# Biotech Daily

Thursday June 12, 2025

*Daily news on ASX-listed biotechnology companies*

*** ASX DOWN, BIOTECH UP: CYNATA UP 9%;**
**- IMMUTEP, UNIVERSAL BIOSENSORS DOWN 6%**

*** COCHLEAR TO RELEASE 'FIRST, ONLY SMART IMPLANT'**

*** COCHLEAR $20m-$30m PROFIT WARNING**

*** BIOXYNE REVENUE GUIDANCE UP $3m TO $28m**

*** TELIX GOZELLIX PROSTATE CANCER IMAGING AVAILABLE IN US**

*** KAZIA UP 114% ON PAXALISIB BREAST CANCER RESULTS, IN MICE**

*** ISLAND: 'ISLA-101 REDUCES DENGUE VIRAL LOAD, SYMPTOMS'**

*** MESOBLAST, FDA REVASCOR HEART FAILURE MEETING**

*** FIVEPHUSION PHASE II DEFLEXIFOL CHILD BRAIN CANCER DOSE**

*** DORSAVI $2.3m PLACEMENT; $1.3m SINGAPORE LICENCE**

*** ANTEOTECH $213k INDIA SERUM INSTITUTE ANTEOBIND ORDER**

*** OPYL SIGNS CARDIALYSIS, EVESTIA TRIALKEY DEALS**

*** FIL (FIDELITY) TAKES 8.6% OF RECCE**

*** MARK AZZI TAKES 13% OF NYRADA**

## MARKET REPORT

The Australian stock market fell 0.31 percent on Thursday June 12, 2025, with the ASX200 down 27.0 points to 8,565.1 points. Twenty-one of the Biotech Daily Top 40 companies were up, 13 fell and six traded unchanged. The four Big Caps were mixed.

Cynata was the best, up 1.5 cents or 9.1 percent to 18 cents, with 409,520 shares traded. Amplia climbed 7.0 percent; Micro-X was up 6.7 percent; Clarity, Dimerix and Nova Eye were up more than four percent; Emvision and Optiscan improved more than three percent; Atomo, EBR and Mesoblast rose more than two percent; 4D Medical, Avita, Botanix, Cyclopharm, Medadvisor, Nanosonics, SDI and Starpharma were up one percent or more; with Cochlear, CSL, Neuren and Telix up by less than one percent.

Both Immutep and Universal Biosensors led the falls, down 5.6 percent to 25.5 cents and 3.4 cents, respectively, with nine million shares and 25,000 shares traded, respectively. Actinogen, Aroa and Resonance fell more than four percent; Polynovo lost 3.1 percent; Curvebeam, Medical Developments and Proteomics shed more than two percent; Clinuvel, Compumedics, Genetic Signatures and Paradigm were down more than one percent; with Pro Medicus and Resmed down by less than one percent.

## COCHLEAR

Cochlear says it will launch its Nucleus Nexa “world’s first and only smart cochlear implant system” in Europe and Asia Pacific in mid-June 2025.

Cochlear said that the Nucleus Nexa was the first implant with internal memory, meaning recipients’ “unique hearing settings on the implant can be transferred to any Nucleus Nexa sound processor, improving patient convenience and reducing clinic visits”.

Cochlear chief technology officer Jan Janssen said the implant had “a state-of-the-art chipset with onboard diagnostics, which has the capability to reduce the burden on carers and recipients by enabling the system to self-monitor”.

The company said the device included “upgradeable implant firmware, enabling recipients to access future innovations through both their implant and sound processor”.

Cochlear said the product included a rechargeable battery that was “the smallest and lightest available, with all-day battery life”, meaning the sound processor was nine percent smaller and 12 percent lighter than its predecessor.

The company said commercialization of the product in additional jurisdictions would follow pending regulatory approvals.

Cochlear did not disclose the expected price of the implant.

Cochlear chief executive officer Dig Howitt said the Nucleus Nexa implant was “the outcome of a 20-year investment in [research and development]”.

“It is the first cochlear implant to run its own firmware,” Mr Howitt said.

“Similar to smartphones, the implant firmware can be updated to enable new features and access to future innovations,” Mr Howitt said.

“Recipients will now have access to a better hearing experience with both implant and sound processor updates,” Mr Howitt said.

“The Nucleus Nexa System builds upon Cochlear's industry-leading portfolio of electrodes, which are designed to optimise the electrode-neural interface and protect cochlea health and opens the door to even greater hearing potential for patients into the future,” Mr Howitt said.

Cochlear was up $1.85 or 0.7 percent to $272.31 with 499,839 shares traded.

## COCHLEAR

Cochlear says it expects net profit after tax of $390 million to $400 million for the year to June 30, 2025 due to “slower-than-expected sales growth over the last few months”.

Last year, Cochlear chief executive officer Dig Howitt said the company was targeting a net profit guidance for the year to June 30, 2025 of $410 million to $430 million, which was a six percent to 11 percent increase (BD: Aug 15, 2024).

Today, the company said it had expected “a single digit decline in services revenue for 2024-’25 after two years of strong growth following the launch of the Nucleus 8 sound processor and now expect it to decline by low double-digits”.

Cochlear said it would identify recipients who could benefit from its latest sound processing technology which, with the introduction of its off-the-ear Nucleus Kanso 3 sound processor, was expected to increase services revenue in 2025-’26.

The company said its implant units were still expected to increase by about 10 percent for the year to June 30, 2025 particularly in emerging markets and that “growth in the higher value developed markets has been impacted by slower-than-expected market growth and a small loss of market share in a few countries”.

Cochlear said its earnings expectations update was based on year-to-date accounts, with the result subject to June trading, an audit and board approval.

The company said its full year result would be released on August 15, 2025.

## BIOXYNE

Bioxyne says it has increased its forecast revenue for the year to June 30, 2025 from $25 million to $28 million due to “Australian pharmaceutical manufacturing and supply”.
Last year, Bioxyne said revenue from its Breathe Life Sciences business and sales of its marijuana, 3,4-methylene-dioxymeth-amphetamine (MDMA) and psilocybin products for the year to June 30, 2024 was up 80.7 percent to $9,325,020, with net loss after tax up 587.2 percent to $13,500,723 (BD: Sep 2, 2024).
Earlier this year, the company said it expected revenue for the year to June 30, 2025 to be up 168.1 percent to $25,000,000, compared to the prior year (BD: Jan 23, 2025).
Today, the company said it expected revenue for the six months to June 30, 2025 to be $15.4 million, a 226 percent increaser on the prior corresponding period.
Bioxyne was up half a cent or 19.2 percent to 3.1 cents with 58.2 million shares traded.

## TELIX PHARMACEUTICALS

Telix says it has begun US commercialization of its gallium-68 Gozellix prostate specific membrane antigen (PSMA) imaging kit for prostate cancer.
Earlier this year, Telix said it had US Food and Drug Administration approval for gallium-68 radio-labelled TLX007-CDx, or ‘Gozellix’, for prostate cancer imaging with PSMA-positron emission tomography (PET) (BD: Mar 21, 2025).
Today, in an announcement not released to the ASX, the company said that Gozellix was available through its distribution partners Cardinal Health Inc, Pharmalogic Holdings Corp, Jubilant Radiopharma, and RLS Radiopharmacies.
Telix said that Gozellix would be used for PET scanning of PSMA-positive lesions in men with prostate cancer who had suspected metastasis and were candidates for initial definitive therapy, and those with suspected biochemical recurrence based on elevated serum prostate-specific antigen level.
The company said that although PSMA-PET imaging had become established as the standard-of-care for prostate cancer imaging, “only a relatively small fraction of the 3.4 million men living with prostate cancer have benefited from this technology, in part due to access and availability challenges”.
In 2022, Telix said it had FDA approval for its Illuccix prostate cancer imaging, making it “the first commercially available FDA-approved product to enable wide accessibility to gallium-68--based PSMA-PET imaging … in the US” (BD: Apr 4, 2022).
Today, the company said Gozellix had an “enhanced formulation, with an extended ‘hot’ shelf-life of up-to six hours [and] offers a greater level of patient access and convenience through an extended transportation distance and clinical administration window”.
Telix said it estimated “that up-to 20 percent of PET cameras in the US are beyond the reach of currently available PSMA-PET imaging agents due to distribution efficiency constraints”.
The company said by overcoming this limitation, Gozellix could “improve access for prostate cancer patients, regardless of where they live, with greater scheduling flexibility for clinicians and their patients”.
Telix did not disclose the expected price of Gozellix in the US.
Telix Precision Medicine chief executive officer Kevin Richardson said the company was “pleased that Gozellix … is now available coast-to-coast across the US”.
“It delivers a new level of flexibility in distribution, production and scheduling, along with the high standard of service and reliability that customers have come to expect from Telix,” Mr Richardson said.
Telix was up six cents or 0.2 percent to $25.65 with 1.5 million shares traded.

## KAZIA THERAPEUTICS

Kazia was up as much as 114 percent on a study showing its paxalisib with Keytruda immunotherapy had “anti-tumor activity in advanced breast cancer”, in mice.

In 2023, the Sydney-based and dual-listed Kazia said that it would delist from the ASX, effective on November 14, 2023, and remain on the Nasdaq, to reduce costs (BD: Oct 11, 2023).

In 2022, Kazia said that with the Queensland Institute of Medical Research Berghofer, it would conduct pre-clinical studies of paxalisib in solid tumors; and last year, said it had licenced the Institute’s PI3K-inhibitor-related intellectual property, which included paxalisib (BD: Dec 15, 2022, Sep 13, 2024).

Earlier this year, QIMR said that with Kazia it would conduct a 24-patient, phase Ib trial of paxalisib with standard-of-care for breast cancer; and last week, said it had dosed the first patient in the phase Ib trial (BD: Jan 30, 2025).

Overnight in the US, Kazia said the pre-clinical study was conducted by QIMR’s Prof Sudha Rao and showed paxalisib could “reprogram the tumor micro-environment and enhance immune response, showing substantial synergy with immune checkpoint inhibitors”.

The company said the data provided “strong scientific and translational rationale for continued development of paxalisib as part of immunotherapy-based regimens”.

Kazia said “dual targeting of PI3K and MTOR (mammalian target of rapamycin) but not PI3K alone inhibits cancer cell proliferation and migration in-vitro”.

According to the US National Library of Medicine, MTOR is a protein related to a family of kinases that “mediate cellular responses to stresses such as DNA damage and nutrient deprivation” and are used in organ transplants as immuno-suppressants.

Kazia said the study showed “paxalisib remodels the [triple-negative breast cancer] tumor micro-environment, increasing CD4+ and CD8+ T-cell infiltration and activation”.

The company said the combination of paxalisib with of pembrolizumab, marketed as Keytruda, “demonstrated synergistic antitumor activity in advanced breast cancer, resulting in robust tumor regression and prolonged survival in preclinical models”.

Kazia said that the study, titled ‘Depleting the action of EZH2 through PI3K-mTOR inhibition to overcome metastasis and immunotherapy resistance in triple-negative breast cancer’ was published in the journal Molecular Cancer Therapeutics, with an abstract available at: https://doi.org/10.1158/1535-7163.MCT-24-0693.

The abstract said “almost half of patients with triple-negative breast cancer (TNBC) develop distant metastases, heralding unfavorable outcomes … [and] dual targeting of PI3K and mTOR but not PI3K alone inhibits cancer cell proliferation and migration in vitro.

“In vivo, paxalisib overcomes immune-therapy resistance to reduce primary tumor burden, circulating tumor cells, and direct and indirect indicators of metastasis with a favorable toxicity profile,” the abstract said.

Kazia chief executive officer Dr John Friend said the study offered “a mechanistic and translational foundation for our newly launched phase Ib clinical trial of paxalisib in advanced breast cancer”.

“It not only extends the therapeutic potential of paxalisib beyond brain cancers but also positions it at the forefront of innovative immunotherapy combinations in solid tumors,” Dr Friend said.

On the Nasdaq, Kazia was up as much as $US5.99 ($A9.21) or 113.9 percent to $US11.25 ($A17.32), before closing up $US4.28 ($A6.59) or 81.5 percent at $US9.54 ($A14.68) with 49,671,825 shares traded.

## ISLAND PHARMACEUTICALS

Island says its 14-patient, phase IIa/b trial shows ISLA-101 led to a “clear reduction in [dengue] virus level … [and] a material reduction in viral load and symptoms”.

Last year, Island said the four patients in the prophylactic arm of its phase IIa/b trial showed ISLA-101’s “safety and anti-dengue activity”; and in January, said it had enrolled all 10 patients in the therapeutic arm of the trial (BD: Nov 27, 2024; Jan 22, 2025).

Earlier this year, the company said it completed the 10-patient therapeutic arm of its 14-patient, phase IIb trial of ISLA-101 for dengue fever (BD: Apr 23, 2025).

Today, Island said that in the phase IIa, prophylactic arm, four subjects received 600mg/$m^2$ per day of ISLA-101, or placebo, three days before being inoculated with a dengue challenge virus provided by the US Army under a Cooperative Research and Development Agreement.

The company said ISLA-101 led to “clinically meaningful anti-dengue activity, which included a material reduction in viral load and symptoms”.

Island said the three of four subjects in the preventative arm treated with ISLA-101 “exhibited a clear reduction in virus level”.

The company said when evaluating the maximum possible number of recorded symptoms, “the control reported about 63.6 percent of all potential symptoms while the ISLA-101 pre-treated subjects reported circa 33.3 percent of all possible symptoms”.

Island said patients dosed with ISLA-101 were “less sick than those that received the placebo and highlights ISLA-101’s potential as a preventative measure in dengue”.

The company said in the phase IIb treatment arm, 10 patients received the same dose as in the phase IIa cohort and were administered ISLA-101 or placebo seven days after challenge virus exposure.

Island said based on a “preliminary review, ISLA-101 impacted viral replication”.

The company said “because some subjects were viraemic and symptomatic at the time of first dosing, alterations in symptoms were less pronounced and are being investigated further”.

Island said the study was conducted at Syracuse’s State University of New York Upstate (SUNY) “in accordance with the SUNY Dengue Human Infection Model, which is a robust protocol that elicits detectable dengue viraemia and symptoms”.

The company said that “while other small molecules have been explored in this model, ISLA-101 is the first to demonstrate a potential benefit”.

Island said that following the initial, unblinded results it had “undertaken an in person meeting with its clinical advisory board to review the data and obtain guidance on recommended subsequent actions for the clinical development of ISLA-101”.

The company said it would “continue to work with its advisory board to gain a better understanding of the data, which will determine the potential course of action”.

Island managing-director Dr David Foster said despite being in a small number of subjects the initial findings were “highly encouraging and advocate for continued development of ISLA-101”.

“We are pleased to advance the pre-clinical work from both Monash [University] and Harvard [University] to further highlight the potential for ISLA-101 as a measure to impact a widespread condition with no treatment,” Dr Foster said.

“Additional work into the dataset alongside our scientific and clinical advisory boards is ongoing and will be the primary focus for the company in the near term,” Dr Foster said.

“We are confident that additional data will provide a clear determination for the next steps in our clinical trial pipeline and look forward to sharing this as it materialises,” Dr Foster said.

Island fell 1.5 cents or 7.5 percent to 18.5 cents with 8.0 million shares traded.

## MESOBLAST

Mesoblast says it has aligned with the US Food and Drug Administration at a type B meeting on rexlemestrocel-L, or Revascor, for ischemic chronic heart failure.
Mesoblast said it held a meeting to discuss a potential filing for a biologics licence application for Revascor in ischemic chronic heart failure with reduced ejection fraction and inflammation.
The company said it and the FDA had “general alignment on items regarding chemistry, manufacturing and controls, potency assays for commercial product release, and proposed design and primary endpoint for the confirmatory trial post-approval”.
Mesoblast said it would “await the final minutes from [the] FDA in order to provide detailed feedback and timelines for potential filing”.
The company said that it had a planned meeting with the FDA to discuss a pivotal trial of Ryoncil, or remestemcel-L, in adults with steroid-refractory acute graft versus host disease to support a label extension in adult patients with the disease.
Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil for children aged two months and older for graft versus host disease (BD: Dec 19, 2024).
Today, the company said trial would be conducted by the National Institutes of Health-funded Bone Marrow Transplant Clinical Trials Network.
Mesoblast chief executive Prof Silviu Itescu said the company was “very pleased with the momentum of interactions with FDA on both our cardiac and [graft versus host disease] programs”.
“We are also encouraged by the strength of the of the Ryoncil commercial launch, the rate of hospital onboarding, physician adoption, and payor coverage exceeding our expectations in the ten weeks since commercial launch,” Prof Itescu said.
“We will be providing an update on sales of Ryoncil in our quarterly activities report at the end of next month,” Prof Itescu said.
Mesoblast was up five cents or 2.8 percent to $1.85 with 4.8 million shares traded.

## FIVEPHUSION

Fivephusion says its nine-patient, phase I trial of Deflexifol for childhood brain cancers has found a safe and tolerated maximum dose for the phase II portion of the study.
In 2023, Fivephusion said it would conduct an up-to 34-patient, dose-ranging, safety and efficacy, phase Ib/IIa trial of Deflexifol co-formulation of 5-fluorouracil and leucovorin for gliomas and ependymoma tumors (BD: Jun 14, 2023).
Today, Fivephusion said an independent data safety monitoring committee reviewed the safety and tolerability data and declared a maximum tolerated dose and recommended phase II dose for Deflexifol in paediatric brain cancer patients.
The company said “all major paediatric oncology centres in Australia are participating in the trial, and major trial funding has been provided by the Kids with Cancer Foundation, through Sydney Children’s Hospitals Foundation, and the Robert Connor Dawes Foundation”.
Fivephusion managing-director Dr Christian Toouli said the completing the first part of the study, and confirmation of a safe and tolerable phase II dose were “major milestones in our plans to develop Deflexifol as a potential treatment for paediatric ependymoma and other brain cancers”.
“We thank the patients and their families for their participation in this trial, and our collaborators and partners for conducting this important study,” Dr Toouli said.
Fivephusion is a private company.

## DORSAVI

Dorsavi says it has “firm commitments” for a $2,275,000 placement and will pay up-to $S1,100,000 ($A1,320,000) for to licence Singapore computer memory technology.
Dorsavi said it would raise $2,275,000 in a placement at 1.3 cents a share, a 4.02 percent discount to the 15-day volume weighted average price and an 18.75 percent discount to the last traded price, in two tranches.
The company said the first tranche would be issued under its existing placement capacity, with $162,500 subject to shareholder approval.
Dorsavi said it would pay $S400,000 over two years and a further $S700,000 over 10 years for the Singapore Nanyang Technological University’s resistive random-access memory (RRAM) technology, which had the “ability to deliver ultra-fast read/write operations while consuming minimal power, making it highly suited for deployment in latency-sensitive, energy-constrained environments”.
Dorsavi said the RRAM device would be used to extend the battery life of its wearable sensors, minimizing recharge cycles and improving usability in continuous monitoring.
The company said the RRAM’s “non-volatile characteristics ensures robust data retention without continuous power supply, and its high endurance, scalability, and resilience make it ideal for wearables … sensors and … computing nodes”.
Dorsavi said the funds raised from the placement would be used to integrate the RRAM device with its existing sensor platform and working capital.
The company said it would pay an introduction fee of 60,000,000 shares to the Melbourne-based Clayton Capital Pty Ltd, subject to shareholder approval.
Dorsavi said 62 Capital was lead manager to the placement and would receive a six percent raising fee as well as 20,000,000 options, exercisable at two cents each within three years from the issue date.
The company said at its extraordinary general meeting shareholders would also vote to approve the issue of 25,000,000 performance rights to chair Gernot Abl and directors Michael Winlo and Leigh Travers, pending share price-related milestones.
Dorsavi was up 0.2 cents or 12.5 percent to 1.8 cents with 60.4 million shares traded.

## ANTEOTECH

Anteotech says it has a further $US138,750 ($A213,000) purchase order from the Pune, Maharashtra-based Serum Institute of India for its Anteobind vaccine tester.
Last year, Anteotech said it had a minimum $US370,000 ($A564,600), five-year deal for the Serum Institute of India to buy its Anteobind vaccine tester (BD: Jul 30, 2024).
Today, the company said the order meant the Serum Institute of India had bought more than the minimum annual order quantity for the year to June 30, 2025, under the terms of the five-year purchase agreement.
Anteotech said it expected about $930,000 in sales from its life sciences business for the year to June 30, 2025, up about 130 percent compared to the prior corresponding period.
The company said its project using Anteobind NXT with Vidcare Innovations was “delayed due to Indian regulatory requirements” and it had completed the development of a prototype lateral flow assay device for Seoul, South Korea’s KOMA Biotech Inc, with the final payment of $17,500 pending.
On Tuesday, Anteotech said it had made eight redundancies in personnel to cut costs following a strategic review to streamline operations and reduce “new product development”, expecting $1.6 million in annual cost savings (BD: Jun 10, 2025).
Anteotech was unchanged at 0.9 cents with 10.1 million shares traded.

## OPYL

Opyl says Cardialysis and Evestia Clinical will use its Trialkey artificial intelligence software for clinical trial design at $20,000 and $5,000 per project, respectively.
Opyl said the Rotterdam-based Cardialysis was a contract research organization for cardiovascular clinical trials and had completed more than 400 trials and enrolled more than 200,000 patients.
The company said Cardialysis would pay $20,000 to use its Trialkey system per trial, payable only if client business was secured.
Opyl said the Letchworth Garden City, England's Evestia Clinical was a clinical research organization for therapeutic trials in oncology, rare disease and immunology and had completed more than 480 clinical studies.
The company said Evestia would pay $5,000 per project to use Trialkey, payable on the successful engagement of a qualifying study.
Opyl said the agreements provided third-party validation, dataset expansion to improve its artificial intelligence models and predictive accuracy as well as a route to recurring revenue.
Opyl executive chair Saurabh Jain said the partnerships proved Trialkey's "value in the field today and propel us toward sustainable growth".
Opyl fell 0.2 cents or 9.1 percent to two cents with 1.4 million shares traded.

## RECCE PHARMACEUTICALS

FIL Investment Management Ltd says it has increased its substantial shareholding in Recce from 16,755,072 shares (6.40%) to 24,705,816 shares (8.57%).
The Sydney and Hong Kong-based FIL (Fidelity) said that on March 6, 2025 it bought 7,950,744 shares for 28 cents share.
Recce was up 1.5 cents or 4.7 percent to 33.5 cents.

## NYRADA

Nyrada says Mark Azzi has increased his substantial shareholding from 25,131,217 Chess depository interests (CDIs) (11.92%) to 27,510,404 CDIs (13.04%).
Nyrada was up 1.5 cents or 8.6 percent to 19 cents.