Biotech Daily

Tuesday June 24, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PARADIGM UP 12%; NOVA EYE DOWN 9%**

*** AMPLIA US PHASE II AMP945, FOLFIRINOX TRIAL APPROVED**

*** COGSTATE EXPECTS REVENUE UP 22% TO $81.7m**

*** CARDIEX RIGHTS RAISE $4.1m; TOTAL $6.5m**

*** ADHERIUM $4m RIGHTS OFFER**

*** CORRECTION: CELLEO**

*** TELIX: EXPANDED FDA ILLUCCIX PROSTATE CANCER LABEL**

*** AUSBIOTECH, UK BIOINDUSTRY PARTNERSHIP**

*** BIOTRON 'UNDISCLOSED HEPATITIS B DRUG SAFE, IN MICE'**

*** INOVIQ TELLS ASX: 'IN-VITRO DATA NEWS FAIR, BALANCED'**

*** RADIOPHARM, CYCLOTEK RAD402 SUPPLY DEAL**

*** RHYTHM GENETYPE NATA CERTIFIED**

*** OPYL 'PATHKEY.AI' NAME CHANGE, 10m CHAIR 'RIGHTS' EGM**

*** FIREBRICK REQUESTS 'PLACEMENT' TRADING HALT**

*** PHILLIP ASSET TAKES 19.9% OF ADHERIUM**

*** TRUDELL INCREASES, DILUTED TO 19.9% OF ADHERIUM**

*** K ONE W ONE (K1W1) TAKES 7.4% OF ADHERIUM**

*** ADVANCE TAKES 8% OF OSTEOPORE**

*** MICHELLE WING BELOW 5% OF RHYTHM**

MARKET REPORT

The Australian stock market was up 0.95 percent on Tuesday June 24, 2025, with the ASX200 up 80.6 points to 8,555.5 points.

Twenty of the Biotech Daily Top 40 companies were up, 14 fell, five traded unchanged and one was untraded.

Paradigm was the best, up 3.5 cents or 12.1 percent to 32.5 cents, with 2.5 million shares traded.

Actinogen improved 10.5 percent; Syntara was up 8.5 percent; Clarity and Clinuvel climbed six percent or more; Alcidion and Cyclopharm were up five percent or more; Curvebeam was up 4.8 percent; Impedimed improved 3.3 percent; 4D Medical, Aroa, Immutep, Neuren, Pro Medicus and Starpharma rose two percent or more; Dimerix, Emvision, Nanosonics and Polynovo were up more than one percent; with Cochlear, CSL, Medical Developments and Mesoblast up by less than one percent.

Nova Eye led the falls, down one cent or 9.1 percent to 10 cents, with 972,801 shares traded. Optiscan lost 8.3 percent; Imugene was down 7.7 percent; Genetic Signatures, Medadvisor, Orthocell and SDI fell more than three percent; Amplia, Micro-X, Prescient and Resonance shed two percent or more; Avita and Proteomics were down more than one percent; with Resmed and Telix down by less than one percent.

AMPLIA THERAPEUTICS

Amplia says it has US approval for a 60-to-70-patient, phase IIa trial of narmafotinib, or AMP945, with 5-fluorouracil, leucovorin, irinotecan and oxaliplatin for pancreatic cancer.
Last week, Amplia was up 202.5 percent on news that its 55-patient, phase Ib/IIa 'Accent' trial of AMP945 with gemcitabine and Abraxane, in Australia and South Korea had two confirmed pancreatic cancer complete responses (BD: Jun 16, 19, 2025).
At that time, the company said a confirmed complete response was "a rare outcome in advanced pancreatic cancer where the disease has spread to other parts of the body".
Today, Amplia said it had US institutional review board approval for a trial of its focal adhesion kinase (FAK) inhibitor narmafotinib with Folfirinox (5-fluorouracil, leucovorin, irinotecan and oxaliplatin) chemotherapy in patients with advanced pancreatic cancer.
The company said the trial was designed to identify the optimal daily dose of orally administered narmafotinib, combined with chemotherapy administered every two weeks.
Amplia said it was working with its clinical trials organization to identify up to six trial sites in the US, with the principal investigators for each of the six selected sites to apply to their local authorities for final approval for the trial.
The company said it was seeking a separate ethics approval to conduct the trial at two clinical trial sites in Australia.
Amplia managing-director Dr Chris Burns said receiving protocol approval was "a critical step in initiating the US trial of narmafotinib in combination with Folfirinox".
"Importantly, results from this trial will complement the existing positive data emerging from our current 'Accent' trial, aiming to establish narmafotinib as the optimal combination partner for chemotherapy in this challenging disease," Dr Burns said.
Amplia fell half a cent or 2.8 percent to 17.5 cents with 18.6 million shares traded.

COGSTATE

Cogstate says it expects revenue for the year to June 30, 2025 to be up 20-to-24 percent to $US52.0 million ($A80.2 million) to $US54.0 million ($A83.2 million).
Last year, Cogstate said revenue from clinical trials contracting services and cognition testing devices for the year to June 30, 2024 was $US43,427,773 (BD: Aug 22, 2024).
Today, the company said it expected net profit before tax to be up 69-to-97 percent to between $US12.0 million and $US14.0 million, compared to the prior period.
Cogstate said the results reflected “strong performance and improved outlook across key financial metrics”.
Cogstate was up 13.5 cents or 10 percent to $1.485.

CARDIEX

Cardiex says it has raised about $4.1 million at 4.0 cents a share in its full-underwritten rights offer, taking the total raised with its placement to $6.5 million.
Earlier this month, Cardiex said it raised $2.4 million at 4.0 cents a share in a placement, with a fully-underwritten, $4.1 million rights offer to follow (BD: Jun 5, 2025).
Today, Cardiex said 50.3 percent of the entitlement offer was raised from shareholders, including $1,350,133 from the chair Niall Cairns and director Craig Cooper-owned C2 Ventures, with the remainder taken-up by the underwriter Blackpeak Capital Pty Ltd.
The company said C2 Venture’s participation in the raise was subject to shareholder approval, and that Blackpeak Capital, Stralis Capital Partners and Taylor Collison were joint-lead managers to the offer.
Cardiex fell 0.1 cents or 2.5 percent to 3.9 cents.

ADHERIUM

Adherium says it hopes to raise up-to $4 million at 0.5 cents a share in a partially-underwritten institutional and retail entitlement offer.
Biotech Daily calculates that the 0.5 cents a share offer price is a 28.6 percent discount to Adherium’s last closing price of 0.7 cents.
Adherium said investors would receive one option for every share issued, exercisable at 0.5 cents each by July 31, 2026, as well as a “bonus option” for every option exercised by November 15, 2025, exercisable 0.5 cents each by November 15, 2026.
The company said funds raised would be used for “customer onboarding”, product development, sales contractors, data scientists, chief executive officer and sales team recruitment and general working capital.
Adherium said it had “firm commitments” for $800,000 of the institutional component of the offer to be taken up by Phillip Thematic Fund Pte Ltd, as well as $1.0 million in sub-underwriting commitments from Phillip Asset Management and Trudell Medical for the retail component of the entitlement offer.
The company said PAC Partners and Stralis Capital Partners were joint lead managers to the raise, with PAC Partners underwriter and bookrunner.
Adherium said the retail offer had a record date of June 26, would open on July 1 and close on July 10, 2025.
Separately, the company requested a trading halt “pending an announcement in relation to a proposed capital raising”.
Trading will resume on June 26, 2025, or on an earlier announcement.
Adherium last traded at 0.7 cents.

CELLEO PTY LTD

Last night's edition incorrectly said that Melbourne's Celleo hoped to raise $5 million at $1.17 a share to further its cell therapy production systems.
In fact, the capital raising is at $1.71 a share.
Biotech Daily apologizes unreservedly for the error.
The Monday sub-editor has been seconded to the Doha Times.
Celleo is a private company.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has approved an Illucix label expansion to include prostate cancer patient selection for radio-ligand therapy.
In 2021, Telix said that it had FDA approval for its Illuccix positron emission tomography (PET)-based prostate cancer imaging product (BD: Jan 16, 2022).
Today, the company said the updated label applied to Illuccix's "third indication for selection of patients who were indicated for [positron specific membrane antigen]-directed therapy as described in the prescribing information of the therapeutic products.
Telix said the expansion followed the FDA's approval of an expanded label for Pluvicto for use in metastatic castration-resistant prostate cancer patients after treatment with androgen receptor pathway inhibitor therapy and before chemotherapy.
The company said with radio-ligand therapy "approved for use earlier … the clinical utilization of Illuccix is expected to increase by at least 20,000 scans annually".
Telix Precision Medicine chief executive officer Kevin Richardson said the company was "pleased" the US Illuccix label had been expanded to support patient selection for radio-ligand therapy "in the pre-taxane setting, aligning with the evolving treatment landscape".
"With this update, patients can now benefit from the high diagnostic accuracy of Illuccix to identify those most likely to respond to [prostate specific membrane antigen]-targeted therapy, even earlier in their treatment journey," Mr Richardson said.
Telix fell nine cents or 0.4 percent to $24.39 with 1.05 million shares traded.

AUSBIOTECH

Ausbiotech says it has signed an agreement with the UK Bioindustry Association for "enhancing policy alignment and fostering industry collaboration".
Ausbiotech said the deal was signed at the BIO International Convention in Boston, from June 16 to 19, 2025.
Ausbiotech chief executive officer Rebekah Cassidy said Australia and the UK were "already strong and trusted partners in the life sciences sector".
"Our complementary innovation systems and shared values have enabled deep collaboration across research, commercialization, and trade," Ms Cassidy said.
"This [memorandum of understanding] signals a shared intent to go further, to scale up our partnership and drive mutual growth through innovation," Ms Cassidy said.
The industry organization said it had discussed "Australia's strengths in clinical trials, tropical and infectious disease, radio-pharmaceuticals and regenerative medicine" with Japan Bioindustry Association, the Japanese Government and the Taiwan Bio Industry Organization.
The organization said it had met with industry association peers in Canada and the US to discuss opportunities "to work more closely in the future, touching on areas from workforce development through to opportunities for greater patient voice and product development".

BIOTRON

Biotron says it has conducted a safety study of its unnamed lead drug for hepatitis B virus (HBV) in mice and has found the correct dose for use in a second study.

Biotron managing-director Dr Michelle Miller told Biotech Daily that the HBV drug was not BIT225 and the company had been "working for some time on a new series of novel compounds for this indication" with the structure and name of the compounds "not in the public domain".

The company said in the first study, at San Francisco's Scripps Research Institute, mice were dosed every 10 hours for seven days with three different doses of the drug to determine safety, with all mice remaining health throughout the study and no organ toxicity observed on autopsy, confirming the safety of the drug at all dosing levels.

Biotron said it would assess the efficacy of the drug for protecting against and treating hepatitis B in mice.

Biotron has been developing BIT225 for hepatitis C, HIV and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) (BD: Jul 12, 2006; Mar 22, 2007, Aug 7, 2008).

Biotron was up 0.05 cents or 25 percent to 0.25 cents.

INOVIQ

Inoviq has told the ASX that its announcement of in-vitro study results was "fair and balanced" as it stressed the results were from studies done in laboratories, or in-vitro.

Last week, Inoviq said its chimeric antigen receptor (CAR)-exosomes had "exceptional efficacy, killing 88 percent of [breast cancer] and lung cancer cells" in 96 hours, in-vitro, telling Biotech Daily the study was conducted in-house (BD: Jun 18, 2025).

Today, the ASX asked whether the announcement "conveyed a fair and balanced impression of the contents of the announcement, given the early stage of the research"?

The ASX noted the company's share price rose as much as 21.3 percent from 38.75 cents immediately prior to the announcement to a high of 47 cents following the announcement.

The query said the announcement appeared to not provide the level of detail concerning the study results that ASX ordinarily expects from a market-sensitive study and asked for additional information.

The ASX said the announcement's header did "not indicate that the studies were in-vitro, and the forward-looking statements appear to be highly aspirational without a present reasonable basis".

Inoviq said in its view the title represented the contents of the announcement fairly as it included the words "cells in lab tests", with the highlights of the study including "in lab studies" and the first paragraph stating "in recent in-vitro studies".

The company said it had a reasonable basis to make forward-looking statements as its exosome platform, if approved, could be used to treat multiple patients and were "faster to produce … safer to use … [and] more effective than traditional cell therapies like CAR-T".

Inoviq said the potential advantages of CAR-exosomes, such as its products, were "general well-known and accepted int eh scientific literature based on previous researchers' in-vitro and in-vivo studies".

The company said it used the term "treatment" because the in-vitro study was a treatment: control design, meaning that the cytotoxic efficacy of its treatment on cells maintained in culture was compared with untreated cell controls.

Inoviq said that in the announcement it had "disclosed all relevant information concerning the study results, and that the announcement is not misleading by omission".

Inoviq was up half a cent or 1.3 percent to 38.5 cents.

RADIOPHARM THERANOSTICS

Radiopharm says Melbourne's Cyclotek will radio-label its RAD402 with terbium-161 in for its phase I clinical trial in prostate cancer.
Radiopharm said RAD402 was an "anti-Kallikrein related peptidase 3 (KLK3) monoclonal antibody radio-therapeutic labelled with the radio-nuclide 161Tb for treatment of prostate cancer", designed to target KLK3, which was highly expressed in the prostate, with very limited to no expression in other tissues and organs.
The company said compared to lutetium-177, terbium-161 emitted "additional auger and conversion electrons alongside its beta-radiation, which can lead to potentially improved anti-tumoral therapeutic efficacy".
Radiopharm said its study would be "the first company-sponsored phase I trial in prostate cancer using terbium-161", and did not disclose the commercial terms of the agreement.
The company said the phase I trial was expected "to start in the second half of 2025".
Radiopharm managing-director Riccardo Canevari said the agreement was "an important milestone for the development of RAD 402 and is the last step needed to submit for ethics approval and begin our phase I clinical trial in prostate cancer".
Radiopharm was up 0.1 cents or 4.35 percent to 2.4 cents with 2.85 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says it has Australian National Association of Testing Authorities (NATA) accreditation for its Genetype cancer risk assessment tests.
Last year, Rhythm said it would acquire Genetic Technologies' Genetype risk assessment test for various diseases for $625,000 in cash; and later, said it had its first commercial sale for an undisclosed price (BD: Jan 19, Mar 19, 2025).
Today, the company said the accreditation milestone was "the successful conclusion of the integration of the Genetype laboratory under Rhythm's ownership and ensures continuity of accredited testing services moving forward".
Rhythm said the reinstatement was "also crucial for advancing the company's Colostat commercialization strategy".
Rhythm managing-director Dr David Atkins said reinstating NATA accreditation for Genetype was "an important enabler for our plans to scale the clinical availability of this important portfolio of cancer risk assessment assays … [and] to allow us to offer Colostat as an in house [in-vitro diagnostic] for the domestic market in the coming months".
Rhythm fell half a cent or 8.3 percent to 5.5 cents with 1.3 million shares traded.

OPYL (FORMERLY SHAREROOT)

Opyl says its extraordinary general meeting will vote to change its name to 'Pathkey.AI', ticker code to 'PKY' and issue 10,000,000 rights to chair Saurabh Jain.
Opyl said investors would vote to change the company's name "primarily to better align the company's legal name with its evolving brand identity and strategic direction".
The company said shareholders would vote to issue managing-director Mr Jain 3,333,333 performance rights exercisable at 1.5 cents each within 12 months and vesting on achieving $100,000 in Trialkey sales; and 6,666,667 rights to Mr Jain exercisable under the same terms on the successful recruitment of a chief executive officer; and if not passed it would pay Mr Jain $50,000 and $100,000 in cash respectively.
The meeting will be held at 6 Middlemiss St, Milsons Point, Sydney on July 25, 2025 at 10.30am (AEST).
Opyl was unchanged at 1.9 cents.

FIREBRICK PHARMA

Firebrick has requested a trading halt “pending an announcement regarding a share placement’.
Trading will resume on June 26, 2025, or on an earlier announcement
Firebrick last traded at 7.0 cents.

ADHERIUM

Phillip Asset Management Ltd says it has increased its substantial shareholding in Adherium from 123,733,827 shares (16.32%) to 178,770,321 shares (19.90%).
The Melbourne-based Phillip Asset says as trustee for Bioscience Managers Translation Fund it acquired 55,036,494 shares through the conversion of convertible notes on June 23, 2025.
Earlier this year, Adherium said it had “firm commitments” to raise $2.6 million in convertible notes, with one option for every two shares issued (BD: Mar 18, 2025).
At that time, the company said Bioscience Managers and Trudell Medical each subscribed for $1.2 million under the raise, with Philip Asset Management and K One W One Ltd taking up $825,000 and $200,000, respectively.
Last month, Adherium said it had “firm commitments” to raise $900,000 in convertible notes, with investors to receive one option for every two shares issued and Philip Asset Management and Trudell Medical committing to take-up $450,000 (BD: May 19, 2025).

ADHERIUM

Trudell Medical says it has increased and been diluted in Adherium from 73,538,685 post-consolidation shares (22.15%) to 178,776,885 post-consolidation shares (19.9%).
The London, Ontario-based Trudell said that on December 7, 2023 its 1,029,541,587 share-holding was consolidated 15-to-one, on May 27, 2024 it bought 50,000,000 shares for $1,000,000 in an entitlement offer, or 2.0 cents share and on July 7, 2024 it bought 11,000,000 shares in a placement at $220,000, or 2.0 cents a share.
In 2023, Adherium said it completed its 15-to-one stock-consolidation and had 333,439,981 post-consolidation shares on issue (BD: Dec 7, 2023).
Last year, the company said it had commitments to raise up-to $1,570,000 in a placement at 2.0 cents a share; and later, said it had raised $6,800,780 in a one-for-one entitlement offer at the same price (BD: Apr 26, 2024)
Today, Trudell said that it had acquired 44,238,200 on June 23, 2025 through the conversion of convertible notes (see above).

ADHERIUM

The Auckland, New Zealand-based K One W One Ltd (K1W1) says it has become a substantial shareholder in Adherium with 66,836,248 shares, or 7.44 percent.
K One W One said it acquired shares at various prices between August 19, 2025 and June 23, 2025 through a share swap agreement, two entitlement offers, three placements and the conversion of convertible notes (see above).

OSTEOPORE

The Cayman Islands-based Advance Opportunities Fund says it has become a substantial shareholder in Osteopore with 15,096,074 shares (8.25%).
Advance said that it bought 5,480,690 shares on May 8 for $70,153, or 1.3 cents a share and 9,615,384 shares on June 19, 2025 for $100,000, or one cent a share.
Last year, Osteopore said that it expected to raise $20 million from Advance for a redeemable convertible note at four percent interest a year, issuing in four equal tranches of 20 equal sub-tranches of $250,000 each (BD: Sep 27, 2024).
At that time, the company said the note had a conversion price at 80 percent of the average closing price on “any five consecutive business days” as selected by the noteholder during the 45 business days immediately preceding the conversion date.
Earlier this year, Osteopore said Advance subscribed for $2.0 million worth of the $20 million redeemable convertible note; and later; said Advance had subscribed for a further $2.0 million (BD: Feb 17, Apr 8, 2025).
Last month, the company said Advance had subscribed for a further $500,000 of the convertible note; and later said $500,000 more was converted (BD: May 19, 26, 2025).
Osteopore fell 0.2 cents or 16.7 percent to one cent with five million shares traded.

RHYTHM BIOSCIENCES

The Melbourne-based Michelle Wing says with Northern Star Nominees Pty Ltd she has ceased her substantial shareholding in Rhythm Biosciences.
Ms Wing said she sold 817,437 shares between June 11 and 20, 2025 for $49,488, or 6.05 cents a share.
Earlier this month, Ms Wing said she had reduced her substantial shareholding in Rhythm from 19,182,261 shares (9.19%) to 14,958,343 shares (5.26%) (BD: Jun 11, 2025).
According to its most recent filing, Rhythm had 284,080,621 shares on issue, meaning that Ms Wing retained 4.98 percent of the company.