

Biotech Daily

Wednesday August 20, 2025

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH DOWN: CYNATA UP 4%; CLARITY DOWN 11%
- * UNIVERSAL BIOSENSORS: 'UBS' IN ADMINISTRATION; TRADING HALT
- * TELIX M-D DR CHRIS BEHRENBRUCH AUSBIOTECH MILLIS ORATION
- * NEURIZON 'NUZ-001 SAFE FOR ALS OVER 2.5 YEARS'
- * INVION FDA INV043 ANAL CANCER ORPHAN DRUG STATUS
- * DORSAVI LAUNCHES ARTEMIS LABS RRAM ROBOTICS SUBSIDIARY
- * INVION PLEADS 'UNAWARE OF FDA DECISION' TO ASX 58% QUERY
- * SONIC TAKES 22% OF MICROBA
- * EMYRIA EGM 19% OPPOSE S3 SHARES, OPTIONS
- * AUSBIOTECH: CSL BIO-CHEERS IN OCTOBER

MARKET REPORT

The Australian stock market was up 0.25 percent on Wednesday August 20, 2025, with the ASX200 up 21.8 points to 8,918.0 points.

Five of the Biotech Daily Top 40 companies were up, 27 fell, five traded unchanged and three were untraded. The four Big Caps were mixed.

Cynata was the best, up 0.75 cents or 3.95 percent to 19.75 cents, with 114,799 shares traded; followed by Actinogen and Curvebeam, climbing more than three percent. Aroa and Emvision rose more than two percent; with Cochlear and Resmed up by less than one percent.

Clarity led the falls, down 44 cents or 11.3 percent to \$3.45, with 4.2 million shares traded.

Avita and Medical Developments lost eight percent or more; 4D Medical was down 7.1 percent; Immutep fell 5.8 percent; Alcidion, Clinuvel, Orthocell, Prescient and Proteomics fell more than four percent; Botanix, Compumedics, Medadvisor, Micro-X, Pro Medicus and Telix were down more than three percent; Amplia, CSL, EBR, Impedimed, Mesoblast and Resonance shed more than two percent; Cyclopharm, Imugene, Neuren, Paradigm, Polynovo and SDI were down one percent or more; with Nanosonics down 0.25 percent.

UNIVERSAL BIOSENSORS

Universal Biosensors Pty Ltd (UBS), a wholly-owned subsidiary of the ASX-listed Universal Biosensors, has appointed KPMG as voluntary administrators of UBS. Universal Biosensors Inc said it was "urgently considering its options with regards to other companies in the group, namely; Universal Biosensors Inc, Universal Biosensors LLC, Hemostasis Reference Laboratory Inc [and] Universal Biosensors BV", all of which were US-based companies, with UBS an Australian subsidiary.

The company said David Hardy, James Dampney and Emily Seeckts of Klynveld Peat Marwick Goerdeler (KPMG) had been appointed joint and several voluntary administrators of UBS.

Universal Biosensors said the administrators would control UBS' "assets, trading and day-to-day operations with the priority being to undertake an immediate assessment of the business and its operations to assess options and notify stakeholders of the appointment". The company said the administrators' current intention was "to continue to trade UBS whilst an urgent assessment of trading is undertaken and options for its sale and, or recapitalization are explored".

Universal Biosensors said that "any interest party wishing to submit a sale or recapitalization proposal in respect of UBS' business and assets should contact the administrators at dtang10@kpmg.com.au".

The company said the first meeting of UBS creditors would take place on August 29, 2025 at 10.30am (AEST), with a notice of meeting yet to be distributed.

Universal Biosensors said UBS' directors' powers were suspended immediately. Requests for further information should be directed to: UBcreditors@kpmg.com.au. Separately, Universal Biosensors requested a trading halt pending an announcement "regarding the company's financial position and the status of its funding strategy". Trading will resume on August 22, 2025, or on an earlier announcement. Universal Biosensors last traded at 1.4 cents.

AUSBIOTECH

Ausbiotech says Telix managing-director Dr Chris Behrenbruch will discuss Australian radio-pharmaceuticals as Millis Orator at its 2025 conference.

Ausbiotech said the Millis Oration, named for microbiologist Prof Nancy Millis and sponsored by CSL, was "one of the biotech industry's most respected honors".

The organization said Dr Behrenbruch's oration would "reflect on Australia's emergence as a radiopharmaceutical powerhouse, shaped by scientific leadership, supply chain advantages, and innovative companies".

"It will also explore how these strengths might extend across the life sciences, and the ecosystem challenges that must be addressed to secure future success," Ausbiotech said. The organization said its 2025 conference would include more than 250 speakers and more than 60 sessions "exploring the issues and innovations shaping the future of biotech, both here in Australia and around the world".

Ausbiotech said the conference would include a rapid-fire pitch competition for companies to present to partners, investors and collaborators as well as keynote addresses and panel discussions on cell and gene therapies, manufacturing, clinical trials and emerging and innovative technologies.

Ausbiotech said it would conduct its annual investor day on October 21, with the conference to be held in Melbourne from October 22 to October 24, 2025. Early registration and ticket prices are available at: https://ausbiotechic.com/register/.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says its 10-patient, open-label extension study of NUZ-001 for amyotrophic lateral sclerosis (ALS) shows it is safe and well-tolerated for more than 2.5 years. Neurizon said the study met its primary endpoint, confirming long-term treatment with NUZ-001 at the recommended phase II dose was safe and well-tolerated, with five patients still receiving treatment under the Australian Therapeutic Goods Administration's special access scheme.

Last year, the then Pharmaust said it had dosed the first of up-to 12 patients in its open-label, phase I, 12-month extension study of the then monepantel, now NUZ-001, for motor neuron disease, or ALS (BD: Feb 14, 2024).

Today, Neurizon said topline, preliminary efficacy results compared NUZ-001 treated patients to matched, untreated historical controls and showed NUZ-001 patients had "significantly increased survival (p = 0.00021).

The company said that NUZ-001 "significantly reduced the risk of death by 76.7 percent (p = 0.0013) ... showed an estimated median survival extension of about 16 months ... slowed the rate of functional decline by 31 percent (p = 0.145) ... [and] reduced the rate of respiratory decline by 43 percent (p = 0.078)".

Neurizon said that at August 15, 2025, six of 12 patients in the phase I study remained alive, with treatment duration ranging from 11.3 months to 34.4 months and median treatment duration of 28.9 months.

The company said it would "advance NUZ-001 to the pivotal phase II/III 'Healey' ALS platform trial [by 2026] ..., pending [US Food and Drug Administration] clinical hold clearance, to confirm the observed benefits in a larger, placebo-controlled setting". Last year, the then Pharmaust said Massachusetts General Hospital had accepted monepantel into its phase II/III 'Healey' amyotrophic lateral sclerosis (ALS), or motor neuron disease (MND) platform trial (BD: Jul 15, 2024).

Later, the company said it filed an investigational new drug application to the FDA for a phase II/III trial of NUZ-001 for ALS "within the 'Healey' ALS platform trial framework"; and earlier this year, the FDA put its application on clinical hold due to "certain concerns about the sufficiency information" (BD: Dec 18, 2024; Jan 19, 2025).

Last month, Neurizon said it filed a formal response to the FDA "to resolve the NUZ-001 clinical hold" including pharmaco-kinetic data in rats and dogs (BD: Jul 25, 2025). Neurizon was up half a cent or 3.2 percent to 16 cents.

INVION

Invion says it has US Food and Drug Administration orphan drug designation for its Photosoft-derived INV043 for anal cancer.

Invion said the milestone complemented promising pre-clinical data from a study with Melbourne's Peter MacCallum Cancer Centre which showed INV043 was effective in treating anal cancer.

Last year, the company said a study of a topical INV043 with immune checkpoint inhibitor therapy for anal squamous cell carcinoma led to about 80 percent of mice being tumor-free (p = 0.0037) (BD: Mar 5, 2024).

Today, Invion said it was working with the Peter MacCallum Centre to conduct a trial of INV043 for ano-genital cancer in combination with immune checkpoint inhibitors. Invion executive chair Prof Thian Chew said the regulatory milestone enhanced the company's "ability to bring INV043 forward more quickly and cost-efficiently, with meaningful benefits for patients suffering from this challenging disease". Invion fell 2.5 cents or 17.2 percent to 12 cents with 2.35 million shares traded.

DORSAVI

Dorsavi says it has launched its wholly-owned subsidiary Artemis Labs for developing and commercializing RRAM, artificial intelligence (A.I.)-enabled sensors and robotics.\
Earlier this year, Dorsavi said it would pay \$\$1,100,000 (\$\$A1,320,000) for the Singapore Nanyang Technological University's resistive random-access memory (RRAM) technology to be used to extend the battery life of its wearable sensors, improving usability in continuous monitoring (BD: Jun 12, 2025).

Later, the company said it would evaluate its licenced RRAM technology for ultra-low latency robotic sensing and response, following validation of the technology in its biomedical sensors (BD: Aug 4, 2025).

Today, Dorsavi said Artemis Labs would consolidate the ongoing research and development of its RRAM technologies and develop the technology for "extending human movement into digital, robotic, and intelligent systems".

The company said potential applications of the technology would include real-time feedback during running, industrial automation, robot training, camera-less spatial tracking, zero-code robot learning and adaptive medical interfaces.

Dorsavi said that with Artemis Labs established, it would focus on artificial intelligence development, technology integration, technology expansion and commercial engagement. Dorsavi chair Gernot Abl said Artemis Labs would "act as the innovation engine to unlock the full commercial potential of this platform spanning clinical, industrial and autonomous applications".

Dorsavi was up 0.1 cents or 2.3 percent to 4.5 cents with 22.3 million shares traded.

INVION

Invion says the US Food and Drug Administration granted orphan drug status for INV043 for anal cancer could explain recent trading in its securities (see above).

The ASX asked the company if it was aware of any information not announced which, if known, could explain the recent trading in its securities.

The ASX said Invion's share price rose 57.6 percent on August 19, 2025 from a low of 9.2 cents to a high of 14.5 cents, with a "significant increase" in the volume of shares traded. Invion said it was not aware the FDA had released a decision on its website, and "only became aware that there was online speculation regarding the FDA decision around the time the trading pause was put in place by ASX".

The company said it "immediately took steps to verify this information and to contact its US-based consultant to confirm the details of the FDA decision".

Invion said it immediately contacted the ASX to discuss a trading halt.

The company said that "the FDA decision was not communicated to Invion prior to becoming available on the FDA website".

MICROBA LIFE SCIENCES

Sonic Healthcare Ltd says it has increased its substantial shareholding in Microba from 68,589,498 shares (19.99%) to 132,033,168 shares (21.68%).

Sydney's Sonic Healthcare said it bought 46,296,296 shares at 9.0 cents a share in a placement on August 13, 2025, but did not disclose how it acquired the remaining shares as required under the Corporations Act (2001).

Earlier this year, Microba said it would raise \$12.5 million at 9.0 cents a share in a placement; and had raised a \$2 million in a share plan (BD: Jun 23, Aug 11, 2025). Microba was up half a cent or 5.8 percent to 9.1 cents with 1.4 million shares traded.

EMYRIA

Emyria says its extraordinary general meeting has passed all resolutions, with up-to 19.22 percent against the issue of shares and options to S3 Consortium Pty Ltd. Last month, Emyria said shareholders would vote to issue 6,250,000 shares and 2,083,333 options to S3 Consortium for investor relations services. Today, the company said the issue of S3 Consortium shares and options both faced 26,381,925 votes (19.22%) in opposition, with 110,846,978 votes (80.78%) in favor. Emyria said the remaining resolutions passed with more than 94.67 percent of the

According to its most recent filing, Emyria had 611,451,030 shares on issue, meaning that the 26,381,925 votes against the S3 Consortium securities amounted to about 4.3 percent of the company, not sufficient to requisition extraordinary general meetings. Emyria fell 0.2 cents or 4.65 percent to 4.1 cents with 3.05 million shares traded.

AUSBIOTECH

meeting in favor.

Ausbiotech says it will host a Bio-Cheers networking event in partnership with CSL and Jumar Bioincubator for Victoria's life sciences sector on October 1, 2025. Ausbiotech said the event included networking from across Victoria's life sciences sector, including therapeutics, medical technology, digital health and agricultural biotechnology. The organization said the event would begin with an optional tour of the Jumar Bioincubator, a joint-venture between CSL, the University of Melbourne, the Walter and Eliza Hall Institute and Breakthrough Victoria to support biotechnology start-ups. Ausbiotech said Bio-Cheers would be held at CSL's headquarters, 655 Elizabeth Street, Melbourne from 4.15pm to 7.30pm (AEST) and was free for members and \$100 for non-members, with registration available at: http://bit.ly/4lzb1VC.