Biotech Daily

Thursday June 5, 2025

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: AMPLIA UP 26%; CYNATA DOWN 6%**

*** CLARITY: 'CU-64 SARTATE BEATS STANDARD-OF-CARE'**

*** PROTEOMICS: 'PROMARKER ESO DIAGNOSES OESOPHAGEAL CANCER'**

*** PROTEOMICS SHARE PLAN RAISES $7.5m; TOTAL $12m**

*** CARDIEX RAISES $2.4m; $4.1m RIGHTS OFFER**

*** PROTO AXIOM, ST VINCENT'S $500k MEDTECH AWARDS**

*** MAYNE COSETTE SCHEME MEETING, DESPITE 'TERMINATION'**

*** AVITA 35% OPPOSE INCENTIVE PLAN, 26% CEO OPTIONS AGM**

*** UNIVERSAL BIOSENSORS RECEIVES $2.2m FEDERAL R&D TAX INCENTIVE**

*** PAINCHEK, FDA REVISE PAIN DE-NOVO TIMELINE**

*** AUSBIOTECH JOINS FEDERAL TRADESTART PROGRAM; SEEKS ADVISOR**

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

*** ADVANCE REDUCES TO 6.7% OF OSTEOPORE**

*** MARK AZZI TAKES 12% OF NYRADA**

*** EMVISION APPOINTS CARMEL MONAGHAN DIRECTOR**

MARKET REPORT

The Australian stock market slipped 0.03 percent on Thursday June 5, 2025, with the ASX200 down 2.9 points to 8,538.9 points. Twenty-one of the Biotech Daily Top 40 companies were up, 12 fell and seven traded unchanged. The four Big Caps were mixed.

Amplia was the best on no news, up 1.3 cents or 26 percent to 6.3 cents, with 9.8 million shares traded. Clarity climbed 12.0 percent (see below); Orthocell and Universal Biosensors rose more than nine percent; Optiscan improved six percent; Actinogen was up 4.8 percent; 4D Medical, Aroa, Compumedics, Impedimed and Proteomics were up three percent or more; Resonance rose 2.6 percent; Botanix, EBR, Mesoblast, Polynovo, SDI, Starpharma and Syntara were up more than one percent; with Cochlear, Emvision, Medical Developments and Resmed up by less than one percent.

Cynata led the falls, down one cent or 5.6 percent to 17 cents, with 84,228 shares traded; followed by Cyclopharm, down six cents or 5.3 percent to $1.08, with 147,866 shares traded. Genetic Signatures fell 4.35 percent; Avita lost 3.7 percent; Alcidion, Medadvisor and Telix shed more than two percent; Clinuvel, CSL, Dimerix, Immutep, Nanosonics and Paradigm were down more than one percent; with Pro Medicus down by 0.9 percent.

CLARITY PHARMACEUTICALS

Clarity says its 45-patient, phase II trial shows its copper-64 Sartate was “safe and highly effective compared to standard-of-care” for detecting neuro-endocrine tumor lesions.

Clarity said about “half of all discordant lesions had an available [standard-of-truth], which yielded a lesion-level sensitivity of 93.4 percent to 95.6 percent … for copper-64 Sartate … and only 4.4 percent to 6.6 percent for [the standard-of-care] gallium-68-Dotatate”.

Clarity executive chair Dr Alan Taylor told Biotech Daily that concordant lesions were those that both tests agreed, while discordant lesions were those identified by only one of the tests.

The company said the trial compared the diagnostic performance of copper-64 Sartate at an average of four hours and 20 hours post-administration, same-day and next-day imaging, respectively, to standard-of-care gallium-68 Dotatate.

Clarity said the study showed that copper-64 Sartate “substantially outperformed that of gallium-68 Dotatate”, detecting 393 to 488 lesions compared to 186 to 265 lesions for gallium-68 Dotatate in 45 study participants.

The company said 230 to 251 lesions were discordant, or only present on one of the scans, with 93.5 percent of the discordant lesions only detected on the copper-64 Sartate PET scans.

Clarity said the number of discordant lesions detected by copper-64 Sartate was comparable for both same-day and next-day scans.

The company said patients with gastro-entero-pancreatic neuro-endocrine tumors were enrolled at four Australian sites dosed with 200 mega Becquerels (MBq) of copper-64 Sartate and both the copper-64 Sartate and gallium-68 Dotatate scans were reviewed by two blinded central readers.

Clarity said patients were followed for up-to 12 months to complete additional investigations, such as biopsy and conventional imaging, and obtain the standard-of-truth used to verify discordant findings between the scan pairs.

The company said copper-64 was “deemed safe and well-tolerated” with seven, or 15.55 percent, of patients experiencing copper-64 Sartate-related adverse events.

Clarity said no serious treatment-emergent adverse events were observed in the study.

The company said that based on the findings from the trial it would “commence the next steps to conduct a registrational phase III study of copper-64 Sartate in [neuro-endocrine tumors] with the US [Food and Drug Administration’s] guidance”.

Dr Taylor said the ‘Disco’ trial showed “a significant advantage of our diagnostic over gallium-68 Dotatate”.

“Copper-64 Sartate detected almost double the number of lesions compared to the [standard-of-care], and, where [standard-of-truth] was available, a very high lesion-level sensitivity of 93.4 percent to 95.6 percent in comparison to just 4.4 percent to 6.6 percent for gallium-68 Dotatate for these discordant findings,” Dr Taylor said.

“In addition to identifying more lesions with our product, lesions detected by copper-64 Sartate also exhibited high uptake with low background on the PET scans, making it easier to identify those lesions by readers,” he said.

“Excellent lesion visualization was also supported by substantial clearance from the liver,” Dr Taylor said.

In 2021, Clarity said it dosed the first ‘Disco’ trial patient, which used positron emission tomography (PET) on patients with known or suspected gastro-entero-pancreatic neuro-endocrine tumors to assess copper-64 Sartate (BD: Apr 15, 2021).

Last year, Clarity said it had assessed all 45 patients in the trial, with results expected “in the first half of 2025” (BD: Nov 28, 2024).

Clarity was up 25 cents or 12.0 percent to $2.33 with 5.3 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 147-volunteer study shows its Promarker Eso blood test diagnoses oesophageal cancer with 91.4 precent sensitivity and 98.9 percent specificity.

In 2022, Proteomics said a 302-patient study of its oesophageal cancer test had a “strong diagnostic performance” with an up-to 90 percent detection rate (BD: Sep 27, 2022).

Later, the company said that the blood test correctly identified 89 percent of patients with the disease and 92 percent without the disease (BD: Sep 8, 2023).

Last year, Proteomics said it presented further data confirming the biomarkers used in its endometriosis and oesophageal cancer blood tests (BD: Feb 1, 2024).

In September, the company said its Promarker Eso blood test for oesophageal adenocarcinoma showed 94 percent accuracy in a 165-sample clinical validation study, with 93.1 percent sensitivity and 96.6 percent specificity (BD: Sep 23, 2024).

Today, Proteomics said a study of the analysis of 259 serum samples from three independent patient cohorts showed Promarker Eso could “diagnose oesophageal adeno-carcinoma with high accuracy”.

The company said the 259-sample study was conducted with the Queensland Institute of Medical Research Berghofer, Adelaide’s Flinders University and the Atlanta, Georgia-based Emory University.

Proteomics said the test compared 48 patients with 40 negative controls, with Promarker Eso showing sensitivity of 97.9 percent and specificity of 87.5 percent.

The company said the test was then studied on a first validation cohort of 10 patients and 14 controls and showed 100 percent sensitivity and 85.7 percent specificity, followed by the 147-participant second cohort.

Proteomics said the study, titled ‘Clinical validation of a diagnostic test for esophageal adenocarcinoma based on a novel serum glycoprotein biomarker panel’ was published in the journal Proteomes, with the full article available at: https://bit.ly/4mNjo1H.

Proteomics managing-director Dr Richard Lipscombe said the published results were “a major advancement in our mission to transform the lives of people living with chronic acid reflux”.

“Promarker Eso has the potential to revolutionize how doctors manage the risk of oesophageal cancer, offering a standard blood test that could reduce reliance on invasive procedures and improve early detection rates,” Dr Lipscombe said.

Proteomics was up 1.5 cents or 3.8 percent to 41 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it raised $7.5 million at 37 cents a share in its “heavily oversubscribed” share plan taking the total with the placement to $12 million.

Earlier this year, Proteomics said it raised $4.5 million at 37 cents a share, a 17.9 percent discount to the 15-day volume weighted average price, to be followed by a $1 million share purchase plan “with the ability to take over-subscriptions” (BD: Apr 22, 2025).

At that time, the company said investors would receive one attaching option for every two shares issued, exercisable at 50 cents each by May 31, 2026.

Today, Proteomics said the funds raised would be used to commercialize its three Promarker tests in Australia and the US, systems upgrades, laboratory platforms, research and development and working capital.

Proteomics managing-director Dr Richard Lipscombe said the company was “humbled by the huge vote of confidence from our shareholders who have supported the share purchase plan in large numbers”.

CARDIEX

Cardiex says it has raised $2.4 million at 4.0 cents a share in its institutional placement, with a fully-underwritten, $4.1 million rights offer to follow.
Cardiex said the chair Niall Cairns and director Craig Cooper-owned C2 Ventures, its largest shareholder, subscribed for $736,383 worth of the placement, subject to shareholder approval at a general meeting expected “in late July”.
Cardiex said the funds raised would “be used for new device manufacturing, marketing and sales activities, and for commercial expansion, including scaling up supply chain operations relating to the Conneqt Pulse device”.
The company said Blackpeak Capital, Stralis Capital Partners and Taylor Collison were joint lead managers to the placement.
Cardiex said the one-for-four, underwritten, non-renounceable entitlement offer had a record date of June 4, would open on June 6 and close on June 20, 2025.
Cardiex was unchanged at four cents.

PROTO AXIOM

Proto Axiom says with Sydney’s St Vincent’s Curran Foundation it will “host Australia’s largest medical pitch day”, with up-to $500,000 of grants in March 2026.
Proto Axiom said the St Vincent’s Curran Foundation “raised philanthropic funds to advance excellence and innovation in patient care, clinical education and medical research at Sydney’s St Vincent’s Hospitals and facilities in New South Wales”.
The biotechnology incubator said its ‘Challenger Pitch for Health’ event would award $500,000 to four “outstanding translational research projects”.
Proto Axiom said finalists would pitch to investors, clinicians and industry leaders and the event would combine with St Vincent’s pitch for health to improve “visibility for researchers, foster collaboration and streamline pathways to capital”.
The company said there would be up-to 16 finalists, eight from each program, presenting five-minute pitches, with panels and keynote addresses discussing “trends in clinical translation, investment and health-tech commercialization”.
Proto Axiom said applications would open in August 2025, with full guidelines, key dates and submission portals for both grant streams available soon.
Proto Axiom chief executive officer Anthony Liveris said the ‘Challenger Pitch for Health’ would give “Australia’s best clinician-scientists a national stage and the capital they need to move bold ideas out of the lab and into patients’ lives”.
Proto Axion is a private company.

MAYNE PHARMA

Mayne Pharma says it will hold a scheme meeting to approve its acquisition by Cosette Pharmaceuticals on June 18, with a second court date on September 18, 2025.
Yesterday, Mayne said it had received a “purported notice to terminate [the] scheme implantation deed” from the Bridgewater, New Jersey-based Cosette which had bid $7.40 a share in cash, valuing the company at $672 million (BD: Feb 21, Jun 4, 2025).
Today, Mayne said that it received court approval to issue a supplementary scheme booklet “after the close of business on June 4, 2025”.
The company said it continued to “unanimously recommend that you vote in favor of the scheme resolution” in the absence of a superior proposal and subject to the independent expert continuing to conclude that the scheme is in the best interest of investors.
Mayne was up 42 cents or 9.4 percent to $4.90 with 2.2 million shares traded.

AVITA MEDICAL

Avita says shareholders passed all resolutions with up-to 34.70 percent against the omnibus incentive plan and 25.8 against chief executive officer James Corbett's options.
Earlier this year, Avita said shareholders would vote to issue 520,000 options to Mr Corbett and 4,925 options, each, to its chair and five directors, exercisable at $8.73 each within 10 years, as well as 60,132 restricted stock units (BD: Apr 23, 2025).
Today, the company said the amended omnibus incentive plan was opposed by 3,655,347 votes (34.70%) with 6,876,570 votes (65.30%) in favor.
Avita said Mr Corbett's options faced 2,772,833 votes (25.75%) opposition, with 7,994,902 votes (74.25%) in support.
The company said the approval to compensate named executive officers on an advisory basis was opposed by 20.81 percent, with the issue of restricted stock units and options to its chair and directors facing between 17.45 percent and 17.63 percent opposition and the remaining resolutions passing more easily.
Between 9.68 percent and 22.51 percent of votes were "withheld" from the election of all directors.
According to its most recent filing, Avita had 132,173,290 Chess depository interest (CDI) equivalents on issue, equivalent to 26,434,658 US shares.
The largest number of votes was the 3,655,347 votes against the amended omnibus incentive plan.
Avita fell seven cents or 3.7 percent to $1.83.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received $2,204,620 from the Australian Tax Office under the Federal Government's Research and Development Tax Incentive program.
Universal Biosensors said the incentive related to research and development expenditure for the year to June 30, 2024.
Universal Biosensors was up 0.3 cents or 9.1 percent to 3.6 cents.

PAINCHEK

Painchek says the US Food and Drug Administration requires additional clinical study information for de novo marketing clearance for its pain assessment application.
Painchek said the meeting was focused on addressing the FDA's final questions related to its recent US clinical trial results, and that based on the meeting discussions it was "compiling additional information collected from the completed clinical study that addresses the FDA feedback".
Last year, the company said it completed its 105-volunteer US validation study at five aged care homes, with results being included in the report; and later, said it would file "positive results" from the study with the FDA application (BD: Oct 2, 29, 2024).
Later, Painchek said it applied for FDA de-novo status for its adult facial pain assessment application for smartphones and tablets (BD: Nov 20, 2024).
Today, the company said the submission of the additional information was expected to be the final step in its US de novo marketing clearance application and would be submitted "prior to the end of June 2025".
Painchek said on receipt of its final submission, there was "a commitment by FDA for a final decision on de novo regulatory clearance within 75 days, giving a projected potential clearance date of mid-to-late September 2025 or sooner".
Painchek fell 1.3 cents or 23.6 percent to 4.2 cents with 22.7 million shares traded.

AUSBIOTECH

Ausbiotech says it will join with the Federal Government's Trade and Investment Commission (Austrade) 'Tradestart' program for Australian life science companies.
Ausbiotech said it was "the first life sciences peak body to join with Austrade as a national partner in delivering Tradestart, joining other industry peak bodies in the program".
The industry organization said it would hire a Tradestart advisor "to support Australian biotechnology, pharmaceutical, medical technology and digital health companies to scale and grow internationally".
Ausbiotech said the advisor would work "directly with life sciences companies across Australia, connecting them with Austrade services and programs globally".
The organization said it was "a significant step forward in Ausbiotech's mission to grow the Australian life science sector and support members in future-focused ways".
Ausbiotech chief executive officer Rebekah Cassidy said the program would "ensure companies across our wider ecosystem have the right support, intelligence, and access to thrive globally … but navigating global markets can be complex".
"This new role will help to unlock growth and global pathways by embedding a new and sophisticated level of strategic support directly into our ecosystem," she said.
"With the life sciences sector playing an increasingly strategic role in Australia's economy, it's an important proof point in how industry and government can work together to match that potential with the right structures of support," Ms Cassidy said.
Ausbiotech said applications for the advisor role were open at: https://bit.ly/4dJrSCU.

FIREBRICK PHARMA

Firebrick has requested a trading halt "pending an announcement regarding a share placement".
Trading will resume on June 10, 2025, or on an earlier announcement.
Firebrick last traded at 6.7 cents.

OSTEOPORE

The Cayman Islands-based Advance Opportunities Fund says it has reduced its holding in Osteopore from 13,678,529 shares (7.89%) to 11,685,415 shares (6.74%).
Advance said that it sold 493,114 shares on June 3, 2025 for $7,890, or 1.6 cents a share and on June 4, 2025 sold 1,500,000 shares for $22,650, or 1.5 cents 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).
Earlier this year, the company 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, Osteopore 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 0.1 cents or 6.7 percent to 1.4 cents with 1.2 million shares traded.

NYRADA

Nyrada says Mark Azzi has increased his substantial shareholding from 22,453,383 Chess depository interests (CDIs) (10.65%) to 25,131,217 CDIs (11.92%).
Nyrada was up one cent or 5.6 percent to 19 cents with one million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has appointed Carmel Monaghan as an independent non-executive director, effective from today.

Emvision said Ms Monaghan was chief executive officer of private health operator Ramsay Healthcare, and previously was Ramsay Australia chief executive officer, Ramsay Healthcare head of staff and head of marketing and public affairs.

According to her Linkedin page, Ms Monaghan held a Bachelor of Business and a Master of Business Administration from Brisbane's Queensland University of Technology.

Emvision was up one cent or 0.6 percent to $1.71.