Biotech Daily

Thursday May 22, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MEDICAL DEVELOPMENTS, PROTEOMICS UP 5%; - ATOMO DOWN 8%**

*** EBR PLACEMENT RAISES $56m; $6m SHARE PLAN TO GO**

*** IMEX DIRECTOR PLACEMENT RAISES $1m; TOTAL $2.6m**

*** AAMRI, CSL $35k RISING STAR 2025 AWARD**

*** DIMERIX PHASE III DMX-200 FSGS TRIAL PASSES 6th REVIEW**

*** BLINKLAB OPENS DX1 AUTISM TEST MAIN TRIAL SITE**

*** ARGENICA GRANTED US PEPTIDE STROKE PATENT**

*** MAYNE TELLS ASX 'FDA LETTER NOT MATERIAL'**

*** ZELIRA FURTHER ZLT-L-007 DATA FOR NERVE PAIN**

*** ONCOSIL REQUESTS 'CAPITAL RAISE' TRADING HALT**

*** MARK AZZI TAKES 6% OF NYRADA**

MARKET REPORT

The Australian stock market fell 0.45 percent on Thursday May 22, 2025, with the ASX200 down 38.1 points to 8,348.7 points. Eight of the Biotech Daily Top 40 companies were up, 22 fell and 10 were unchanged.

Medical Developments was the best, up three cents or 5.17 percent to 61 cents, with 86,336 shares traded; followed by Proteomics, up two cents or 5.13 percent to 41 cents, with 117,388 shares traded. Universal Biosensors rose 4.2 percent; Compumedics climbed 3.5 percent; Micro-X was up 1.8 percent; with Clinuvel, CSL, Mesoblast and Orthocell up by less than one percent.

Atomo led the falls, down 0.15 cents or 8.3 percent to 1.65 cents, with 203,138 shares traded. EBR and Genetic Signatures lost seven percent or more; 4D Medical, Cynata, Impedimed, Imugene and Syntara were down five percent or more; Medadvisor, Nova Eye, Paradigm and Polynovo fell four percent or more; Avita was down 3.3 percent; Prescient and Pro Medicus shed more than two percent; Amplia, Botanix, Clarity, Immutep, Resmed, SDI and Telix were down more than one percent; with Cochlear, Dimerix and Neuren down by less than one percent.

EBR SYSTEMS

EBR says it will raise $55.9 million in “a fully under-written placement” at $1.00 per Chess depository interest (CDI), with an up-to $6 million share plan to follow.
EBR said the issue price was a 12.6 percent discount to the 10-day volume weighted average price and a 17.7 percent discount to the last closing price.
The company said the funds raised from would be used for US commercialization of its Wise cardiac resynchronization therapy (CRT) system, with a focus on scaling-up manufacturing and sales force capabilities.
Last month, EBR said it had US Food and Drug Administration approval for its Wise cardiac re-synchronization therapy for left ventricular pacing (BD: Apr 14, 15, 2025).
Today, the company said its commercialization strategy included receiving final out-patient reimbursement approval from the US Centers for Medicare and Medicaid, an limited first-year market release, continued expansion of its leadership and sales force and leasing manufacturing facilities to increase production in-line with demand.
EBR said the non-underwritten share purchase plan would raise about $6 million at the lower of the placement price and a 2.0 percent discount to the five-day volume weighted average price up-to and including the closing of the share plan.
The company said the placement was fully-underwritten by JP Morgan Securities Australia and Morgans Corporate, with JP Morgan, E&P Capital and Wilsons Corporate joint lead managers and bookrunners to the placement.
EBR said the share purchase plan had a record date of May 21, would open on May 28 and close on June 12, 2025.
EBR fell 9.5 cents or 7.8 percent to $1.12 with 3.3 million shares traded.

IMEX HEALTH SERVICES

Imex says it has raised $1.0 million at 35 cents a share in its conditional placement to directors following annual general meeting approval on May 19, 2025.
Last month, Imex said it raised $1.5 million in a placement at 35 cents a share, a 13.2 percent discount to the five-day volume weighted average price and would raise a further $1.0 million in a conditional placement to its directors and up-to $1.0 million in a non-underwritten share purchase plan (BD: Apr 3, 2025).
At that time, company said the funds would be used to “provide working capital and drive growth in Aquila+ [picture archiving communications system] sales”.
Later, Imex said raised $103,000 of a hoped-for $1.0 million in the share plan, meaning the total raised was about $2,600,000 (BD: May 15, 2025).
Imex was untraded at 34 cents.

ASSOCIATION OF AUSTRALIAN MEDICAL RESEARCH INSTITUTES (AAMRI), CSL

The Association of Australian Medical Research Institutes says CSL is sponsoring its third $35,000 Rising Star Award for early-to-mid-career researchers.
The Association said it would announce four finalists in September, with the winner to be announced at a dinner at Parliament House, Canberra on October 14, 2025.
AAMRI said law firm Minter Ellison would sponsor an award for the remaining three finalists to each receive a cash prize of $2,500.
AAMRI said the award was open to researchers at its member institutes with fewer than five years of post-doctorate conferral experience, excluding career interruptions.
The Association said applications were open and closed on June 18, 2025.
For more information and applications go to: https://aamri.org.au/members/rising-star/.

DIMERIX

Dimerix says its phase III 'Action' trial of DMX200 for focal segmental glomerulo-sclerosis (FSGS) has passed its sixth safety review, with no recommended changes.
In 2022, Dimerix said it had recruited the first of 286 patients in the trial of DMX200 for FSGS kidney disease; with proteinuria, or percentage of protein in the urine, and estimated glomerular filtration rate, as primary endpoints (BD: May 31, 2022).
Last November, the company said it completed the fifth scheduled independent data monitoring committee review, which evaluated the available study data for participant safety, study conduct and progress, with "no safety concerns" (BD: Nov 20, 2024).
Today, Dimerix said there were no safety concerns raised in the review, the committee recommended the trial continue as planned, with the next meeting expected by 2026.
Dimerix fell half a cent or 0.85 percent to 58.5 cents with 2.9 million shares traded.

BLINKLAB

Blinklab says it has opened the main part of an up-to 1,000-children pivotal study of its Dx1 autism test at Phoenix, Arizona's Southwest Autism Research and Resource Center.
Last year, Blinklab said the US Food and Drug Administration had confirmed the study design and data requirements needed for 510(k) clearance of its Dx1 smartphone application autism diagnostic (BD: Dec 19, 2024)
At that time, the company said it would conduct an initial study of 100 children followed by a main study of 750-to-900 children with autism between two and 11 years of age.
Earlier this year, Blinklab said it opened sites at Dayton, Ohio's Primed Clinical Research and Chicago's North Shore Pediatric Therapy; and had enrolled 54 children in the study (BD: Feb 5, 10, Apr 1, 2025).
Today, the company said the Southwest Center was "the first new clinical site for the main study phase" which would begin following the initial 100-participant pilot phase.
Blinklab said site activation would begin "in the coming weeks with the recruitment commencing after completion of the pilot phase".
The company said it had recruited 117 participants in the initial pilot phase, with analysis scheduled to start next month.
Blinklab said the 750-to-900 participant main phase would be conducted at up-to 10 sites in the US and it expected to lodge its final FDA 510(k) submission by April 2026.
Blinklab was unchanged at 35.5 cents.

ARGENICA

Argenica says the US Patent and Trademark Office has granted a patent for its neuro-protective peptides, extending its protection to include cerebral ischaemia or stroke.
Argenica said the patent, titled 'Neuroprotective peptides', would protect its intellectual property until October 30, 2034.
The company said the patent "builds on the protection provided by Argenica's previously granted parent patent for novel neuro-protective peptides covering a broad range of neurological conditions including, but not limited to ischaemic stroke, traumatic brain injury [and] hypoxic ischaemic encephalopathy".
Argenica said the additional patent extended the scope of tis earlier patent covering specific use of its peptides "in a method of treating a surgery patient at risk of suffering cerebral ischaemia or stroke".
Argenica was up 3.5 cents or 4.4 percent to 82.5 cents.

MAYNE PHARMA

Mayne has told the ASX the FDA 'untitled letter' is not material and it shares "a significant volume of information with Cosette, most of which is not materially price sensitive".
Last week, Mayne told the ASX it was not aware of any information it had not announced which, if known, could explain a 12.1 percent fall in its share price and the significant increase in the volume of shares traded (BD: May 15, 2025).
At that time, the company said it was aware that "on May 12, 2025 US time the US Food and Drug Administration published on its website an 'untitled letter' received by Mayne Pharma on April 28, 2025 US time, related to certain promotional claims used in a speaker presentation for Nextstellis".
Mayne said that it believed "in and of itself, the FDA untitled letter is not materially price sensitive" and confirmed that it had a near finalized response to the letter which it proposed to provide to the FDA within the prescribed timeframe.
Yesterday, Mayne fell as much as 33.5 percent on Cosette Pharmaceutical's claim that a "material adverse change" had occurred and that its proposed $672 million acquisition by Cosette might be terminated (BD: May 21, 2025).
Today, the ASX asked the company "if the untitled letter was considered … to be important enough to inform [Cosette] … why it didn't consider it of sufficient importance to disclose to the market?".
Mayne said that under the terms of its scheme implementation deed it was required to provide Cosette with "reasonable access to information concerning Mayne's businesses, operations and affairs" as well as its premises, management and records.
The company said the access included "copies of correspondence with regulators and keeping them appraised of matters relevant to implementation and the business as a whole", with "no materiality threshold attached" to Cosette's right to access information.
Mayne fell 20 cents or 4.4 percent to $4.35 with 2.2 million shares traded.

ZELIRA THERAPEUTICS

Zelira says it has further data from a 60-patient trial of its oral ZLT-L-007 marijuana, formerly ZLD007, compared to pregabalin, marketed as Lyrica, for diabetic nerve pain.
In 2023, Zelira said ZLT-L-007 met its phase I primary endpoint of a "significant reduction" in pain score for diabetic nerve pain as well as secondary endpoints and was safe and well-tolerated, but with no probability values (BD: Nov 21, 2022; Mar 31, 2023).
At that time, Zelira said that at 90 days, pregabalin monotherapy led to a median 36.00 percent reduction in pain scores, ZLT-L-007 alone had a 78.57 percent decrease and the combination reduced pain by 72.50 percent.
Today, the company said that at 90 days there was a 30 percent reduction in daily pain numeric rating scale scores with Lyrica monotherapy compared to an 85 percent median decrease with ZLT-L-007 monotherapy and a 67 percent reduction with the combination.
Zelira did not disclose the difference between the original 2023 data and today's results.
The company said both ZLT-L-007 and the combination led to a 64 percent reduction in 'visual analog scale' pain intensity, compared to 50 percent with Lyrica, at day 90.
Zelira said ZLT-L-007 outperformed the combination therapy and Lyrica alone in reducing symptom-specific pain and improving sleep quality.
Zelira said the study, titled 'Comparative Evaluation of ZLT-L-007, a Proprietary Cannabinoid-Based Therapy, and Pregabalin (Lyrica) for Pain Reduction in Diabetic Neuropathy' had been made available for public and scientific review.
Zelira was unchanged at 49.5 cents.

ONCOSIL MEDICAL

Oncosil has requested a trading halt “pending an announcement by the company in relation to a capital raise”.
Trading will resume on May 26, 2025, or on an earlier announcement.
Oncosil last traded at 0.35 cents.

NYRADA

Nyrada says Mark Azzi has increased his shareholding from 10,814,420 Chess depositary interests (CDIs) (5.14%) to 13,301,800 CDIs (6.31%).
Nyrada said that Mr Azzi became a substantial shareholder on April 7, 2025 following its “deed poll dated January 6, 2020 issued by the company in favor of ASX Limited in respect of the initial public offering of its Chess depository interests”.
In 2020, Noxopharm spin-out Nyrada opened 52.5 percent above its 20-cent initial public offer at 30.5 cents, having raised $8.5 million for cholesterol and pain drug development (BD: Jan 19, 2020).
Nyrada was up one cent or 7.4 percent to 14.5 cents with 2.65 million shares traded.