Biotech Daily

Wednesday August 6, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: 4D MEDICAL UP 18%; AMPLIA DOWN 27%**

*** NANOSONICS FDA TROPHON3, TROPHON2 PLUS CLEARANCE**

*** TRANSLATION RESEARCH INSTITUTE $100m 'ENTRI' BIO-FACTORY**

*** AMPLIA FALLS 29% ON AMP945 PANCREATIC CANCER INTERIM RESULTS**

*** CARTHERICS OPENS $3m CELL THERAPY FACTORY**

*** EHJ: 'SLEEP APNOEA TREATMENT MIXED CARDIAC RESULTS'**

*** WEHI DEVELOPS mRNA MALARIA VACCINE**

*** CSIRO DEVELOPS X-RAY REPORT A.I. MODEL**

*** PERCHERON 'HMBD-002 BLOCKS TUMOR GROWTH, IN MICE'**

*** SAHMRI TRIALS HB-1 COMBINATION FOR PANIC DISORDER**

*** NYRADA: 'ALL 6 PHASE I NYR-BI03 DOSES SAFE'**

*** MAYNE 3rd COSETTE TERMINATION NOTICE ALLEGES BREACHES**

*** AROA 1m M-D BRIAN WARD RIGHTS AGM**

*** RHYTHM PLEADS 'SCHULTZ' TO ASX 121% PRICE QUERY**

*** ARGENICA APPOINTS SHARON HANEGRAAF REGULATORY HEAD**

MARKET REPORT

The Australian stock market was up 0.84 percent on Wednesday August 6, 2025, with the ASX200 up 73.3 points to 8,843.7 points. Twenty of the Biotech Daily Top 40 companies were up, 14 fell and six traded unchanged. The four Big Caps were mixed.

4D Medical was the best, up six cents or 17.9 percent to 39.5 cents, with 5.1 million shares traded. Atomo, Curvebeam, Dimerix and Medical Developments climbed five percent or more; Nanosonics was up 4.6 percent; Micro-X, Prescient and Proteomics rose more than two percent; Aroa, Clarity, Pro Medicus, Starpharma and Syntara were up one percent or more; with Avita, Clinuvel, CSL, Cyclopharm, EBR, Mesoblast, Neuren and Telix up by less than one percent.

Amplia led the falls, down 6.5 cents or 27.1 percent to 17.5 cents, with 48.7 million shares traded. Medadvisor lost 7.1 percent; Optiscan and Resonance were down five percent or more; Actinogen, Alcidion, Compumedics and Impedimed fell more than four percent; both Imugene and SDI were down 3.45 percent; Paradigm shed 2.9 percent; Emvision, Immutep and Resmed were down more than one percent; with Cochlear and Orthocell down by less than one percent.

NANOSONICS

Nanosonics says the US Food and Drug Administration has cleared both its Trophon3 ultrasound probe cleaning system and Trophon2 Plus, a software upgrade for Trophon 2.
Nanosonics said it would launch the Trophon3 and Trophon2 Plus in the US "soon".
The company said Trophon3 delivered “a range of new benefits to customers while maintaining the highest standard in clinical efficacy for patient safety”.
In 2011, Nanosonics said it had FDA 510(k) clearance for the original Trophon EPR ultra-sound probe cleaner and the chemical indicator accessory (BD: Feb 28, 2011).
In 2018, the company said it received FDA approval for its Trophon2 second-generation ultra-sound probe decontamination device (BD: Apr 27, 2018).
Last month, Nanosonics said it had launched its Trophon3 third-generation device and Trophon2 Plus, in Europe, the UK, Australia and New Zealand (BD: Jul 7, 2025).
Today, the company said the Trophon3 was more than 40 percent faster than previous generations, had expanded digital integration capabilities and “the widest traceability capabilities in the ultrasound reprocessing market including new digital traceability through customer’s [digital imaging and communications in medicine] imaging database systems”.
Nanosonics said Trophon3 was “fully programmable and adaptable … [and could] be customized to suit a range of customer workflows enhancing efficiency while delivering consistent, reliable disinfection in a safe, effective, and environmentally friendly way”.
The company said Trophon3 was “expected to support continued growth in the company’s installed base in both the hospital and private physician market segments, as well as drive a significant upgrade opportunity for approximately 10,000 original Trophon EPR devices”.
Nanosonics said Trophon2 Plus was a software upgrade package that allowed existing Trophon2 users to access the additional features of Trophon3.
The company said there were about “20,000 Trophon2 devices globally [and] this new package represents a significant software upgrade opportunity”.
Nanosonics managing-director Michael Kavanagh said “the FDA clearance and US launch of Trophon3 and Trophon2 Plus mark important milestones for Nanosonics”.
Nanosonics was up 18 cents or 4.6 percent to $4.07 with 2.2 million shares traded.

TRANSLATIONAL RESEARCH INSTITUTE

The Translational Research Institute says it will open the more than $100 million Entri, an “Australia-first bio-manufacturing facility”, with Queensland Government funding.
Brisbane’s Translational Research Institute (TRI) is backed by the University of Queensland, Queensland University of Technology, Mater Research and Brisbane’s Princess Alexandra Hospital, where the Entri factory was located.
The TRI said the facility had been “named Entri, acknowledging its important role in lifting barriers to entry for [biotechnology] and [medical technology] scale-ups in Australia and enabling the translation of research from bench to bedside”.
The Institute said the facility would “address a critical capability gap in Australia, enabling companies to access [good manufacturing practice] cleanrooms, the global gold standard for bio-manufacturing”.
The Translational Research Institute said the translational manufacturing site was 7,000 square meters across four floors, “making this one of the largest end-to-end translational research facilities of its kind in Australia”.
The Institute said the factory was jointly funded with the Queensland Government and would include wet labs and open plan office spaces as well as cleanrooms, to enable process development, analytical development and on-site quality control testing.

AMPLIA THERAPEUTICS

Amplia fell up-to 29.2 percent on news that AMP945 and chemotherapy led to 7.6 months progression free survival, a two-month improvement on chemotherapy alone.

In June, Amplia climbed as much as 202.5 percent on news that AMP945 led to two confirmed complete responses in the 55-patient, phase Ib/IIa trial; and last month, said the trial reported 17 confirmed partial responses (BD: Jun 16, 19, Jul 11, 2025).

Previously, Amplia managing-director Dr Chris Burns told Biotech Daily that the company's statistician had nominated 15 partial responses of the 55 pancreatic cancer patients (27.3%) as the benchmark compared to the historical 23 percent rate.

Today, the company said the trial showed AMP945 led to an objective response rate of 30.9 percent, or 17 of 55 patients, with disease control rate of 72.7 percent, or 40 of 55 patients, which included stable disease.

Dr Burns told Biotech Daily that the 17 with an objective response rate included one complete response, while the 16 partial responses included one patient who later had a complete response.

Amplia said seven patients had stayed on trial for more than 12 months, 17 patients remained on study and the mean days on trial for evaluable patients was 202 days, "substantially better than 117 days reported for chemotherapy alone".

The company said the study showed narmafotinib had an "excellent tolerability profile apparent with adverse events being very similar in type and occurrence to those observed for chemotherapy alone".

Amplia said further data was expected by the end of 2025, with mature data by April 2026 and the opening of a phase IIb/III trial by 2027.

Amplia fell as much as 29.2 percent to 17.0 cents before closing down 6.5 cents or 27.1 percent at 17.5 cents with 48.7 million shares traded.

CARTHERICS PTY LTD

Cartherics says it has opened a $3 million, upgraded cleanroom facility for clinical-scale cell therapy manufacturing at its site in Notting Hill, Victoria.

Cartherics said the factory was opened by former Federal Minister for Industry and Science Ed Husic and was an investment by the company, showing "its commitment to be a major player in Victoria's thriving [biotechnology] sector and strengthening Melbourne's position as a leader in advanced medical manufacturing and translational research".

A spokesperson for Cartherics told Biotech Daily that the upgraded and equipped clean rooms cost $3 million and were fully-funded by the company with investor capital.

The company said once validated the site would be used to manufacture clinical batches of its lead cell therapy product CTH-401 for relapsed and refractory ovarian cancer.

Cartherics said the factory was "equipped with comprehensive environmental control systems which monitor particle counts, airflows, air pressures, humidity, and temperature".

The company said the site incorporated "advanced manufacturing technologies, including closed processing systems, bio-reactors, cleanroom-grade incubators and a bio-burden testing facility".

Cartherics chief executive officer Prof Alan Trounson said the "completion of the cleanrooms means that clinical manufacturing can now begin for Cartherics' therapeutic products targeting ovarian cancer and endometriosis".

"These advanced manufacturing facilities will provide a much-needed addition to Victoria's translational capacity in oncology, regenerative medicine and other therapeutic applications," Prof Trounson said.

Cartherics is a private company.

EUROPEAN HEART JOURNAL

European Heart Journal research says CPAP machines may lower the risk of serious cardio-vascular events in some obstructive sleep apnoea patients, but not others.
The European Heart Journal (EHJ) said in a media release published on Scimex, that a three-year study of 3,549 obstructive sleep apnoea patients was conducted by Boston's Brigham and Women's Hospital and Harvard Medical School.
The Journal said the research, titled 'Cardiovascular benefit of continuous positive airway pressure according to high-risk obstructive sleep apnoea' was authored by Dr Ali Azarbarzin, but the links provided appearing to be broken.
The media release said the study suggested that continuous positive airway pressure (CPAP) machines "may offer long-term cardio-vascular benefit in people with high-risk [obstructive sleep apnoea] but may have unintended harmful effects in those without high-risk [obstructive sleep apnoea]".
Fisher & Paykel markets and sells respiratory and acute care products including CPAP pumps and masks and Resmed commercializes CPAP therapy units.
Somnomed has developed and commercialized its continuous open airway therapy, or COAT, which unlike CPAP does not use masks and pumps.

WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

WEHI says it has found a protein complex in malaria parasites which it has used to develop a messenger (m) RNA vaccine to stop the spread of the disease.
WEHI said it used cryo-electron microscopy to capture "the first detailed structure of a protein complex essential for malaria parasite fertilization", which has led to the development of an mRNA vaccine candidate "which stopped the parasite from reproducing in mosquitoes, cutting transmission by up-to 99.7 percent".
The Institute said it discovered two small domains of the fertilization complex that were "crucial for the parasite's ability to fertilize and spread" which it used as a vaccine target.
WEHI said the study, titled 'Cryo-EM structure of endogenous Plasmodium falciparum Pfs230 and Pfs48/45 fertilization complex' was published in the journal Science, with an abstract available at: https://www.science.org/doi/10.1126/science.ady0241.
The Institute said the research revealed "the critical contact points for binding the Pfs230 and Pfs48/45 proteins [and] when these were removed in genetically modified parasites, fertilization failed, and transmission was blocked".
WEHI said its researchers "designed a next generation mRNA vaccine which was formulated … with the Monash Institute of Pharmaceutical Sciences".
The Institutes said transmission-blocking vaccines, like this one, targeting the malaria parasite inside the mosquito, offered "a strategic way to halt the spread of malaria, where its numbers are lowest and its life cycle most vulnerable".
WEHI said that by combining transmission-blocking vaccines with those that acted on blood or liver stages in people, researchers hoped "to build a comprehensive defence that could dramatically reduce malaria burden and move closer to elimination".
WEHI lead researcher Prof Wai-Hong Tham said "to eliminate malaria, we need to stop transmission".
"This vaccine candidate could be one piece of that puzzle," Prof Tham said.
MIPS researcher Prof Colin Pouton said that "drawing on experience through mRNA core, the MIPS team shifted focus to tackle a new challenge in malaria vaccination".
"The success of the malaria vaccine program illustrates the versatility of mRNA technology, which has many applications beyond the Covid-19 vaccines," Prof Pouton said.

COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says it has developed an artificial intelligence (A.I.) which can “write more accurate chest x-ray reports [with] … the same information doctors use in real life”.
The CSIRO said it used more than 46,000 real-world patient cases from a US hospital dataset to train a powerful multi-modal A.I. language model to generate detailed radiology reports, with the results showing “17 percent better diagnostic insights and stronger alignment with expert radiologist reporting”.
The Organisation said the research “could pave the way for faster, safer, and more reliable x-ray reporting in clinical settings”.
The CSIRO said previous A.I. tools for interpreting chest x-rays relied solely on the images and doctor’s referral and it had developed an A.I. model that combined imaging with emergency department data like vital signs, medication history and clinical notes.
The Organisation said its researchers were trialling the technology with Brisbane’s Princess Alexandra Hospital to explore how well the A.I. reporting compared with a human radiologist and was looking for other sites to trial the technology.
CSIRO researcher and study lead Dr Aaron Nicolson said the artificial intelligence was “functioning as a diagnostic detective and we’re equipping it with more evidence”.
“When you combine what’s in the x-ray with what’s happening at the bedside, the A.I. gets more accurate, and much more useful,” Dr Nicolson said.
The A.I. model code is freely accessible at: https://huggingface.co/aehrc/cxrmate-ed.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says pre-clinical data shows its licenced HMBD-0002 “substantially blocked tumor growth entirely” in mice with VISTA-positive breast cancer ($p < 0.0001$).
Last month, Percheron said it would pay $4.6 million up-front and up-to $443 million in milestones to licence the Singapore-based Hummingbird Bioscience’s HMBD-002 for cancer, with a clinical trial expected to begin in 2026 (BD: Jun 26, 2025).
At that time, the company said HMBD-002 was a monoclonal antibody with potential applications in a variety of cancer indications that targeted the v-domain immuno-globulin suppressor of T-cell activation (VISTA).
Last month, Percheron said HMBD-002 with radio-therapy increased “the level of VISTA expression on both tumor cells and immune cells”, in mice (BD: Jul 23, 2025).
Today, the company said the study, titled ‘A Four Amino Acid Intracellular Motif of VISTA Blocks Growth Receptor Signaling in Cancer Cells to Induce Tumor Suppression’ was published in Cancer Research, with an abstract available at: http://bit.ly/40P1sdV.
Percheron said the research indicated “that the activity of HMBD-002 is not purely immune driven but may also derive from modulation of growth signals such as [epidermal growth factor receptor]” which may be an important point of differentiation with existing immuno-therapies such as Keytruda, which was thought to act only through the immune system.
The company said the study was conducted by the Dallas-based University of Texas Southwestern Medical Center.
Percheron managing-director Dr James Garner said the company continued “to evaluate a range of potential avenues via which HMBD-002 may progress into phase II, and we expect to share further detail with investors [by 2026]”.
“Our consideration will undoubtedly be influenced and encouraged by some of the very high-quality pre-clinical data that has recently been published with the drug,” he said.
Last year, Percheron said its 48-patient, phase IIb trial of avicursen for Duchenne muscular dystrophy (DMD) did not meet its primary endpoint (BD: Dec 18, 2024).
Percheron was unchanged at 0.8 cents with 2.1 million shares traded.

SOUTH AUSTRALIAN HEALTH AND MEDICAL RESEARCH INSTITUTE

The South Australian Health and Medical Research Institute (SAHMRI) says it is conducting an up-to 600-patient trial of combination therapy HB-01 for panic disorder.
SAHMRI said panic disorder was characterized by sudden and unpredictable panic attacks, often without any obvious triggers, and HB-01 was a combination of two unnamed existing Australian Therapeutic Goods Administration-approved medications.
According to the National Library of Medicine Clinical Trials website, the phase II trial was sponsored by New York's Honeybrains Biotech LLC and would enrol between 240 and 600 adult patients at 20 clinical sites.
The website said HB-1 was orally dosed and a combination of the high blood pressure medication telmisartan, marketed by Boehringer Ingelheim as Micardis, and the high blood pressure and chest pain medication verapamil, marketed by Viatris as Cordilox.
The webpage said the trial would compare the efficacy of HB-1 with telmisartan and verapamil monotherapies as well as placebo for patients with panic disorder.
More information is available at: https://sahmri.org.au/panic-disorder-study.

NYRADA INC

Nyrada says its 48-participant, phase I trial shows Xolatryp, or NYR-BI03, is safe and well tolerated at all six dose levels and concentrations, with no dose-limiting toxicities.
Earlier this year, Nyrada said it had begun recruiting its 40-volunteer, phase I trial of NYR-BI03; and last month, said it had safety review committee approval to dose the sixth and final cohort in the trial (BD: Mar 17, Jul 14, 2025).
Today, the company said in its final safety review committee meeting the committee "confirmed an absence of safety signals, dose-limiting toxicities, or unexpected side effects among the 48 participants dosed in this phase I study".
Nyrada said "no serious adverse events were reported, and all observed adverse events were classified as either mild or moderate".
The company said pharmaco-kinetic assessment of blood samples taken from cohort six participants were considered by the safety review committee, with confirmation that participants were exposed to twice as much Xolatryp as cohort five participants.
Nyrada said it expected top-line data on primary and secondary endpoints to be available by October 2025, with a final report to be finalized ahead of a phase IIa study ethics filing.
Nyrada fell three cents or 9.4 percent to 29 cents with 2.2 million shares traded.

MAYNE PHARMA GROUP

Mayne says it has a third termination notice from Cosette Pharmaceuticals alleging "breaches of misleading or deceptive conduct laws and continuous disclosure obligations".
In February, Mayne said that the Bridgewater, New Jersey-based Cosette would buy it for $7.40 a share in cash, valuing the company at $672 million (BD: Feb 21, 2025).
In June, the company said it had received "a purported notice to terminate [the] scheme implantation deed" from Cosette; and later, said it had received a second termination notice and that it would start court proceedings against Cosette (BD: Jun 4, 16, 2025).
Today, Mayne said in a third notice of intention to terminate received on August 5, 2025, Cosette had indicated "an intention to terminate the [scheme implementation deed] if the circumstances giving rise to the alleged breach continue to exist for five business days".
The company said the alleged breaches "all related to the circumstances surrounding the FDA 'untitled letter' disclosed to ASX on May 14, 2025".
Mayne was up 12 cents or 2.4 percent to $5.07 with 261,088 shares traded.

AROA BIOSURGERY

Aroa says its annual general meeting will vote to issue 1,051,869 long-term incentive performance rights worth $NZ568,000 ($A518,500) to managing-director Brian Ward.
Aroa said Mr Ward's performance rights were subject to service and performance milestones and valued at $NZ568,000, reflecting a value per performance right of 54 NZ cents, based on the 20-day volume weighted average price of its shares at June 20, 2025.
The company said the performance rights were in addition to Mr Ward's $NZ584,822 annual salary, inclusive of superannuation, as well as his between $NZ461,043 and $NZ1,106,504 "on-target [short-term incentive]" inclusive of superannuation.
Aroa said the meeting would vote on the re-election of director James McLean, the auditor's remuneration and the approval to issue securities under the incentive plan.
The meeting will be held online and at 64 Richard Pearse Drive, Auckland on August 20, 2025 at 11am (NZST).
Aroa was up one cent or 1.6 percent to 62 cents.

RHYTHM BIOSCIENCES

Rhythm has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.
The ASX said the company's share price rose 121.05 percent from a low of 9.5 cents at the close of trading yesterday to a high of 21 cents today and noted a "significant increase" in the volume of securities traded.
On Monday, Rhythm said its second-generation Colostat test reached final production validation and was effective for all colorectal cancer stages (BD: Aug 4, 2025).
Rhythm was up four cents or 42.1 percent to 13.5 cents with 13.7 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has appointed Sharon Hanegraaf as its head of regulatory affairs, effective from August 11, 2025.
Argenica said Ms Hanegraaf had been head of drug development and strategy at Kinoxis Therapeutics and worked in regulatory affairs at Neuren, Acrux, Prota Therapeutics and Facet Life Sciences.
According to her Linkedin page, Ms Hanegraaf had worked for IDT Australia and Phosphagenics (now Avecho) and held a Bachelor of Science from Melbourne's Swinburne University of Technology.
Argenica was up 1.5 cents or 2.2 percent to 69 cents.