Biotech Daily

Monday June 16, 2025

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: AMPLIA UP 16%; UNIVERSAL BIOSENSORS DOWN 19%**

*** AMPLIA AMP945: '1 PATHOLOGICAL COMPLETE PANCREATIC CANCER RESPONSE'**

*** EMVISION FEDERAL $5m FOR 1st FIRST RESPONDER BRAIN SCANNER**

*** ARTRYA FILES SALIX CORONARY PLAQUE TO FDA**

*** TAIWAN $140k FOR MEDICAL, HEALTH COMPANIES, RESEARCHERS**

*** CSIRO 'INNOVATE TO GROW' HEALTH CARE R&D PROGRAM**

*** TRUSCREEN: UZBEKISTAN APPROVES CERVICAL CANCER TEST**

*** EMYRIA REQUESTS 'AGREEMENT, CAPITAL RAISING' TRADING HALT**

*** MAYNE 2nd COSETTE TERMINATION NOTICE; COURT DATE**

*** HERAMED, RMIT $1.2m FOR 'CULTURALLY DIVERSE' MATERNAL HEALTH**

*** NEURIZON: 'NUZ-001 SIGNIFICANT NEURO-PROTECTION', IN ZEBRAFISH**

*** NYRADA APPROVAL FOR 5th PHASE I NYR-BI03 COHORT**

*** ANTEOTECH: WYON TRIALS ULTRANODE FOR BATTERIES**

*** CANN TAKES $316k RADIUM CAPITAL RDTI LOAN**

*** ADVANCE BELOW 5% OF OSTEOPORE**

*** PENGANA DILUTED BELOW 5% OF ENLITIC**

*** NEUROTECH APPOINTS DR BONNI GOLDSTEIN US MEDICAL ADVISOR**

*** PACIFIC EDGE BOARD INVITES CHAIR CHRIS GALLAHER RE-ELECTION**

MARKET REPORT

The Australian stock market edged up 0.01 percent on Monday June 16, 2025, with the ASX200 up 1.0 points to 8,548.4 points. Eight of the Biotech Daily Top 40 companies were up, 26 fell, five traded unchanged and one was untraded. All four Big Caps were up.

Amplia was the best up 0.9 cents or 15.8 percent to 6.6 cents, with 26.3 million shares traded. Resonance rose 5.4 percent; Cochlear and Optiscan climbed four percent or more; Clarity, Mesoblast, Polynovo and Telix were up three percent or more; Pro Medicus was up 1.4 percent; with CSL, Emvision and Resmed up by less than one percent.

Friday's best, Universal Biosensors, led the falls, down 0.8 cents or 18.6 percent to 3.5 cents, with 207,250 shares traded. Syntara lost 14.9 percent; 4D Medical was down 8.6 percent; Medical Developments slipped 6.8 percent; Avita, Cynata and Prescient were down more than five percent; Micro-X and Nova Eye fell more than four percent; Alcidion, Immutep, Impedimed, Nanosonics, Orthocell and Starpharma were down more than three percent; Cyclopharm, Dimerix and Proteomics shed more than two percent; Aroa, Botanix, EBR, Genetic Signatures, Medadvisor and Neuren were down one percent or more; with Clinuvel and SDI down by less than one percent.

AMPLIA THERAPEUTICS

Amplia says its 55-patient, phase Ib/IIa 'Accent' trial of narmafotinib, or AMP945, with chemotherapy for pancreatic cancer has led to one 'pathological complete response'.
Last month, Amplia said that narmafotinib with standard-of-care chemotherapies gemcitabine and Abraxane had 15 metastatic pancreatic cancer partial responses, beating the historical average for chemotherapy alone (BD: May 15, 2025).
Today, the company said one patient from the trial had "a pathological complete response, an extremely rare observation in this patient population".
Amplia said during routine assessment of tumor burden in the patient there was a "significant reduction in the size and number of hepatic metastases" or secondary tumors in the liver and in the primary tumor in the pancreas.
The company said that "the medical team decided that this enabled them to change the treatment plan for this patient, and surgery was performed to remove both the secondary tumors in the liver and the primary tumor in the pancreas".
Amplia said the surgically removed lesions were subjected to pathological examination and were determined to contain no live tumor tissue.
The company said this outcome was classified as a pathological complete response, which was "very rarely reported in patients with advanced pancreatic cancer, where the disease has spread to other organs in the body".
Amplia said about five percent of patients with locally advanced, or non-metastatic, pancreatic cancer, recorded a pathological complete response when treated with chemotherapy before surgery.
The company said in these earlier stage patients, a pathological complete response was "associated with improvements in overall survival".
Amplia managing-director Dr Chris Burns said the company was "extremely excited to learn that a patient from our study has achieved a pathological complete response".
Amplia climbed as much as 2.8 cents or 49.1 percent to 8.5 cents before closing up 0.9 cents or 15.8 percent at 6.6 cents with 26.3 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says the Federal Department of Industry, Science and Resources has provided $5 million to commercialize its first responder portable brain scanner.
Emvision said the Federal Industry Growth Program funding was payable "quarterly in advance, based on forecast eligible expenditure" and subject to project progress against agreed activities, with reports every three months and to be completed by May 22, 2027.
The company said the Federal Government might end the agreement if it didn't comply with an obligation under the agreement and the Government believed the non-compliance was incapable of remedy, or if Emvision failed to comply with a notice to remedy.
Emvision managing-director Scott Kirkland said the company's "first responder portable brain scanner device is a genuine world first product with potential to transform the landscape of pre-hospital stroke and traumatic brain injury care".
"It is designed to be easily carried to, and operated at the scene, by paramedics and first responders, to enable earlier diagnosis and earlier triage, transfer or treatment decision making," Mr Kirkland said. "In both stroke and traumatic brain injury, time is a critical determinant of outcome."
"Having recently returned from engaging with dozens of healthcare professionals across the US, their feedback is clear, our technology's advanced development stage and unique value proposition wholly sets it apart in the pre-hospital landscape," Mr Kirkland said.
Emvision was up one cent or 0.6 percent to $1.80.

ARTRYA

Artrya says it has applied for US Food and Drug Administration 510(k) clearance to market and sell its Salix coronary plaque module for detecting high-risk plaque.
Earlier this year, Artrya said it had FDA 510(k) clearance to commercialize its Salix coronary anatomy platform in the US (BD: Mar 28, 2025).
Today, the company said the Salix Coronary Plaque module would allow “a near real-time, point-of-care assessment of plaque and stenosis for patients who have undergone a coronary [computed tomography] angiogram”.
Artrya said that subject to FDA approval, the Salix Coronary Plaque module would “qualify for an existing US Category 1 [current procedural terminology] code, with a reimbursement rate of $US950 ($A1,467) for each automated plaque assessment”.
The company said the Salix Coronary Plaque module was expected to receive FDA clearance by October 2025 and would “integrate with the Salix coronary anatomy platform”.
Artrya chief executive officer Mathew Regan said the company was “pleased to have submitted our FDA application for the Salix coronary plaque module, following the successful clearance of our Salix coronary anatomy platform earlier this year”.
“Building on that experience, we’ve developed strong clinical evidence for this submission showing our module’s results closely match those of expert clinicians,” Mr Regan said.
“We’re also making strong progress finalizing integration with our three US hospital partners as we prepare for commercial launch in the US,” Mr Regan said.
Artrya fell two cents or 2.8 percent to 70 cents.

TAIWAN EXTERNAL TRADE DEVELOPMENT COUNCIL

The Taiwan External Trade Development Council (TAITRA) says it will award $US90,000 ($A140,000) to three medical companies and/or researchers.
A media release said the Taiwan Ministry of Economic Affairs’ International Trade Administration had commissioned TAITRA “to initiate a worldwide call for proposals that use “Taiwan’s high-quality health products and holistic solutions”.
The Council said that the funds included cash and support as part of its ‘Go Health with Taiwan’ program for biotechnology companies, entrepreneurs, innovators or researchers with health-related initiatives or ideas that would benefit from the inclusion of Taiwanese products or technology.
The media release said it hoped to receive more than 500 submissions from five continents.
The Council said that the best three proposals would be awarded $US30,000, each, and “all high-quality entries … given the opportunity to explore collaboration and commercialization with Taiwanese companies”.
The Council said the program’s objective was to jointly improve health standards, through sectors including “smart healthcare technologies, medical aesthetics and wellness checkups, fitness equipment, sports technologies, and bicycles”.
The media release said that “Taiwan, long recognized as the ‘Bicycle Kingdom’ boasts a robust and integrated bicycle industry cluster and leading research and development capabilities”.
“As a global hub for high-end bicycle manufacturing, Taiwan is also driving the transition toward net-zero emissions and playing a pivotal role in global sustainable supply chains,” the Council said.
Submissions are open until August 14, 2025 with more information available at: https://gohealthy.taiwanexcellence.org/about.html.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says applications are open for its eight-week 'Innovate to Grow' program for small-to-medium companies developing health care devices and services.
The CSIRO said the program would help small-to-medium enterprises "transform health care innovation ideas into research and development projects".
The Organisation said it would connect companies with "facilitators who understand both the science and commercial realities, to provide expert feedback, researchers with project experience [and] other [small-to-medium enterprises]".
The CSIRO said the program was open for companies developing bio-medical devices, multi-omics, bio-statistics and bio-informatics, medical imaging and genomics, drug discovery, vaccines and therapeutics, advanced cell models, digital health as well as public health and wellbeing.
CSIRO human health research director Dr Erica Bremner Kneipp said more than 700 small-to-medium enterprises had benefitted from the program since 2020.
"Having a great idea is one thing," Dr Kneipp said.
"Turning that idea into a genuine health care solution means matching it to patient and clinical need and understanding the pathway to market," Dr Kneipp said.
"That pathway involves ensuring the innovation can be developed to ensure it is safe, effective, and can be manufactured, and alert to all regulatory requirements," Dr Kneipp said.
"CSIRO's 'Innovate to Grow' gives founders a structured way to stress-test their innovative ideas and plan their [research and development] project before any expensive lab work begins," Dr Kneipp said.
"This ultimately de-risks the idea and makes it more investable," Dr Kneipp said.
Applications close on July 13, 2025 and are available at: https://bit.ly/4lcMvtX.

TRUSCREEN

Truscreen says the Uzbekistan National Pharmaceutical Safety Committee has approved its non-invasive, electrical-optical cervical cancer screening system.
Truscreen said the approval was "a precursor to the planned public screening program starting with 14 women and children's healthcare clinics" in Uzbekistan's capital city Tashkent.
The company said its artificial intelligence-enabled technology was "a transformative step for Uzbekistan, with the aim of extending from Tashkent to a national program".
Truscreen said its 14,000 women public screening program in Zimbabwe's Masvingo Province was expected to be completed by July 21, 2025 (BD: Nov 6, 2023).
The company said that its 260,000 women screening program in Vietnam was expected to begin on July 28, 2025 (BD: Apr 22, 2025).
Truscreen said India distributor Renovate Biologicals had placed its first order of 10 devices and 1,080 single use sensors, but did not disclose the commercial terms of the transaction (BD: Apr 30, 2025).
Truscreen was unchanged at 1.8 cents with 1.2 million shares traded.

EMYRIA

Emyria has requested a trading halt pending "the release of an announcement by the company regarding a material commercial agreement and capital raising".
Trading will resume on June 18, 2025, or on an earlier announcement.
Emyria last traded at 2.5 cents.

MAYNE PHARMA

Mayne says it has a second notice from Cosette to terminate its acquisition scheme and will start court proceedings against Cosette on September 9, 2025.

In February, the company said that the Bridgewater, New Jersey-based Cosette would buy it for $7.40 a share in cash, valuing the company at $672 million and earlier this month, said it had received “a purported notice to terminate [the] scheme implantation deed” from Cosette (BD: Feb 21, Jun 4, 2025).

On Friday, Mayne said it received a second notice in which Cosette “purported to terminate the scheme implantation deed … on the same grounds”.

The company said the further notice did “not provide any additional information in relation to the grounds for termination and is framed as a notice of termination if for any reason the [scheme implantation deed] has not already been terminated”.

Mayne said that as part of the court proceedings begun in the New South Wales Supreme Court against Cosette, the matter had been listed for hearing from September 9, 2025.

Mayne said “on the evening of June 13, 2025 Cosette served … its response” to Mayne challenging the validity of the Cosette termination notices and a cross-claim.

The company said “Cosette is seeking a declaration that the [scheme implantation deed] has been validly terminated or is otherwise void, orders that Mayne Pharma pay to Cosette the Mayne Pharma break fee, and alternatively, unspecified damages”.

Mayne said “in addition, by the cross-claim Cosette alleges Mayne Pharma has engaged in misleading or deceptive conduct in breach of the Australian Consumer Law”.

The company said it rejected “the validity of the Cosette termination notice and the further Cosette termination notice and denies the claims set out in the cross-claim and intends to defend them”.

Mayne said all the claims made by Cosette would be heard together as part of the proceedings commenced on June 4, 2025.

Mayne Pharma fell 12 cents or 2.3 percent to $5.08.

HERAMED

Heramed says with the Royal Melbourne Institute of Technology it will conduct a $1,245,300 research project for culturally and linguistically diverse maternity care.

Heramed said the project was co-funded by the company, RMIT and the Federally-funded Digital Health Cooperative Research Centre both in-kind and with cash, with an overall project value of $1,245,300.

The company said the project would recruit 200 pregnant “culturally and linguistically diverse” pregnant women using its Heracare foetal heart rate monitor to monitor and collect data through personalized care plans.

Heramed said the funding would be used for a post-doctoral researcher, Heracare licences, Herabeat and regulatory compliance, with its cash contribution to about $250,000 over 18 months and it would receive fees relating to its licences and devices.

Heramed said the culturally and linguistically diverse dataset from the research would be “a unique resource to inform clinical decision making and generate insights relevant to both healthcare providers and the broader health system”, with any intellectual property developed under the collaboration to be licenced as mutually agreed.

The company said the project was scheduled to begin by July “with key deliverables including validated [artificial intelligence] model, clinical decision-support tool, and regulatory pathway mapping for scaled commercial rollout”.

Heramed said ethics approvals and recruitment was “the next step”.

Heramed was unchanged at 0.9 cents with 4.1 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says a pre-clinical study shows NUZ-001, formerly monepantel, leads to "significant neuroprotective effects in a zebrafish model of Huntington's disease".
Neurizon said treatment with NUZ-001 or active metabolite NUZ-001 sulfone following huntingtin protein knockdown "prevented developmental and morphological abnormalities, attenuated neuronal cell death, restored the delayed production of haemoglobin and rescued [brain-derived neurotrophic factor] expression".
The company said the study provided evidence of NUZ-001 and NUZ-001 sulfone's "potential to counteract early neuro-degenerative damage".
Last year, Neurizon said that after eight months, its nine-patient phase I study showed NUZ-001 "significantly reduced the risk of death by 78.1 percent" for the neuro-degenerative disease amyotrophic lateral sclerosis (ALS) (BD: Dec 16, 2024).
Neurizon was up half a cent or 3.1 percent to 16.5 cents with 1.5 million shares traded.

NYRADA

Nyrada says it has safety review committee approval to dose the fifth cohort of its phase I trial of NYR-BI03 for traumatic brain injury and stroke.
Earlier this year, Nyrada said it had begun recruiting its 40-patient, phase I trial of NYR-BI03 for traumatic brain injury and stroke (BD: Mar 17, 2025).
Today, the company said the safety review committee raised no issues and that final phase I trial readouts were expected by October 2025.
Nyrada was unchanged at 20 cents.

ANTEOTECH

Anteotech says the Appenzell, Switzerland-based Wyon AG will conduct trials of its Ultranode, high silicon anode technology for use in commercial device production.
Anteotech said use of its Ultranode technology in Wyon's batteries was expected to "yield greater energy capacity by up-to about 30 percent when compared to current graphite-based batteries" with potential benefits to users including 30 percent longer battery life and reduced battery weight.
The company said on successful evaluation, the agreement was expected to lead to the licencing of its Ultranode technology to Wyon for manufacturing and commercial use.
Anteotech said Wyong was "a market leader for rechargeable batteries in hearing devices, including for cochlear implants".
The company said there was "no immediate financial impact from this arrangement".
Anteotech was up 0.1 cents or 10.0 percent to 1.1 cents with 18.4 million shares traded.

CANN GROUP

Cann says it has taken a $315,552 loan from Melbourne's Radium Capital at 15.0 percent annual interest against its Federal Research and Development Tax Incentive.
Cann said the loan was repayable on the earlier of the receipt of its research and development tax incentive for the year to June 30, 2025, or October 31, 2025 and was in addition to its previous $836,469 loan from Radium Capital (BD: Apr 28, 2025).
The company said the total amount borrowed was $1,152,021.
Cann was unchanged at 1.3 cents with 2.55 million shares traded.

OSTEOPORE

The Cayman Islands-based Advance Opportunities Fund says it has ceased its substantial shareholding in Osteopore.

Advance said that it sold 619,674 shares on June 10, 2025 for $8,366, or 1.35 cents a share and on June 13, 2025 sold 1,500,000 shares for $19,500, or 1.3 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).

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, 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).

Earlier this month, Advance said it had reduced its holding in Osteopore from 11,685,415 shares (6.74%) to 9,580,079 shares (5.52%).

According to its most recent notice, Osteopore had 173,427,723 shares on issue, meaning that Advance retained 4.3 percent of the company.

Osteopore fell 0.2 cents or 13.3 percent to 1.3 cents with 3.3 million shares traded.

ENLITIC

Sydney’s Pengana Capital Group says its 40,474,040 share-holding in Enlitic was diluted from 5.61 percent to 4.90 percent on June 12, 2025 due to the issue of shares.

Last month, Enlitic said it had an up-to $50 million deal with GE Precision Healthcare and had “firm commitments” to raise $10 million at 4.0 cents per Chess depository interest in a non-underwritten placement (BD: May 5, 2025).

Enlitic fell 0.1 cents or 3.6 percent to 2.7 cents with 3.8 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Dr Bonni Goldstein as its US chief medical advisor.

Neurotech said Dr Goldstein would support its US regulatory strategy, clinical advancement and patient advocacy.

The company said Dr Goldstein had more than 25 years of clinical experience with 17 years of experience in marijuana-based therapeutics and had “personally treated thousands of children, including those with autism spectrum disorder, epilepsy, and Rett syndrome”.

Neurotech said Dr Goldstein held a Doctor of Medicine from Newark, New Jersey’s Rutgers University.

According to her Linkedin profile, Dr Goldstein was chief executive and co-founder of Goldstein Wellness and had been medical director of Canna-Centers Wellness and Education and Medical Advisor for Weedmaps and Cannformatics.

Neurotech was up 0.1 cents or 5.9 percent to 1.8 cents.

PACIFIC EDGE

Pacific Edge says chair Chris Gallaher “has accepted an invitation by the company’s directors to seek re-election” to the board at its annual shareholder meeting.

Last year, Mr Gallaher said he would retire by the end of 2024 (BD: Mar 14, 2024).

Later, Pacific Edge said Mr Gallaher had “agreed to delay his retirement until 2025” to “provide stability and confidence” with the uncertainty over the Medicare coverage for the company’s Cxbladder tests (BD: Sep 5, 2024).

Today, the company said Mr Gallaher was due to retire from the board by rotation at its annual shareholder meeting … but will now be standing for re-election”.

Pacific Edge said its directors “extended the invitation because they believe shareholders’ best interests are served with the continuity and stability of Mr Gallaher’s leadership while the company continues to navigate the loss of Medicare coverage for Cxbladder products”.

Mr Gallaher said as the company moved “through the process to seek re-coverage, I am happy to continue as chair to ensure we have board stability and continuity”.

Pacific Edge was untraded at 10.5 cents.