Biotech Daily

Tuesday August 5, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: MEDICAL DEVELOPMENTS UP 13%**
- TELIX DOWN 8.45%

*** TELIX FALLS 21% ON 'RECAST FINANCIAL STATEMENT'**

*** TRAJAN EXPECTS RECORD $166.5m REVENUE, BEATING GUIDANCE**

*** EBR WINS CMS WISE CARDIAC PACING 'NEW TECHNOLOGY ADD-ON'**

*** UNIVERSAL BIOSENSORS H1 REVENUE DOWN 11% TO $2.8m**

*** AUDEARA: EAR SCIENCE INSTITUTE $100k FOR HEARING PROJECT**

*** QBIOTICS DOSES 1st PHASE I EBC-1013 LEG ULCER COHORT**

*** IMMUTEP 'POSITIVE' FDA EFTI HEAD, NECK CANCER FEEDBACK**

*** NOXOPHARM, TEZCAT SOFRA IN-VITRO STUDIES**

*** ARGENT: 'CANNEPIL BENEFITS 1 CHILD WITH EPILEPSY'**

*** IDT REQUESTS 'MANAGEMENT CHANGE' TRADING HALT**

*** MARK AZZI INCREASES, DILUTED TO 15% OF NYRADA**

*** VITRAFY CO-FOUNDER BRENT OWENS REPLACES M-D KATE MUNNINGS**

MARKET REPORT

The Australian stock market was up 1.23 percent on Tuesday August 5, 2025, with the ASX200 up 106.7 points to 8,770.4 points. Fifteen of the Biotech Daily Top 40 stocks were up, 17 fell, seven traded unchanged and one was untraded. All four Big Caps were up.

Medical Developments was the best, up 7.5 cents or 13.2 percent to 64.5 cents, with 189,661 shares traded. Medadvisor was up 12.9 percent; Curvebeam climbed 6.4 percent; Optiscan and Universal Biosensors were up five percent or more; Resmed rose four percent; Botanix and EBR were up more than three percent; Cynata rose 2.9 percent; Clarity, Immutep, Mesoblast, Nanosonics, Proteomics, SDI and Starpharma were up one percent or more; with Cochlear, CSL and Pro Medicus up by less than one percent.

Telix led the falls (see below), down $1.71 or 8.45 percent to $18.53, with 11.15 million shares traded. Amplia lost 7.7 percent; 4D Medical fell 5.6 percent; Alcidion was down 4.35 percent; Imugene was down 3.3 percent; Compumedics, Dimerix, Neuren and Prescient shed two percent or more; Nova Eye, Orthocell, Paradigm, Polynovo and Syntara were down more than one percent; with Clinuvel, Cyclopharm and Emvision down by less than one percent.

TELIX PHARMACEUTICALS

Telix fell as much as 20.95 percent to $16.00 following a “summary of recast key financial information” including increased operational expenditure.

Telix said it expected operating expenditure for the six months to June 30, 2025, excluding research and development, to be 36 percent of revenue, an increase on last year.

Last month, the company said unaudited revenue from sales of its Illuccix prostate cancer imaging kit for the six months to June 30, 2025 was up 63.2 percent to $US390,000,000 ($A594,000,000) (BD: July 23, 2025).

Biotech Daily calculates that Telix expects operating expenditure for the six-month period to therefore be about $US140,400,000.

Last year, the company said record revenue for the six months to June 30, 2024 rose 64.8 percent to $363,964,000, with $41,553,000 net profit after tax (BD: Aug 23, 2024).

Today, Telix said unaudited recast revenue for the six months to June 30, 2024 was $US239,611,000 ($A359,017,000) and operating expenditure for the period excluding research and development costs was $US74,049,000, or 30.9 percent of revenue.

The company said it had voluntarily provided an “unaudited recast of its historical financial information in US dollars following a change in reporting currency from Australian dollars, effective January 1, 2025” (BD: Feb 25, 2025).

Telix said the recast reports were “provided to assist with comparisons to upcoming financial reports, including interim results for the half-year ended June 30, 2025”.

The company said the recast historical financial information was “prepared using accounting policies consistent with those applied in the preparation of Telix's audited or reviewed consolidated financial statements for these periods”.

Telix said its US operations had “expanded significantly following a number of acquisitions, including RLS Radiopharmacies, which completed on January 27, 2025”.

In January, Telix said that it had acquired the Orlando, Florida-based RLS Inc Radiopharmacies network for up to $US250 million; and later, said it had completed its up-to $US230 million acquisition of the Los Angeles-based antibody engineering company Imaginab Inc (BD: Jan 28, 31, 2025).

At that time, the company said the RLS acquisition “immediately enhances [its] presence in the US with a network of over 30 radio-pharmacies dispensing radio-pharmaceuticals manufactured by Telix and other companies, while bringing a team of highly-skilled and multi-disciplinary radiopharmaceutical professionals into the company”.

Telix said RLS would continue to operate under the same name and as a standalone business within Telix Manufacturing Solutions, which included its other brands ARTMS, Isotherapeutics and Optimal Tracers.

Today, the company said the increased operating expenditure reflected “the expanded business activities and the company’s ongoing strategy to reinvest earnings in commercial growth and pipeline development opportunities”.

Earlier this year, Telix said revenue for the year to December 31, 2024 was up 55.85 percent $783,207,000, with profit after tax up 9.6-fold to $49,919,000 (BD: Feb 21, 2025).

Last month, the company said revenue for the year to December 31, 2025 was expected to be $US700 million to $US800 million, reflecting “revenue from Illuccix sales in jurisdictions with a marketing authorization, and 11 months of revenue contribution from RLS” (BD: Jul 23, 2025).

At that time, Telix said it confirmed “research and development expenditure guidance, expecting a year-over-year increased investment range for 2024-’25 of 20 percent to 25 percent compared to 2023-’24”.

Telix fell as much as 20.95 percent from $20.24 to $16.00, before closing down $1.71 or 8.45 percent to $18.53, with 11.15 million shares traded.

TRAJAN GROUP HOLDINGS

Trajan says it expects record revenue for the year to June 30, 2025 of $166.5 million, exceeding “the upper end of financial guidance”.
In May, Trajan said revenue guidance for the year to June 30, 2025 remained at $160 million to $165 million, with “risk” to normalized earnings before interest, taxation, depreciation and amortization (Ebitda) due to margin performance (BD: May 29, 2025).
Today, the company said based on initial unaudited accounts, normalized Ebitda was expected “to fall short of the lower end of guidance, $17 million, by around 8.8 percent at about $15.5 million”.
Trajan said the $15.5 million normalized Ebitda was a 26.6 percent increase compared to $12.3 million in the prior corresponding period.
The company said the result was impacted by “the loss of $3.9 million caused by the … loss of a specialized biotech syringe revenue stream”, the US dollar exchange rate, incomplete shipping of $1 Million in micro-sampling orders worth in June and a change in sales of capital equipment to more price sensitive emerging markets.
Trajan said the result was also negatively affected by “the [US] tariff announcements, which caused the company to pivot operations towards more local fulfilment of orders, with supply chains having to be repositioned for the emerging market environment”.
The company said it was “positioned well for continued Ebitda and margin expansion in 2025-’26, with our diversified portfolio, strong customer relationships, and leadership in our key segments supporting our purpose to deliver science that benefits people”.
Trajan was up nine cents or 11.1 percent to 90 cents.

EBR SYSTEMS

EBR says it has US Centers for Medicare & Medicaid Services (CMS) approval for the “new technology add-on payment” for its Wise wireless cardiac pacing device.
In April, EBR said the US Food and Drug Administration approved its leadless Wise cardiac re-synchronization therapy (CRT) for left ventricular pacing (BD: Apr 14, 2025).
Later, the company said the US CMS recommended its Wise CRT system receive the “new technology add-on payment”; and this month, said it had preliminary US CMS approval for transitional pass-through reimbursement (TPT) (BD: Apr 15, Jul 15, 2025).
Today, EBR said the confirmed new technology add-on payment secured “the maximum reimbursement rate of up-to $US41,145 ($A63,696) based on an average Wise selling price of $US63,300 ($A97,995)”.
The company said the “new technology add-on payment” was “designed to bridge the financial gap between the costs of innovative technologies and the standard Medicare Severity Diagnosis Related Groups (DRG) payment structure in place, while encouraging early adoption of breakthrough medical advancements”.
EBR said the approval was “in addition to the DRG payments, which are intended to cover the procedure and remaining device costs” and would remain for three years to allow the CMS to collect costs for the device and procedure based on Medicare claims data.
The company said it would “petition CMS during the second year to move Wise procedures to a DRG that fully covers the cost of the Wise system and procedure”.
EBR said the approval was “a significant advancement in EBR’s commercialization strategy” establishing a reimbursement pathway for the Wise system for Medicare inpatients form October 1, 2025, which coincided with the initial limited market release.
The company said it expected to receive final transitional pass-through (TPT) payment approval from CMS prior to October 1, 2025, subject to final ruling.
EBR was up five cents or 3.7 percent to $1.39 with 1.1 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says revenue for the six months to June 30, 2025 fell 10.7 percent to $2,763,423, with net loss after tax up 44.5 percent to $10,448,624.
Universal Biosensors said revenue from sales of its blood coagulation electro-chemical test Xprecia, laboratory testing services, wine testing product Sentia and veterinary diabetes test Petrackr for the three months to June 30, 2025 were down 17.8 percent to $1,127,750, compared to the prior corresponding period.
The company said diluted loss per share was up 33.3 percent to four cents a share, with net tangible assets per security down 66.7 percent to three cents.
Universal Biosensors said it had cash and cash equivalents of $2,198,490,000 at June 30, 2025 compared to $16,675,984 at June 30, 2024.
Universal Biosensors was up 0.1 cents or five percent to 2.1 cents.

AUDEARA

Audeara says it has $100,000 from Perth's Ear Science Institute Australia to develop and evaluate "bone conduction hearing enhancement solutions".
Audeara said it would provide "in-kind support … including technical expertise, product supply and project coordination" to the project targetting children.
The company said bone conduction hearing products transmitted sound vibrations through bones, bypassing the eardrum "allowing users to hear ambient sounds".
Audeara said the project was expected to begin this month and include "product evaluation, stakeholder engagement and pilot [program] implementation aimed to improve access to hearing support for children who require assistance hearing in classroom settings".
Audeara chief executive officer Dr James Fielding said the partnership was "closely aligned with our purpose to deliver world-class hearing solutions that help people engage more fully in their communities".
"Supporting children to hear well in and outside the classroom has lifelong benefits, and we're proud to play a role in exploring how this technology can make a difference," Dr Fielding said.
Audeara was up 0.2 cents or 9.5 percent to 2.3 cents.

QBIOTICS GROUP

Qbiotics says it has dosed the first cohort in its 33-participant, phase I trial of EBC-1013 for venous leg ulcers, with recruitment underway for the second cohort.
Qbiotics said the placebo-controlled, dose-escalation study was assessing the safety and tolerability of five ascending doses of its topical, semi-synthetic small molecule EBC-1013 for venous leg ulcers at four sites in Australia.
The company said the primary endpoint of the study was safety, with other endpoints including pharmaco-kinetics, toxicity, wound healing efficacy and quality of life.
Qbiotics managing-director Stephen Doyle said the company was "encouraged by the safe dosing of the initial patient cohort in our EBC-1013 phase I clinical trial, marking the beginning of what we anticipate will be a meaningful contribution to the treatment of venous leg ulcers".
"These wounds are painful, slow to heal, and represent a significant global unmet medical need - often referred to as a 'silent epidemic'," Mr Doyle said..
Qbiotics is a public unlisted company.

IMMUTEP

Immutep says it has “positive feedback” from the US Food and Drug Administration regarding the clinical development of ‘efti’ for head and neck cancer.

Immutep said that based on its review of the encouraging data from its 171-patient, phase IIb trial, the FDA had agreed on the potential of efti, or eftilagimod alpha, in combination with pembrolizumab, or Keytruda, to address the high unmet need in this CPS < 1 patient segment and was “supportive of the combination’s further development”.

Last year, the company said the phase IIb trial showed efti, with pembrolizumab, in patients with a combined positive score of more than one (CPS > 1) in cohort A, led to overall response rates exceeding Keytruda alone” (BD: Jun 27, 2024).

In May, Immutep said the trial of ‘efti’ and Keytruda for head and neck cancer had median overall survival of 17.6 months in 31 cohort B patients with CPS < 1 (BD: May 5, 2025).

Today, the company said future development included a randomized registrational trial of efti with Keytruda compared to standard-of-care therapy or a smaller 70 to 90-patient, single-arm study with safety, response rate, and duration of response as key endpoints, followed by a confirmatory randomized study that built on the existing data.

Immutep chief executive officer Marc Voigt said the company was “pleased with the FDA’s feedback and guidance that underscores the high unmet need of head and neck cancer patients whose PD-L1 expression level is below one”.

“The FDA feedback positions Immutep to evaluate options for future collaborative clinical development paths to bring a new, effective and safe treatment option to this underserved patient population,” Mr Voigt said.

“Our primary focus clearly remains the pivotal ‘Tacti-004’ phase III evaluating efti as first line therapy for non-small cell lung cancer and we are excited with its progress to date and the consistent, encouraging feedback we hear from physicians,” Mr Voigt said.

Immutep was up half a cent or 1.9 percent to 26.5 cents with 3.4 million shares traded.

NOXOPHARM

Noxopharm says New York’s Tezcat Biosciences has conducted in-vitro studies of its Sofra assets with “highly promising outcomes”.

Noxopharm said the studies showed that Sofra oligo-nucleotides could “be successfully attached to Tezcat’s delivery system to create a novel drug candidate with strong anti-inflammatory activity”.

Noxopharm said with Tezcat it would conduct “additional and more complex studies in animal models”, which was expected to take several months.

Noxopharm was up half a cent or 4.35 percent to 12 cents.

ARGENT BIOPHARMA

Argent says a case study has shown its marijuana-based Cannepil led to “clinical benefits” in one paediatric patient with Lennox-Gastaut syndrome, a type of epilepsy.

Argent said the case study showed Cannepil led to “reduced seizure clusters and daily seizure frequency, recovery of speech, fine motor control, and independent mobility [as well as] reintegration into a full-time educational environment”.

The company said the study, titled ‘Management of Lennox-Gestaut Syndrome with a CBD/THC Isolate Combination’ was authored by Argent’s Dr Jonathan Grunfeld and Jasna Jarc and published in the International Journal of Clinical Studies and Medical Case Reports at: https://ijclinmedcasereports.com/pdf/IJCMCR-CR-01331.pdf.

Argent fell 0.4 cents or five percent to 7.6 cents.

IDT AUSTRALIA

IDT has requested a trading halt “to finalize details of a change in management”.
Trading will resume on August 7, 2025, or on an earlier announcement.
IDT last traded at nine cents.

NYRADA

Nyrada says Mark Azzi has increased his substantial shareholding and been diluted from 34,947,597 Chess depository interests (CDIs) (16.57%) to 35,618,250 CDIs (14.92%).
Nyrada said Mr Azzi purchased 200,000 CDIs in a placement at 30 cents a share.
Yesterday, Nyrada said it had raised $8.25 million at 30 cents per CDI, a five percent discount to the 150-day volume weighted average price (BD: Aug 4, 2025).
Nyrada was unchanged at 32 cents.

VITRAFY LIFE SCIENCES

Vitrafy says co-founder and deputy chief executive office Brent Owens will replace managing-director and chief executive officer Kate Munnings on September 1, 2025.
Vitrafy said Ms Munnings would retire from her executive role and continue as a non-executive director.
The company said it would pay Mr Owens $440,554 a year, inclusive of superannuation, as well as a short-term incentive of up-to 60 percent of his salary and long-term incentive performance rights worth up-to 60 percent of his annual pay, subject to performance.
Vitrafy said Ms Munnings had “agreed to waive the company’s obligation to pay the remaining 11 months’ notice period in lieu” and would be paid $66,000 a year in fees as a non-executive director, inclusive of superannuation.
The company said given its immediate priorities of product and business development for its cryo-preservation hardware and cloud-based software for storing biological samples, it had concluded its “next phase of growth would benefit from a leader with deep knowledge of Vitrafy’s novel cryo-preservation technology, as well as the biotechnology sector”.
Vitrafy said Mr Owens had been “instrumental in the development of Vitrafy’s novel cryo-preservation technology and strategic vision, and his deep knowledge of the science of cryo-preservation is widely respected globally”.
Vitrafy fell five cents or three percent to $1.60.