Biotech Daily

Monday June 23, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: ALCIDION UP 10%; AMPLIA DOWN 12%**

*** MICROBA $12.5m PLACEMENT; UNDERWRITTEN $2m SHARE PLAN**

*** CELLEO HOPES FOR $5m FOR CELL THERAPY PRODUCTION**

*** ALCIDION EXPECTS FULL-YEAR EBITDA UP 50% TO $4.5m**

*** OPTISCAN, LONG GROVE AK-FLUOR CONTRAST AGENT DEAL**

*** PROTEOMICS PROMARKER D FINDS 86% MISSED KIDNEY DISEASE**

*** IMMUTEP 'POSITIVE' PHASE I IMP761 AUTO-IMMUNE DATA**

*** PYC, FDA AGREE ON VP-001 RP11 TRIAL ENDPOINTS**

*** TRYPTAMINE TRP-8803 PSILOCIN BINGE-EATING TRIAL APPROVAL**

*** LUMOS RECEIVES FEDERAL $215k R&D TAX INCENTIVE**

*** UNIVERSAL BIOSENSORS TAKES 'CAPITAL RAISING' HALT TO SUSPENSION**

*** BVF, MARK LAMPERT EXIT SYNTARA**

*** GAVIN FOX-SMITH TO REPLACE RHYTHM CHAIR OTTO BUTTULA**

MARKET REPORT

The Australian stock market fell 0.36 percent on Monday June 23, 2025, with the ASX200 down 30.6 points to 8,474.9 points. Five of the Biotech Daily Top 40 companies were up, 28 fell, six traded unchanged and one was untraded. The four Big Caps were mixed.

Alcidion was the best (see below), up 0.9 cents or 9.9 percent to 10 cents, with 10.4 million shares traded; followed by Optiscan, up one cent or 9.1 percent to 12 cents, with 85,865 shares traded. Aroa climbed 4.2 percent; SDI rose 2.4 percent; with CSL, Emvision and Resmed up by less than one percent.

Amplia led the falls for the second day in a row, following Thursday's 190 percent leap, down 2.5 cents or 12.2 percent to 18 cents, with 15.9 million shares traded. Curvebeam and Cyclopharm lost more than eight percent; Imugene was down 7.1 percent; Prescient shed six percent; 4D Medical, Compumedics, Dimerix, Orthocell and Proteomics were down more than five percent; Genetic Signatures, Immutep, Mesoblast, Nova Eye and Syntara fell more than four percent; Clarity, Clinuvel, Cynata, Impedimed and Paradigm were down three percent or more; Neuren, Polynovo, Resonance and Starpharma shed more than two percent; Pro Medicus and Telix were down more than one percent; with Avita, Cochlear, EBR and Nanosonics down by less than one percent.

MICROBA LIFE SCIENCES

Microba says it has “commitments” to raise $12.5 million at 9.0 cents a share in a placement and expects to raise $2 million in a fully-underwritten share purchase plan.
Microba said the issue price was a 25.9 percent discount to the five-day volume weighted average price and a 21.7 percent discount to the last closing price.
The company said the placement and share plan included one option for every two shares issued, exercisable at 14 cents each within two years from the issue date.
Microba said the funds would be used to “drive expanded clinical adoption of the company’s core microbiome testing products”, product development to support clinical adoption in Australia and the UK, sales, marketing and commercial operations, developing clinical evidence to drive clinical adoption and working capital.
The company said board and management had committed about $290,000 to the placement, with largest shareholder Sonic Healthcare investing $4.16 million, which would increase its voting power to 21.68 percent pending shareholder approval.
Microba said it would issue Sonic Healthcare an additional option, subject to approval, exercisable for a total of $4.16 million in shares and options within 17 months.
The company said it had signed a two-year, exclusive commercial laboratory services agreement with Sonic Healthcare subsidiary the Doctors Laboratory, to provide processing services for its tests in the UK.
Microba said Canaccord Genuity Australia and Morgans Corporate were joint lead managers to the placement.
The company said the share purchase plan had a record date of June 20, would open on June 27 and close on August 6, 2025.
Microba fell 2.5 cents or 21.7 percent to nine cents.

CELLEO PTY LTD

The Melbourne-based Celleo says it hopes to raise $5 million at $1.71 a share to further its cell therapy production systems.
Celleo told Biotech Daily that at $1.71 a share the company would be valued at a pre-raise $20.0 million.
The company said it would be able to take over-subscriptions and the funds would be directed to product development of its Larkem system and next generation products, as well as manufacturing infrastructure, supply chain expansion and working capital.
Celleo said its co-founders were chief executive officer David Kneen and chief technology officer Mark Rob, and both had medical technology commercialization experience.
The company said the chair was Invetech founder Alexander Gosling, with directors including Medical Developments chair and former CSL chief financial officer Gordon Naylor and Colin White.
Celleo said that it “specializes in automated formulate and fill production systems for cell therapy” including chimeric antigen receptor (CAR) T-cell therapy for blood cancers.
The company said that as cell therapies gained wider adoption “they are running into production bottlenecks, in particular at the [formulate and fill] process with over 80 percent of the current market being manual fill”.
Celleo said it was “engaged with five of the world’s seven largest cell therapy developers … to automate their high-value, high-touch production runs”.
The company said that professional and sophisticated investors should contact Alpine Capital’s Charles Reed via email: charles@alpinecapital.au for further details.
Celleo is a private company.

ALCIDION GROUP

Alcidion says it has increased its expected Ebitda for the year to June 30, 2025 by 50 percent, from more than $3.0 million to more than $4.5 million.

Alcidion said the increased earnings before interest, taxation, depreciation and amortization (Ebitda) was “driven by progressive smaller contract upgrades and extensions, continued diligent cost management and favorable [foreign exchange]”.

The company said further details would be released in its report for the three months to June 30, 2025, expected on July 24, 2025, as well as its full year report in August.

Alcidion managing-director Kate Quirke said the company continued “to perform strongly in 2024-’25 which has enabled us to upgrade our expected Ebitda for the full year”.

“Deployments of our Miya platform continue to build ‘reference-ability’ and a positive net return for our customers who subsequently look to Alcidion for assistance in solving other challenges within the hospital ecosystem,” Ms Quirke said.

“Over the past few months this has resulted in several customers, of varying size, seeking extensions or module upgrades which has helped contribute to our improved financial position,” Ms Quirke said.

Alcidion was up 0.9 cents or 9.9 percent to 10 cents with 10.4 million shares traded.

OPTISCAN IMAGING

Optiscan says with Chicago’s Long Grove Pharmaceuticals it will develop further uses for Long Grove’s intra-venous fluorescein sodium contrast agent (AK-FLUOR).

Optiscan said Long Grove’s AK-FLUOR was an intravenous drug used in its fluorescence-based endo-microscopic imaging devices, including Invue for surgical applications.

The company said the five-year collaboration included Long Grove supplying AK-FLUOR for use in US clinical studies and trials of its endo-microscopic imaging devices for breast surgery as well as gastro-intestinal endoscopy, gastro-intestinal surgery, robotic surgery and laparoscopic surgery.

Optiscan said data from the studies would be used to support US Food and Drug Administration regulatory submissions for its Invue device.

The company said Long Grove would support its regulatory submissions by providing access to AK-FLUOR’s existing pharmaco-kinetic and chemistry, manufacturing and controls data, which would expedite its efforts to obtain the necessary regulatory approvals for its surgical devices to be used in the US.

Optiscan said it would provide support to Long Grove in relation to US FDA supplementary new drug application submissions for AK-FLUOR “should new applications for this drug in combination with Optiscan’s devices be identified”.

The company did not disclose the commercial terms of the agreement.

Optiscan managing-director Prof Camile Farah said the agreement gave the company “a supply of Long Grove’s AK-FLUOR, which will be used in combination with our fluorescence-based endomicroscopic imaging devices to undertake studies and clinical trials”.

“This collaboration agreement represents another significant step in Optiscan’s ongoing efforts to integrate its ground-breaking technology into clinical practice,” Prof Farah said.

“Having Long Grove’s assistance as we work through FDA regulatory approval processes for Optiscan’s devices is a significant bonus as we pursue a toe-hold in the large and lucrative US market,” Prof Farah said. “It provides further evidence that more and more healthcare sector-related groups are wanting to partner with Optiscan’s technology, as they search for ways to enhance and, or expand usage of their own product offerings.”

Optiscan was up one cent or 9.1 percent to 12 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its next-generation Promarker D kidney disease test identifies 86 percent of at-risk diabetic kidney disease individuals missed by standard-of-care tests.

Last week, Proteomics said it launched its Promarker D blood test for predicting diabetes-related chronic kidney disease in the US at the American Diabetes Association in Chicago, June 20 to 23, 2025 (BD: Jun 20, 2025).

Today, the company said that data from a 948-participant study showed its next-generation Promarker D test "retained its excellent predictive discrimination, with the high-risk Promarker D group demonstrating 44-fold greater odds of kidney decline versus the low-risk group".

Proteomics said its next-generation Promarker D test used "a high-throughput immune-assay that aligns with routine pathology workflows" and measured two plasma protein biomarkers, ApoA4 and CD5L, along with age and estimated glomerular filtration rate (eGFR) to generate a personalized diabetes-related kidney disease risk score.

The company said the data was presented at the American Diabetes Association meeting in an abstract, titled 'Next-Generation Promarker D vs Standard of Care for Assessing Kidney Function Decline in Type 2 Diabetes'.

The abstract said that Promarker D stratified 619 participants into low (65.3%), 229 participants into moderate (24.2%), and 104 participants into high (11.0%) risk groups, "with kidney outcomes observed in 2.6 percent, 16.2 percent and 54.0 percent of each group, respectively".

Proteomics said Promarker D was "positioned for global commercialization and regulatory expansion, opening new pathways to transform diabetic care through precision medicine'.

Proteomics fell two cents or 5.6 percent to 34 cents.

IMMUTEP

Immutep says it has "positive initial efficacy data and continued favorable safety data" from its 49-patient, first-in-human, phase I study of IMP761 for auto-immune diseases.

Immutep said the highest dosing level to date of 0.9 milligrams per kilogram (mg/kg) of its IMP761 lymphocyte activation gene (LAG)-3 agonist showed "no treatment-related adverse events in healthy participants".

The company said pharmaco-dynamic data at the highest dosing level to date showed "the inhibition of T-cell infiltration in the skin at day-10 following a neo-antigen re-challenge has already reached 80 percent".

Immutep said that given the encouraging efficacy and safety it was continuing with single ascending dose levels of 2.5mg/kg, 7.0mg/kg and 14mg/kg.

The company said LAG-3 immune checkpoint had "been identified as a promising therapeutic target for rheumatoid arthritis, type 1 diabetes, and multiple sclerosis".

Immutep said further data from the phase I trial was expected by 2026.

Immutep chief scientific officer Dr Frédéric Triebel said the data was "very promising, especially in conjunction with its continued favorable safety profile, and highlight the potential efficacy of this LAG-3 agonist in treating auto-immune diseases".

"LAG-3 expression on activated T-cells is known to be highly specific to disease sites, and particularly in areas of chronic inflammation," Dr Triebel said.

"This unique specificity enables the potential for IMP761 to have a more targeted approach with fewer side effects than other therapies," Dr Triebel said. "We look forward to evaluating higher dosing levels of IMP761 and hope to further enhance its ability to safely silence the dysregulated T-cells responsible for many auto-immune diseases."

Immutep fell one cent or 4.3 percent to 22.5 cents with 4.1 million shares traded.

PYC THERAPEUTICS

PYC says it has confirmed with the US Food and Drug Administration the primary endpoints for a registrational trial of its VP-001 for retinitis pigmentosa type 11 (RP11).
The company said that a type B meeting the FDA confirmed that improvements in both visual acuity assessed by low luminance visual acuity and retinal sensitivity assessed by microperimetry could be used as the sole primary endpoint in a registrational trial.
In April, PYC said its phase I/II trial of VP-001 for RP11 showed “statistically significant improvements in vision”, but did not disclose patient numbers (BD: Apr 28, 2025).
At that time, the company said the study showed a statistically significant increase in visual acuity as assessed by low luminance visual acuity when compared to the untreated eye and the history of RP11 disease progression ($0 < 0.002$ and $p < 0.0001$, respectively).
The company said patients treated with 30 micrograms or more of VP-001 had improved visual function as measured by microperimetry, “which compared favorably to other precision therapies for different forms of inherited retinal disease”.
Today, PYC said the FDA set out an expectation that its application contained a minimum of 24-months of data; a sham control arm, for comparison with the interventional arm; and the proposed inclusion and exclusion criteria for the trial were acceptable.
PYC said it would use the guidance to finalize its registrational study design before seeking endorsement of the proposal from the FDA through a type D meeting by 2026.
PYC was up five cents or 4.35 percent to $1.20.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it has ethics approval to begin its 12-patient, open-label study of TRP-8803 intra-venous psilocin with psychotherapy for adults with binge eating disorder.
Earlier this year, Tryptamine said it would conduct a trial of TRP-8803 for binge eating disorder with Melbourne’s Swinburne University of Technology (BD: Apr 10, 2025).
Previously, the company said that psilocin was the active psychedelic metabolite of psilocybin found in ‘magic mushrooms’ (BD: Jul 1, 2024).
Today, Tryptamine said two cohorts would receive two doses of TRP-8803 14 days apart in a monitored setting, with one cohort to be dosed over 140 minutes and the second cohort over 60 minutes.
The company said the primary objective was safety and efficacy during the 12-weeks following the second dose, with secondary and exploratory objectives including the drug’s ability to induce a psychedelic state and effects of the frequency of binge-eating episodes and other weight—related indicators over four and 12 weeks from second dosing.
Tryptamine said the study followed positive interim data from its University of Florida trial which showed oral TRP-8802 psilocybin led to a more than “80 percent improvement in patient binge-eating scores”.
The company said Swinburne University had begun patient recruitment, with the first cohort dosing expected by October and top-line results by 2026.
Tryptamine chief executive officer Jason Carroll said while binge-eating disorder was “not widely publicized, it is incredibly widespread with many sufferers also experiencing a range of other neuro-psychiatric conditions including anxiety, depression and [post-traumatic stress disorder] amongst others”.
“While the primary objective of this world first trial is to assess TRP-8803’s utility in binge eating disorder, it will also provide valuable insight into how TRP-8803 may help with other neuro-psychiatric disorders, in line with the company’s goal of delivering treatments to large, unmet conditions,” Mr Carroll said.
Tryptamine fell 0.2 cents or 6.45 percent to 2.9 cents with 2.3 million shares traded.

LUMOS DIAGNOSTICS

Lumos says it has received $215,485 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Lumos said the incentive related to research and development expenditure for the year to June 30, 2024.
Lumos fell 0.1 cents or 3.6 percent to 2.7 cents with 1.7 million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors has requested a voluntary suspension following Thursday's trading halt "in connection with a proposed capital raising" (BD: Jun 19, 2025).
Trading will resume on June 30, 2025, or on an earlier announcement.
Universal Biosensors last traded at 3.5 cents.

SYNTARA

San Francisco's BVF Partners says with Mark Lampert it sold all 104,789,174 Syntara shares on June 20, 2025 for $4,706,082, or 4.5 cents a share.
Earlier this year, BVF said its 104,789,174 share-holding in Syntara was diluted from 8.80 percent to 6.46 percent due to a share issue (BD: Mar 24, 2025).
Syntara fell 0.2 cents or 4.1 percent to 4.7 cents with 13.6 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says chair Otto Buttula will resign as chair and director, with director Gavin Fox-Smith appointed chair, effective at its 2025 annual general meeting.
In 2019, Rhythm said Mr Buttula was appointed non-executive chair and director, replacing Shane Tanner (BD: Oct 25, 2019).
Today, the company said Mr Buttula led the company through "transformative milestones, including proteomic platform expansion into other cancers and the rebuilding of the Colostat kit program into a more useable commercial product".
Rhythm said Mr Buttula "oversaw the diversification into genetic testing, via the acquisition of Genetype and first commercial sales".
Last year, the company said it appointed Mr Fox-Smith as an independent, non-executive director, effective from December 2, 2024 (BD: Nov 11, 2024).
Today, Rhythm said Mr Fox-Smith was chair of the Australian National Digital (AND) Health Initiative and a director of Omnigon, Bowel Cancer Australia, the Sydney Adventist Hospital (SAN) Foundation and United Way Australia.
Rhythm fell 0.2 cents or 3.2 percent to six cents.