

Biotech Daily

Wednesday May 21, 2025

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: ATOMO UP 12.5%; IMUGENE DOWN 10.5%
- * MCRI, RETRO BIOSCIENCES \$54m BLOOD STEM CELL LICENCE
- * COMPUMEDICS \$1m SOMFIT DEAL; REVENUE WARNING
- * MAYNE FALLS 34% ON COSETTE 'ADVERSE CHANGE' CLAIM
- * ISLAND PLACEMENT RAISES \$4m
- * EMVISION: EMU ISCHAEMIC STROKE 95% SENSITIVITY, 80% SPECIFICITY
- * MICROBA: 'METAPANEL DETECTS PATHOGENS MISSED BY ROUTINE TESTS'
- * CHIMERIC TAKES CHM2101 TO 150m CELL DOSE
- * NYRADA APPROVAL FOR 4th PHASE I NYR-BI03 COHORT
- * ECHO IQ TO RESUBMIT ECHOSOLV CPT APPLICATION
- * EPSILON FILES PROCEEDINGS AGAINST FORMER CHAIR JOSH (XIAO) CUI
- * NANOSONICS PLEADS 'SCHULTZ' TO ASX 13% PRICE FALL QUERY
- * EBR REQUESTS 'CAPITAL RAISING' TRADING HALT
- * BVF, MARK LAMPERT BELOW 5% OF ACTINOGEN
- * MERCER BELOW 5% OF MEDADVISOR
- * NOXOPHARM BELOW 5% OF NYRADA
- * COGSTATE LOSES 15-YEAR DIRECTOR RICHARD VAN DEN BROEK
- * LTR PHARMA APPOINTS PROF DARREN KATZ ADVISOR
- * CAMBIUM DR WALLER CHAIR, SECHOS OUT; PROF MARKS; LICCIARDO, LEUNG

MARKET REPORT

The Australian stock market was up 0.52 percent on Wednesday May 21, 2025, with the ASX200 up 43.5 points to 8,386.8 points. Fourteen of the Biotech Daily Top 40 companies were up, 15 fell, nine were unchanged and two were untraded.

Atomo was the best, up 0.2 cents or 12.5 percent to 1.8 cents, with 604,793 shares traded. Impedimed improved 9.7 percent; Cynata was up 8.1 percent; Paradigm climbed 7.9 percent; Medical Developments was up 5.45 percent; Resmed rose four percent; Dimerix was up 3.5 percent; Emvision rose 2.65 percent; 4D Medical, Clarity, Curvebeam, Immutep, Pro Medicus and Telix were up more than one percent; with CSL, Nanosonics and Neuren up less than one percent.

Imugene led the falls, down 0.2 cents or 10.5 percent to 1.7 cents, with 45.1 million shares traded. Cyclopharm lost 8.7 percent; Micro-X was down 6.7 percent; Compumedics fell five percent; Genetic Signatures, Mesoblast, Nova Eye and Starpharma were down more than three percent; Clinuvel, Orthocell, Resonance and Syntara shed more than two percent; Alcidion and Proteomics were down more than one percent; with Cochlear and Polynovo down by less than one percent.

MURDOCH CHILDREN'S RESEARCH INSTITUTE

The Murdoch Children's Research Institute says it will licence its blood stem cell discovery technology to the California's Retro Biosciences for \$US35 million (\$A54.4 million). Last year, the Melbourne's Royal Children's Hospital-based Murdoch Children's Research Institute (MCRI) said it had grown and transplanted human-derived blood stem cells in mice, having injected immune deficient mice with laboratory-engineered human blood stem with the cells becoming functional bone marrow at similar levels to those seen in umbilical cord blood cell transplants, a proven benchmark (BD: Sep 4, 2024). Today, the Institute said it would licence its blood stem cell intellectual property to Redwood City, California's Retro "for the development of new, personalized therapies". The Institute said Retro's mission was to "add 10 years to the healthy human lifespan with programs that ... replace malfunctioning cells through the use of stem cell technologies". The MCRI said Retro Biosciences used cellular reprogramming, autophagy enhancement and artificial intelligence (A.I.)-driven protein engineering to target the mechanism of aging and age-related disease; and the agreement addressed "urgent unmet needs in haematology ... [and was] a critical step toward enabling regenerative solutions that support a longer, healthier lifespan".

The MCRI's Prof Elizabeth Ng said the researchers had "shown that we can take any cell from a patient, reprogram it into a stem cell and then turn these into specifically matched blood cells for transplant, preventing complications from mismatched donors". "By joining forces with Retro Biosciences, we are now on our way to providing personalized, patient-specific blood stem cells to treat children and adults with blood diseases ... [with] first-in-human clinical trials within the next five years," Prof Ng said.

COMPUMEDICS

Compumedics says it has a \$1.0 million contract its Somfit to an unnamed contract research organization, with expected 2024-'25 revenue reduced by up-to \$10 million. Compumedics said the contract research organization had been contracted by an undisclosed pharmaceutical company for drug trials assessing impact on sleep. The company said the organization would use its Somfit electro-encephalogram (EEG) athome sleep test to assess the impact on sleep and Somfit was selected "amongst other reasons, for its ability to collect brain EEG signals directly, by applying the Somfit devices on the forehead using a disposable adhesive sensor ... rather than relying on surrogate or secondary signals, such as competitive finger-based home sleep testing systems". The company said US sales of Somfit for the financial year to May 16, 2025 were about \$2.8 million, compared to \$300,000 in the prior year, it had won several Somfit orders from a continuous positive airway pressure company and continued to work with other sleep service providers in Australia, with ongoing sales in Europe.

Compumedics said as a result, it continued to expect orders to be more than \$60 million for the year to June 30, 2025, with "revenues shipped and invoiced lagging sales orders taken, as [it] adjusts for the significant growth in the business, particularly in the US". The company said it expected "reported revenues to be between \$50 million and \$55 million for [the year to June 30, 2025] ... below the \$55 million previously advised", with earnings before interest, taxation, depreciation and amortization (Ebitda) expected to be about \$3 million, compared to \$5 million as previously advised.

In March, Compumedics said it expected revenue for the year to June 30, 2025 to be "more than \$60 million" with Ebitda of about \$5 million and revenues for the year to June 30, 2026 of "at least \$70 million", which it reconfirmed today (BD: Mar 21, 2025). Compumedics fell 1.5 cents or five percent to 28.5 cents.

MAYNE PHARMA GROUP

Mayne fell as much as 33.5 percent on Cosette's claim that a "material adverse change" has occurred and the scheme implementation deed might be terminated.

Earlier this year, Mayne said that the Bridgewater, New Jersey-based Cosette Pharmaceuticals Inc would buy it for \$7.40 a share in cash, valuing the company at \$672 million (BD: Feb 21, 2025).

At that time, the company climbed \$1.79 or 33.1 percent to \$7.20 a share. Last week, Mayne said it had Supreme Court of New South Wales approval to convene a shareholder meeting to vote on its sale to Cosette (BD: May 15, 2025).

Today, the company said Cosette correspondence from May 17 claimed a "material adverse change" had occurred but Mayne was "of the view that no Mayne material adverse change as defined in the [scheme implementation deed] had occurred".

Mayne did not specify the alleged "material adverse change" and said the Cosette notice did not "quantify the full financial impact of the cumulative matters that Cosette asserts constitute a Mayne material adverse change, being [its] trading performance including the circumstances associated with [its] April 22, 2025 earnings update, the previously disclosed litigation with TXMD, and certain correspondence with regulators including the FDA untitled letter disclosed ... on May 14, 2025".

Mayne said the two parties would engage in consultation and Cosette had "indicated that if the consultation process does not achieve a satisfactory outcome ... it intends to issue a notice to terminate the [scheme implantation deed] at the end of the consultation period". Mayne closed down \$1.93 or 29.8 percent at \$4.55 with 5.4 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has "firm commitments" to raise \$3.6 million at 15 cents a share in a placement to institutional, sophisticated and professional investors.

Island said the issue price was an 11.86 percent discount to the 15-day volume weighted average price and a 16.67 percent discount to the last traded price.

The company said the funds would be used for ISLA-101, including an additional, larger trial, its merger and acquisition strategy and trial requirements for additional molecules. Island said Perth's ORA Capital was the lead manager and would receive a six percent capital raise fee, with S3 Consortium Pty Ltd to be issued 2,500,000 shares for services. Island was up three cents or 16.7 percent to 21 cents with 3.9 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says its 'Emu' portable brain scanner determines ischaemic or non-ischaemic stroke with 95 percent sensitivity and 80 percent specificity.

Last year, Emvision said a 307-participant study showed its artificial intelligence (A.I.)based Emu brain scanner had 85 percent sensitivity and 78 percent specificity for diagnosing patients with ischemic strokes (BD: Nov 12, 2024).

Today, the company said "as part of continuous innovation efforts, the A.I.-powered 'ischemia or not' diagnostic algorithm had been re-trained, using cleaned training data and re-evaluated" in 20 ischaemic and 50 not ischaemic stroke cases, and in a sensitivity analysis of the 20 ischaemic cases, the Emu device missed one case, whereas in firstline, non-contrast computed tomography imaging nine cases were not detected. The company said the study was "encouraging" but due to the design and limited sample size, it did not allow statistically significant or generalisability conclusions to be drawn. Emvision was up 4.5 cents or 2.65 percent to \$1.74.

MICROBA LIFE SCIENCES

Microba says 78.4 percent of pathogens detected by its Metapanel pathogen test were those "often missed by routine pathology tests" in an analysis of 899 Metapanel tests. Microba said 178 of the 889 samples, or 20.0 percent, tested positive for a pathogen that could cause gastro-intestinal infection, with 518 tests, or 58.3 percent, showing abnormal microbiome results, supporting referral to a Metaxplore test.

The company said its Metapanel gastro-intestinal pathogen detection panel screened for 115 pathogens and virulence factors, including bacteria, viruses and parasites and was "designed to address the limitations of conventional diagnostics, which only detect a limited range of clinically relevant pathogens".

Microba said that a separate independent study by Brisbane's Colonoscopy Clinic of 42 patients with chronic diarrhoea found 19 percent, or eight patients, tested positive for a pathogen with Metapanel.

The company said all patients who were treated for a pathogen detected by Metapanel experienced "complete symptom resolution", with the promising early results supporting the inclusion of Metapanel in routine testing protocols.

The company said "current routine gastro-intestinal testing approaches leave approximately 50 percent of patients with chronic gastro-intestinal symptoms without symptom resolution"; and Metapanel offered "a novel diagnostic and therapeutic pathway for these patients".

Microba chief scientific officer Prof Lutz Krause said the study showed that Metapanel could "detect clinically significant pathogens that are missed by standard pathology tests". "The symptom resolution observed in all treated patients underscores its potential to transform outcomes for patients with chronic [gastro-intestinal] conditions," Prof Krause said. "This data exemplifies the strength of our partnership with the Colonoscopy Clinic in demonstrating the … utility of Microba's tests and advancing precision gastro-enterology." Microba fell one cent or 6.25 percent to 15 cents.

CHIMERIC THERAPEUTICS

Chimeric says its 15-patient, phase I/II trial of CHM CDH17 has advanced to its second dose level of 150 million cells, with no safety concerns at the first 50 million cell dose. Last year, Chimeric said it had enrolled the first of 12 patients in its phase I/II trial of its CHM CDH17, or CHM2101, for colorectal and gastric cancers and intestinal neuro-endocrine tumors to determine a dose level and evaluate safety and objective response rate (BD: Jul 22, 2024).

Today, Chimeric said the initial dose was tested on three colorectal cancer patients and one intestinal neuro-endocrine tumor patient, with "no dose-limiting toxicities or unexpected safety findings".

The company said "one patient experienced grade one cytokine release syndrome, 10 days after receiving CHM CDH17, that was associated with peripheral [chimeric antigen receptor T-cell-positive] cell expansion and persistence".

Chimeric said it was "encouraged by these safety findings and early signs of clinical activity with one [neuro-endocrine tumor] patient experiencing stable disease for five months and one [colorectal cancer] patient with stable disease ... at four months". The company the phase I portion of the study was "expected to enrol up to 15 patients and lead to dose selection and expansion with indication-specific phase II cohorts". Chimeric chief executive officer Dr Rebecca McQualter said the results were "a major milestone for Chimeric".

Chimeric was unchanged at half a cent with 40.1 million shares traded.

<u>NYRADA</u>

Nyrada says it has safety review committee approval to dose the fourth 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 up 2.5 cents or 22.7 percent to 13.5 cents with 5.6 million shares traded.

ECHO IQ

Echo IQ says it will resubmit its application for a category III CPT code for reimbursement of its Echosolv echo-cardiogram software for aortic stenosis.

Yesterday, Echo IQ told the ASX that the American Medical Association had rejected its request for a category III CPT code for reimbursement of its Echosolv AS device, which may have explained a 12.5 percent drop in its share price and the significant increase in the volume of shares traded (BD: May 20, 2025).

Today, the company said it was "actively progressing revisions to its submission" including all feedback and guidance it had received from the American Medical Association, with resubmission expected prior to the June 11, 2025 deadline.

Echo IQ said active use of its device at sites in the US would "not be interrupted due to this development".

Echo IQ was up 2.5 cents or 10.4 percent to 26.5 cents with 19.3 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has filed proceedings in the New South Wales Supreme Court against former chair Josh (Xiao) Cui and Watercrest Capital Pty Ltd.

Epsilon said that Mr Cui was the sole director and secretary of Watercress.

The company said that the proceedings related to "agreements purportedly entered into by Epsilon, and payments made by Epsilon to Watercrest and other parties".

Epsilon said the proceedings followed "a professionally-guided lookback, including a legal, forensic and financial review of the company's affairs in the period prior to the company being placed into administration" (BD: Nov 21, 22, 23, 24; Dec 4, 15, 18, 2023). Epsilon was in a suspension and last traded at 2.4 cents.

NANOSONICS

Nanosonics has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company's share price fell 12.6 percent from \$4.83 on May 19, 2025 to a low of \$4.22 yesterday and noted a "significant increase" in the volume of shares traded. Nanosonics was up four cents or 0.9 percent to \$4.46 with 1.5 million shares traded.

EBR SYSTEMS

EBR has requested a trading halt pending an announcement "to be made by the company to the market in relation to a proposed capital raising".

Trading will resume on May 23, 2025, or on an earlier announcement. EBR last traded at \$1.215.

ACTINOGEN MEDICAL

The San Francisco-based BVF Partners says with Mark Lampert it has ceased its substantial shareholding in Actinogen.

BVF said it sold shares in more than 40 transactions between April 22 and May 19, 2025, with the largest sale 95,568,497 shares on May 19 for \$1,812,170, or 1.9 cents a share. Actinogen was unchanged at 2.1 cents with 2.9 million shares traded.

MEDADVISOR

Mercer Investments (Australia) Ltd says it has ceased its substantial shareholding in Medadvisor and retains 28,339,194 shares, or 4.539 percent.

The Melbourne-based Mercer Investments said that on May 16, 2025 it sold 2,565,351 shares for \$226,520, or 8.8 cents a share.

Medadvisor was unchanged at 8.8 cents with 1.7 million shares traded.

NYRADA, NOXOPHARM

Nyrada says Noxopharm has ceased its substantial shareholding, reducing from 10,825,002 Chess depositary interests (CDIs) (5.13%) to 3,003,334 CDIs (1.42%). Yesterday, Nyrada said Noxopharm would sell all 33,373,245 CDIs at 7.5 cents each, raising \$2,502,993 "over the coming days" (BD: May 20, 2025).

The company said 100 percent of Noxopharm's holding in the company had been "acquired by a syndicate of current and new Nyrada holders".

Noxopharm fell 0.2 cents or 2.9 percent to 6.6 cents.

COGSTATE

Cogstate says that 15-year, US-based, non-executive director Richard van den Broek has retired, effective from today.

Cogstate said Mr van den Broek had been appointed to the board as its first US-based director on August 30, 2010, was an existing shareholder at the time of his appointment and currently held 4,458,500 shares in the company.

Cogstate chair Martyn Myer said Mr van den Broek had "brought incredible value to Cogstate through his intimate knowledge of the drug development pipelines and industry trends ... [and had] been a thoughtful and meaningful contributor to board discussions". "We expect that Mr van den Broek will remain close to the Cogstate team and will continue to be a valuable adviser to our management team," Mr Myer said. Cogstate fell 3.5 cents or 2.6 percent to \$1.305.

LTR PHARMA

LTR Pharma says it has appointed urologist and erectile dysfunction specialist Prof Darren Katz to its scientific advisory board.

LTR said the University of Melbourne's Prof Katz would advise it on research and development and clinical development activities for Spontan and Roxus.

The company said Prof Katz was medical director of Men's Health Melbourne, had led the Urological Society of Australia and New Zealand's Andrology Special Advisory Group and was a clinical advisor for the Federal Government's Department of Health.

LTR fell 4.5 cents or 11.5 percent to 34.5 cents with two million shares traded.

CAMBIUM BIO (FORMERLY REGENEUS)

Cambium says Dr Edmund Waller replaces chair Barry Sechos, Acclime's Mark Licciardo replaces company secretary Helen Leung, with Prof Denese Marks appointed a director. Cambium said that director Dr Waller had been appointed executive chair and chief scientific officer, effective from today (BD: Apr 28, 2023).

The company said Dr Waller was a co-founder of Cambium Medical Technologies and a professor of haematology and oncology at the Atlanta, Georgia-based Emory University. The company said that Prof Marks had "30 years' experience in blood and platelet-based therapeutics" and was national research program leader for product development and transfusion studies at Australian Red Cross Lifeblood.

Cambium said Mr Sechos had been a director since 2012 and non-executive chair since 2013, guiding the then Regeneus through its ASX listing and acquisition of Cambium. Cambium chief executive officer Karolis Rosickas said: "On behalf of the entire team, I extend my heartfelt thanks to Barry for his 13 years of dedicated leadership." "Barry's strategic insight, steady guidance and unwavering commitment laid the

foundations for Cambium Bio's transformation into a late-stage ophthalmology innovator," Mr Rosickas said.

"We wish him every success in his well-deserved retirement," Mr Rosickas said. Cambium was untraded at 19 cents.