Biotech Daily

Wednesday June 18, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MICRO-X UP 11%; AROA, OPTISCAN DOWN 8%**

*** INOVIQ: 'CAR-NK-EVS KILL 88% BREAST, LUNG CANCER CELLS, IN-VITRO'**

*** ARGENICA 'ARG-007 REDUCES BRAIN CELL DAMAGE, IN FERRETS'**

*** CLINUVEL: 'SCENESSE ALONE DOES NOT RE-PIGMENT VITILIGO'**

*** EBR SHARE PLAN RAISES $20m; TOTAL $76m**

*** EMYRIA $4m PLACEMENT; MEDIBANK COVERS PTSD PROGRAM**

*** BIOXYNE: ADREX, FARMAKEM $5.6m MARIJUANA SUPPLY DEAL**

*** AUDEARA RECORD $3.6m 11-MONTH REVENUE**

*** LUMOS $460k BARDA FEBRIDX CLIA STUDY MILESTONE**

*** IMUGENE: US PTO ALLOWS CF33-CD19 ONCOLYTIC PATENT**

*** BIOXYNE WINS MARIJUANA GMP COMPLIANCE**

*** OPYL, INNOVATRIX DEVELOP TRIALKEY INSURANCE**

*** MAYNE EGM 99% BACK COSETTE ACQUISITION**

*** PENGANA TAKES 16.5% OF ONCOSIL**

*** AUSBIOTECH 2025 VIC 'BIO-CHEERS'**

MARKET REPORT

The Australian stock market fell 0.12 percent on Wednesday June 18, 2025, with the ASX200 down 10.1 points to 8,531.2 points. Eleven of the Biotech Daily Top 40 stocks were up, 20 fell, seven traded unchanged and two were untraded. All four Big Caps rose.

Micro-X was the best, up 0.5 cents or 10.9 percent to 5.1 cents, with 300,591 shares traded. Amplia and Cynata climbed more than six percent; EBR and Medadvisor were up five percent or more; Curvebeam was up 4.1 percent; Medical Developments rose 2.7 percent; CSL, Pro Medicus and Starpharma were up more than one percent; with Cochlear, Emvision, Neuren, Resmed and Telix up by less than one percent.

Both Aroa and Optiscan led the falls, down 7.7 percent to 48 cents and 12 cents, respectively, with 190,721 shares traded and 259,267 shares traded, respectively. Genetic Signatures and Imugene lost seven percent or more; Avita, Immutep and Nova Eye fell four percent or more; Impedimed was down 3.45 percent; Alcidion, Clarity, Prescient and Proteomics shed two percent or more; 4D Medical, Dimerix, Mesoblast, Orthocell and Syntara were down one percent or more; with Clinuvel, Cyclopharm and Polynovo down by less than one percent.

INOVIQ

Inoviq says its chimeric antigen receptor (CAR)-exosomes have “exceptional efficacy, killing 88 percent of [breast cancer] and lung cancer cells” in 96 hours, in-vitro.
Inoviq said its CAR-natural killer (NK) cell-derived extracellular vesicles (EVs) “exerted a significant cytotoxic effect” on triple negative breast cancer cells and non-small-cell lung cancer cells, compared to control treatments.
The company said that data from six independent experiments showed that treatment with 2,500,000 CAR-NK-EVs per cell led to 87.8 percent breast cancer cell death within 96 hours, compared to no cell death in controls; as well as 87.9 percent lung cancer cell death within 96 hours, compared to no cell death in controls.
Inoviq said its CAR-NK-EVs were designed to target and kill cancer cells more precisely and were produced using its Exo-Ace to purify the particles for quality and shelf life.
Earlier this year, Inoviq said Melbourne’s Peter MacCallum Cancer Centre would conduct in-vitro and in-vivo studies of CAR-exosome therapy for solid tumors including triple negative breast cancer and lung cancer (BD: Mar 31, 2025).
Today, Inoviq chief executive officer Dr Leearne Hinch told Biotech Daily that the studies in today’s announcement were conducted in-house.
Inoviq said the products could lead to an ‘off-the-shelf’ therapy made in advance and used on many patients, unlike other treatments that must be customized making it “faster to produce, safer to use and more effective than traditional cell therapies like CAR-T”.
The company said animal studies were the next step before human clinical trials.
Inoviq chief scientific officer Prof Greg Rice said the exosome therapy platform had been validated showing “its potential to deliver transformative ‘off-the-shelf’ therapies … [and] our platform offers potential cost, safety and efficacy advantages over traditional CAR-T cell therapies, enabling development of targeted therapeutics for multiple cancer types”.
Inoviq was up 5.75 cents or 14.8 percent to 44.5 cents with 1.6 million shares traded.

ARGENICA THERAPEUTICS

Argenica says a 56-ferret study shows AR-007 can “significantly reduce damage to the axons of brain cells (neurons)” and reduce the expression of inflammatory markers.
In 2023, Argenica said it had a $1.2 million Federal Government Cooperative Research Centre Projects grant for pre-clinical studies of ARG-007 in traumatic brain injury with organizations including the University of Adelaide (BD: Jan 22, 2023).
Today, the company said the University of Adelaide study used ferrets “because their brains more closely resemble the gross anatomy of the human brain … compared with the rodent brain”; and it assessed the extended duration effect of ARG-007 for 14 days confirming “brain cell protection was long lasting, rather than transient”.
The company said the 11 uninjured and 45 injured ferrets were administered either saline, a single dose of intravenous 0.3mg/kg ARG-007 30-minutes after injury or a double-dose of ARG-007 with the second dose subcutaneous 24 hours post-injury. Argenica said there was “no statistically significant difference between the results of the single dose of ARG-007 and the double-dose groups of ARG-007 in any of the bio-marker analysis”.
The company said that “the only single dose of ARG-007 produced statistical differences on behavior assessments [and] only the single dose ARG-007 treatment animal data has been presented across the biomarker and behavioral analysis”.
Argenica said ARG-007 was “effective at reducing both axonal injury and inflammation biomarkers up-to 14 days post-injury” confirming the drug tackled secondary-injury cascades driving disability after brain injury, leading to potential functional benefits.
Argenica fell half a cent or 0.7 percent to 70 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says a three-patient, phase II study of Scenesse, or 16mg afamelanotide, monotherapy for vitiligo failed to show re-pigmentation of depigmented skin.

In 2022, Clinuvel said it had approval for an up-to six-patient, 'CUV104' phase II study of Scenesse as a monotherapy in darker-skin vitiligo patients (BD: May 10, 2022)

Today, the company said the single-arm, open-label study enrolled and treated three patients with up-to six Scenesse implants over three months after priming with narrowband ultra-violet B (NB-UVB).

Clinuvel said "of the three patients enrolled, one completed the full treatment regimen, with the other two withdrawing early due to the darkening of unaffected skin showing a contrast with vitiligo affected skin".

The company said Scenesse was well-tolerated at a high dose of six implants administered at 14-day intervals, with no serious or severe adverse reactions.

Clinuvel said the trial studied "whether afamelanotide monotherapy, following NB-UVB, would re-pigment the skin" using the vitiligo area scoring index (VASI); and at the end of up-to three months of therapy, none of the three patients achieved VASI re-pigmentation.

The company said the lack of re-pigmentation seen in the three patients showed "the utility of adjunct narrowband ultra-violet B (NB-UVB) photo-therapy for treating vitiligo patients with afamelanotide"; and the data would be included in the dossier to be submitted for marketing authorization for afamelanotide in vitiligo.

Clinuvel director of clinical affairs Dr Emilie Rodenburger said the company had "clinical evidence supporting our scientific hypothesis that afamelanotide requires concomitant activation of pigment producing cells by NB-UVB to effectively re-pigment vitiligo patients".

"These data confirm the company's decision to pursue afamelanotide and adjunct NB-UVB as part of its pivotal study designs, while at the same time addressing regulatory questions as to the effects of afamelanotide as monotherapy," Dr Rodenburger said.

"The CUV104 results have once and for all confirmed our thinking and expertise that vitiligo cannot be treated with a single modality," Dr Rodenburger said.

"We are making clinically meaningful steps towards offering vitiligo patients with darker skin complexions a treatment derived from our natural pigmentation hormone," Dr Rodenburger said.

"We can now answer the regulatory suggestion to use monotherapy afamelanotide in vitiligo," Dr Rodenburger said.

"With these data in hand, we inch towards a robust set of data to be part of a future submission of Scenesse for vitiligo patients," Dr Rodenburger said.

Clinuvel fell seven cents or 0.7 percent to $9.69 with 152,252 shares traded.

EBR SYSTEMS

EBR says it has raised $20 million at $1.00 per Chess depository interest (CDI) in a "heavily oversubscribed" security purchase plan, taking the total raised to $75.9 million.

Last month, EBR said it would raise $55.9 million in a placement at $1.00 per CDI, with an up-to $6 million share plan to follow (BD: May 22, 2025).

Today, the company said it received applications for $35.3 million, in excess of the targeted $6.0 million, with an eligible shareholder participation rate of 42.76 percent.

EBR said "given the strong support" it had exercised its discretion to increase the size of the offer and would scale-back valid applications.

The company said the funds would be used for commercialization of its wireless Wise system for left ventricle cardiac pacing.

EBR was up six cents or 5.4 percent to $1.17 with 1.8 million shares traded.

EMYRIA

Emyria says it has “firm bids” for a $4 million placement at 2.4 cents a share and Medibank will cover patients in its post-traumatic stress disorder (PTSD) program.

Emyria said the placement price was a 6.15 percent discount to the 15-day volume weighted average price and a 4.0 percent discount to the last closing price.

The company said investors would receive one option for every three shares issued, exercisable at five cents each within 18 months; and its directors had subscribed for $197,000 of the placement, subject to shareholder approval.

Emyria said the funds would be used for its treatment programs, including those funded under the Medibank agreement and working capital.

The company said following the capital raise, it would issue Emyria shareholders one loyalty option for every four shares, exercisable at five cents each within 18 months.

Emyria said Sydney’s GBA Capital was the placement lead manager and would receive a 2.0 percent fee of funds raised and an additional 4.0 percent on funds introduced directly by GBA as well as 2,500,000 options, subject to approval.

The company said it would separately issue 6,250,000 shares and 2,083,333 options to S3 Consortium for investor relations services, subject to shareholder approval.

In the same announcement, Emyria said Medibank would “fund eligible customer participation in [its] … post-traumatic stress disorder care program through Perth Clinic, with no-out-of-pocket costs”.

Last year, Emyria said it had opened an Empax Centre with Perth’s Pax Centre for the delivery and evaluation of 3,4 methylene-dioxy-meth-amphetamine (MDMA)-assisted therapy for PTSD; and later opened a second site (BD: Apr 10, 2024; Apr 14, 2025).

Today, the company said that the 24-month agreement allowed eligible and screened Medibank customers to receive Empax’s PTSD program once admitted to Perth Clinic, “reducing a major barrier to access for those with complex mental health conditions”.

Emyria said its MDMA and psychotherapy program was accessible by eligible customers, with no minimum or maximum patient quotas.

The company said “due to the individualized nature of the treatment the associated cost per customer will vary according to clinical requirements”, with similar programs “typically involving a course of care valued at between $20,000 and $30,000”.

Emyria said “an excess or co-payment may still be payable, depending on the product a Medibank member has chosen and whether they are claiming under their hospital cover for the first time in a calendar year”.

The company said “the Medibank member guide and fund rules sets out hospital benefit exclusions, which apply to all hospital admissions for Medibank members”.

Emyria said there “may be out-of-pocket expenses associated with outpatient appointments, such as initial visits with a participating specialist in their consulting rooms”.

The company said the agreement included a standard termination clause allowing either party to provide 90 days’ notice.

Emyria executive chair Greg Hutchinson said that “whilst we’ve seen great advances in many areas of medicine over the past 20 years, mental health incidence and prevalence have increased to unacceptable levels”.

“It’s clear that mental health requires not just more resources, but a multi-faceted, multi-stakeholder and more innovative approach,” Mr Hutchinson said.

“We commend Medibank for their leadership in funding new mental health initiatives, support that will expand access to promising therapies for more Australians suffering with complex and persistent mental health challenges,” Mr Hutchinson said.

Emyria was up 0.3 cents or 12 percent to 2.8 cents with 17.7 million shares traded.

BIOXYNE

Bioxyne says it has an EUR3,200,000 ($A5,600,000) marijuana manufacturing and supply deal with the Adrex Pharmaceuticals GmbH and Farmakem d.o.o.

Bioxyne said the deal committed the Koblenz, Germany-based Adrex and the Bohova, Slovenia-based Farmakem to purchase and distribute a minimum 1,600 kilograms of its medical marijuana flower and finished product and was expected to generate a minimum of $5.6 million revenue for the year to June 30, 2026.

The company said Adrex was a leading importer, manufacturer and distributor of marijuana in Germany and Farmakem was a certified manufacturer and supplier of medical marijuana products to Europe.

Bioxyne said subsidiary Breathe Life Sciences and Adrex were working to establish its brands, including Dr Watson, in Germany.

Bioxyne said delivery of 580kg was scheduled for September 2025, with a second shipment planned for November.

Bioxyne was up 0.1 cents or 3.2 percent to 3.2 cents with 11.5 million shares traded.

AUDEARA

Audeara says record unaudited revenue for the 11 months to May 31, 2025 was more than $3.64 million, up 14 percent compared to the year to June 30, 2024.

Last year, Audeara said revenue for the year to June 30, 2024 was up 9.6 percent to $3,185,107 with net loss after tax down 57.2 percent to $1,602,574 (BD: Aug 30, 2024).

Today, the company said the increased revenue was underpinned by the maiden purchase order worth $570,000 for the launch of the Clinico co-branded Audeara Buds, and a follow-up $917,000 order from instrument manufacturer Avedis Zildjian.

Audeara managing-director Dr James Fielding said the trading update for the first 11 months of the 2024-'25 period highlighted the momentum we've established.

"Growth … has been underpinned by a series of strategic engagements with international counterparties, as well as key product launches," Dr Fielding said.

Audeara was up 0.2 cents or 10 percent to 2.2 cents with 1.1 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has $US298,457 ($A459,840) for enrolling 500 patients in a BARDA trial of its Febridx blood test for differentiating bacterial from viral respiratory infections.

Last year, Lumos said it had $US2,984,571 from the US Biomedical Advanced Research and Development Authority (BARDA) to conduct an 800-patient, Clinical Laboratory Improvement Amendments (CLIA)-waiver study to support a US Food and Drug Administration filing for its Febridx, point-of-care, finger-prick (BD: Oct 3, Dec 20, 2024).

Today, Lumos said the "next BARDA milestone payment of $US746,143 will be triggered on … the last patient enrolled in the study", expected with an FDA CLIA waiver application by October 2025.

The company said the study recorded 78 bacterial positive patients to date, 65 percent of the target of 120 bacterial positive patient results required for the study.

Lumos said the result implied an average bacterial prevalence rate in the study so far of 15.6 percent, or 78 of 500 patients, but that since it "implemented its enrichment strategy in late March 2025, the bacterial prevalence rate in the trial has been around 35 percent".

Lumos managing-director Doug Ward said the company was "very pleased to have reached this important enrolment milestone in the Febridx CLIA waiver study".

Lumos was up 0.2 cents or 7.4 percent to 2.9 cents with 1.95 million shares traded.

IMUGENE

Imugene says the US Patent and Trademark Office (USPTO) has allowed a patent for its oncolytic viro-therapy CF33-CD19 and its combination with CAR-T cell therapies.
Imugene said the patent, titled 'Oncolytic Virus Expressing a CAR-T Cell Target and Uses Thereof' would protect the method of composition and method of use of its Oncarlytics technology until August 10, 2038.
Imugene managing-director Leslie Chong said receiving the US patent allowance for the CF33-CD19 Oncarlytics platform was "a crucial step forward for our [intellectual property] position, with the US being the largest healthcare market in the world".
"This follows patent allowance in China, an equally large cell therapy market, earlier in 2025," Ms Chong said.
Imugene fell 0.1 cents or 7.1 percent to 1.3 cents with 47.1 million shares traded.

BIOXYNE

Bioxyne says it has good manufacturing practice (GMP) certification for its marijuana in Australia, Singapore, the Eurozone, European Union, Canada and the UK.
Bioxyne said that it complied with the GMP requirements for medicinal products in Australia and through the agreement of mutual recognition between Australia and the other territories it had complied with the requirements of those territories.
The company said it was "please to gain certification as it moves to expand its presence globally, with particular emphasis on European markets and the UK".

OPYL

Opyl says it will develop a product with London's Innovatrix Capital Ltd to insure against the risk of clinical trial failure using its Trialkey artificial intelligence (A.I.).
Opyl said its Trialkey platform would be used as an "an independent calculation agent providing its industry-leading 'probability of success' estimates, with 95 percent confidence intervals, at key stages of a clinical trial".
The company said the A.I.-based metrics from Trialkey would "form the foundation of Innovatrix's novel insurance underwriting, pricing, and claims process".
Opyl said Innovatrix would refer the use of Trialkey to clients in early planning stages of trial design "to optimize protocol design, improve predicted success rates, reduce insurance premiums and improve patient and commercial outcomes".
The company said the non-binding agreement had an initial three-year term, with automatic yearly renewal and that either party could terminate the agreement with six months' notice, but only after the initial term.
Opyl said it would be paid a 1.0 percent fee of the risk premium for each insurance policy, a 20 percent share of Innovatrix's mid-term adjustment administration fees for interim 'probability of success' re-estimates, and a 5.0 percent fee on capital raised through its introductions.
The company said a GBP50,000 ($A103,400) non-refundable retainer was payable once Innovatrix earned GBP500,000 in relevant commissions and was credited against future Trialkey invoices.
Opyl was unchanged at two cents with 1.05 million shares traded.

MAYNE PHARMA

Mayne says its extraordinary general meeting has voted 99.06 percent in favor of the company's acquisition by Bridgewater, New Jersey's Cosette Pharmaceuticals.
In February, Mayne said that Cosette would buy it for $7.40 a share in cash, valuing the company at $672 million; and later, said it had received "a purported notice to terminate [the] scheme implantation deed" from Cosette (BD: Feb 21, Jun 4, 2025).
On Monday, the company said it had received a second notice from Cosette to terminate its acquisition scheme and would start proceedings in the Supreme Court of New South Wales against Cosette on September 9, 2025 (BD: Jun 16, 2025).
Today, Mayne said the scheme was approved by 35,835,625 votes (99.06%), with 339,546 votes (0.94%) in opposition.
The company said that subject to it successfully challenging Cosette's purported termination of the scheme implementation deed it would seek court orders Wales for the approval of the scheme at the second court hearing, scheduled for September 18, 2025.
Mayne was up 12 cents or 2.3 percent to $5.34.

ONCOSIL MEDICAL

Pengana Capital Group says it has increased its holding in Oncosil from 1,339,286 post-consolidation shares (11.97%) to 2,349,702 post-consolidation shares (16.52%).
The Sydney-based Pengana said that it held 535,714,286 pre-consolidation shares and bought a further 404,166,670 pre-consolidation shares in a placement on June 3, 2025 for $1,212,500, or 0.3 cents a share, taking the total to 939,880,956 pre-consolidation shares.
Last month, Oncosil said it raised $6.7 million at 0.3 cents a share in a placement, with a share purchase plan for $2.0 million to follow (BD: May 26, 2025).
Earlier this month, the company said it completed its 400-to-one stock consolidation following extraordinary general meeting approval and had 14,224,271 post-consolidation shares on issue (BD: May 29, Jun 6, 2025).
Oncosil was up six cents or 6.3 percent to a post 400-to-one consolidation $1.01.

AUSBIOTECH

Ausbiotech says it will hold its Victoria 'Bio-Cheers' networking event at Level 7, 120 Collins Street, Melbourne on July 24, 2025 from 5pm to 7.30pm (AEST).
Ausbiotech said the event was in partnership with consulting services firm RSM (Robson Rhodes, Salustro Reydel, McGladrey) Australia.
The industry organization said the event connected "members and non-members from across the life sciences sector, including therapeutics, medical technology, digital health and [agricultural]-biotech".
Ausbiotech said the event provided an "opportunity to reconnect with colleagues, exchange ideas, establish new professional relationships, and engage with Victoria's thriving life science community", with complimentary drinks and canapés.
The organization said the event was free for members and $100 for non-members, with registration at: https://www.ausbiotech.org/events/event/vic-biocheers-july-2025.