Biologic in Box Hill and the first Australian patient had been "formally consented into the trial".
Paradigm said informed consent was "the initial step that allows a patient to participate after they have received and understood all relevant information about the study, including objectives, procedures, potential risks, and benefits".
The company said it had selected 11 clinical sites in Australia that had agreed to participate in the study, with 48 sites in the US selected and preparing for activation.
Paradigm said it remained "on track to have first patient consent in the coming weeks with randomization and dosing in the US to follow in the coming quarter, marking a critical step forward in its global development timeline".
Paradigm managing-director Paul Rennie said the activation of the "first site in Australia and the consenting of our first patients in Australia, with the US soon to follow, mark a significant operational achievement for the company".
"I am particularly pleased to see the high level of engagement from leading clinical investigators and trial sites," Mr Rennie said.
Paradigm was unchanged at 31 cents.

INHALERX

Inhalerx says it has approval to increase the number of patients from 60 participants to 156 participants in its phase II trial of IRX-211 marijuana for breakthrough cancer pain.
Earlier this year, Inhalerx said it had a study order with chief executive officer Darryl Davies and advisor Dr Sud Agarwal-related contract research organization Ingenu CRO for a phase II trial of IRX-211 marijuana for cancer pain (BD: Mar 13, 2025).
Today, the company said it had ethics committee approval for a revised protocol to "significantly expanded trial scope and an enhanced design that aims to strengthen the statistical significance of the study data".
Inhalerx said there were no queries raised for the redesigned protocol and that approval was "granted faster than initially anticipated".
The company said the expanded trial scope may allow it "to reduce or even eliminate the need for a separate phase III trial, expediting the path to market and potentially shortening the overall development timeline".
Inhalerx said it had drawn down $247,500 from its $38.5 million Clendon Capital facility to fund manufacturing and stability testing of IRX-211 for the trial (BD: Oct 18, 2024).
Inhalerx chief executive officer Darryl Davies said that with manufacturing already booked patient dosing was expected to commence by October 2025.
Inhalerx was up 0.3 cents or 10 percent to 3.3 cents.

ARAVAX PTY LTD

Aravax says it has appointed Louise Peacock as its chief regulatory and quality officer, with Ms Peacock to be based at its Oxford, England site.
Aravax said the appointment was in anticipation of a phase III trial of its PVX108 therapy for peanut allergy.
The company said Ms Peacock had more than 35 years of experience in the pharmaceutical industry and had worked on the approval of Palforzia "the first and only" US Food and Drug Administration-approved oral peanut allergy immunotherapy.
Aravax said Ms Peacock had been chief regulatory affairs and quality officer at Vaderis Therapeutics AG and Alladapt Immunotherapeutics and was head of pharmaceutical research and development at Aimmune Therapeutics which was acquired by Nestle Health Science in 2020; and previously worked at Abbott Laboratories, Auxilium Pharmaceuticals, Intermune and Circassia.
Aravax said Ms Peacock held a Bachelor of Science from London's Kings College and a Bachelor of Laws from the University of West London.
Aravax is a private company.

PATRYS

Patrys has requested a voluntary suspension following Friday's trading halt "pending an announcement … in relation to an operations update".
Trading will resume on June 6, 2025, or on an earlier announcement.
Patrys last traded at 0.15 cents.

NYRADA

Nyrada says Mark Azzi has increased his substantial shareholding from 20,092,318 Chess depository interests (CDIs) (9.53%) to 22,453,383 CDIs (10.65%).
Nyrada was up half a cent or 2.8 percent to 18.5 cents with 1.4 million shares traded.

ISLAND PHARMACEUTICALS

MWP Partners Ltd says it has reduced its substantial shareholding in Island and was diluted from 20,891,365 shares (9.94%) to 19,264,773 shares (8.25%).

The Hong Kong-based MWP Partners said that between May 21 and 27, it sold 1,626,592 shares for $368,373, or 22.65 cents a share and was diluted on May 29, 2025.

Last week, Island said it had “firm commitments” to raise $3.6 million at 15 cents a share in a placement to fund a trial of ISLA-101 (BD: May 21, 2025).

Island was up one cent or 4.8 percent to 22 cents.