



Biotech Daily

Tuesday October 6, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: IMPEDIMED UP 20%; CURVEBEAM DOWN 12.5%**
- * **SALUDA US CAP24 SURGICAL PADDLE LEAD COMMERCIALIZATION**
- * **ENLITIC: ENSIGHT V2.3 IMAGING SYSTEM RELEASE**
- * **LTR 1st US ROXUS ERECTILE DYSFUNCTION PRESCRIPTIONS**
- * **DORSAVI 'FIRM COMMITMENTS' FOR \$3m PLACEMENT**
- * **TETRATHERIX: FDA CONFIRMS TEGENIX 510(k) FILING DETAILS**
- * **FLINDERS UNI: 'VANILLA COST-EFFECTIVE CHRONIC WOUND HEALING'**
- * **NEURIZON: 'FDA SAYS HEALEY TRIAL COULD SUPPORT APPROVAL'**
- * **STARPHARMA 961k M-D CHERYL MALEY RIGHTS AGM**
- * **FIRSTCAPE, HARBOUR REDUCE TO 8% OF AROA**
- * **JAGEN, BORI LIBERMAN TAKE 12.45% OF CERYVYN**

MARKET REPORT

The Australian stock market was up 0.57 percent on Tuesday October 6, 2026, with the ASX200 up 49.3 points to 8,735.7 points. Eleven of the Biotech Daily Top 40 stocks were up, 18 fell, 10 traded unchanged and one was untraded. The four Big Caps were mixed.

Impedimed was the best, up 0.1 cents or 20 percent to 0.6 cents, with 33.9 million shares traded. Lumos climbed 10.0 percent; Resonance rose 6.85 percent; Optiscan was up 5.9 percent; Amplia improved 4.55 percent; Cyclopharm was up 3.4 percent; Avita rose 2.7 percent; Aroa, CSL, Prescient, Resmed and Saluda were up one percent or more; with Starpharma up by 0.6 percent.

Curvebeam led the falls, down 0.3 cents or 12.5 percent to 2.1 cents, with 3.1 million shares traded. Syntara lost 9.1 percent; Orthocell was down 5.3 percent; Imricor, Imugene and Proteomics fell four percent or more; Artrya, Clarity, Mesoblast and Racura were down more than three percent; Dimerix shed 2.1 percent; Medical Developments, Micro-X, Nanosonics, Neuren and Polynovo were down one percent or more; with Clinuvel, Cochlear, Pro Medicus and Telix down by less than one percent.

SALUDA MEDICAL

Saluda says it has begun full US commercial release of its CAP24 surgical paddle lead for neurosurgery and orthopaedic spine practices.

Last year, Saluda said it had US Food and Drug Administration clearance for its Evoke spinal cord stimulation for pain relief; and this year, said it had FDA approval to market and sell its CAP24 paddle lead (BD: Dec 5, 2025; Jun 30, 2026).

Today, the company said CAP24 broad commercial availability followed completion of a successful limited market release, with physicians providing “positive feedback on the device’s performance and its integration into clinical practice”.

Saluda said CAP24 was “the first and only FDA-approved surgical paddle lead purpose-built for physiologic, dose-controlled closed-loop therapy”.

The company said that CAP24 allowed the Evoke System “to measure each patient’s unique neural response and adapt stimulation with every pulse [and] ... its low-profile, anatomically contoured design supports stable placement and broad coverage”.

Saluda chief executive officer Mike Mathias said Evoke therapy had “changed what patients and treating physicians can expect from [spinal cord stimulation]”.

“The full commercial release of CAP24 expands access to our one-of-a-kind therapy for patients who require a paddle lead,” Mr Mathias said.

Saluda was up half a cent or 1.2 percent to 42.5 cents.

ENLITIC

Enlitic says it has released its Ensign version 2.3 for its artificial intelligence (A.I.)-driven medical imaging data standardization and governance software.

Enlitic said the release added four commercial capabilities and introduced “integration with Sectra software systems, a leading provider to health systems worldwide, expanding both what Enlitic can sell to each customer and the imaging environments it can sell into”.

The company said its Ensign version 2.3 “migration and archive standardization integration [application programming interface] allows Ensign to be deployed from the start of a migration project, creating a more direct pathway from project-based migration work into potential recurring revenue”.

Enlitic said the additional workflow and analytics capability provided Ensign customers “more to adopt on the same standardized data layer, without new infrastructure”.

The company said the integration with Sectra picture archiving and communication systems “greatly expands the addressable market for Ensign by enabling healthcare organizations operating Sectra’s enterprise imaging environment to access Enlitic’s A.I.-driven standardization for data management, and migration capabilities without replacing their existing core imaging infrastructure”.

Enlitic said Sectra was a medical imaging and enterprise healthcare information technology provider, managing more than 170,000,000 imaging examinations a year.

The company said with Ensign inter-operable with both Sectra and Intelrad, it could “deploy a repeatable integration framework across two major medical imaging [original equipment manufacturer] ecosystems, reducing implementation friction and supporting faster, more scalable adoption of Ensign by healthcare providers worldwide”.

Enlitic managing-director Michael Sistenich said Ensign version 2.3 expanded “both what we can sell and where we can deploy it”.

“Moving from eight to 12 commercial applications means customers can apply the same governed data foundation to more workflows, while the new migration and ... capabilities give us additional points of entry into large health systems,” Mr Sistenich said.

Enlitic was unchanged at 3.7 cents.

LTR PHARMA

LTR says the first patient-specific Roxus prescriptions for erectile dysfunction have been filled in the US through Shed's men's health telehealth platform, Mavrox.

Previously, LTR said that it was developing Roxus, a nasal spray based on vardenafil, marketed by Bayer as Levitra, for erectile dysfunction with a "pharmaceutical partner in Australia" (BD: Mar 26, 2025).

Earlier this year, the company said Salt Lake City, Utah's Shed Holdings would distribute its intra-nasal Roxus for erectile dysfunction through direct-to-consumer telehealth in the US (BD: Jun 9, 2026).

Today, LTR said that the commercial milestone was the beginning of the Roxus prescription activity through its telehealth and pharmacy deal with Shed Holdings and Strive Pharmacy.

The company said the first prescriptions followed completion of the operational work required to support Roxus prescription fulfilment in the US.

LTR said Roxus was compounded and dispensed in the US by a licenced pharmacy under the patient-specific compounding provisions of section 503A of the US Federal Food, Drug and Cosmetic Act.

The company said Roxus was a compounded medication prepared for identified individual patient needs based on a valid prescription from a prescribing healthcare practitioner and, as such, was not reviewed or approved by the US Food and Drug Administration for safety or efficacy.

LTR executive chair Lee Rodne said fulfilment of the first Roxus prescriptions in the US was "an important milestone for LTR and our US partners".

"With our first prescriptions now received through Mavrox, we have moved from implementation to serving patients under these arrangements," Mr Rodne said.

"Our focus is now on supporting our partners as prescribing and prescription activity builds," Mr Rodne said.

"This milestone comes less than three months after we announced our agreement with Shed to establish a US telehealth route to patients," Mr Rodne said.

LTR was up half a cent or one percent to 50 cents.

DORSAVI

Dorsavi says it has "firm commitments" to raise \$3 million at 2.2 cents a share in a placement "to a restricted group of high-net-worth investors".

Dorsavi said the issue price was an eight percent discount to the 15-day volume weighted average price, a 15 percent discount to the 10-day volume weighted average price and a 12 percent discount to the last traded price.

The company said investors would receive one option for every two shares issued, exercisable at 4.5 cents each within three years.

Dorsavi said the funds raised would be used to expand its "clinical-grade human movement data library and bespoke data-capture capability, wearable sensors and video [artificial intelligence] to meet the requirements of humanoid robotics developers for balance, coordination and recovery data".

The company said the discussions with prospective robotics and defence partners had "reinforced the board's view that the value of Dorsavi's sensor business extends well beyond its established clinical, sport and workplace markets".

Dorsavi said 62 Capital was the lead manager to the placement and would receive a six percent fee as well as 24,000,000 options on the same terms as the attaching options.

Dorsavi fell 0.1 cents or four percent to 2.4 cents.

TETRATHERIX

Tetratherix says the US Food and Drug Administration has confirmed the device classification, nominated predicate device and testing data for its Tegenix 510(k) filing. Earlier this year, Tetratherix said it had an exclusive distribution and supply deal with New York's Henry Schein for its Tegenix dental bone product (BD: Jan 19, 2026).

At the time, the company said the deal provided a pathway to commercialize its first product for bone regeneration applications in 2026 and it had begun constructing an additional manufacturing facility in Sydney to support expanded production of its synthetic polymer platform products to meet expected demand.

Today, Tetratherix said it had a substantive review update from the FDA on its 510(k) submission for Tegenix and that the FDA had requested extra detail on "basic chemical characterization and final product-labelling, which is mostly administrative".

The company said "this level of [FDA] initial enquiries was expected considering the Tetramatrix platform polymer is entering the pathway as a novel material".

Tetratherix said with its partners it was "actively compiling the information on-hand for expedited submission".

Tetratherix chief executive officer Will Knox said the FDA had examined the foundations of the Tegenix submission and "there were no questions raised on the classification, the predicate and the performance data".

"Those elements carry the substance of any 510(k), and for a new material they carry the most risk," Mr Knox said. "The Tetramatrix platform polymer is being reviewed for the first time by the FDA, its questions on chemical characterization and labelling are the questions a careful regulator asks of something innovative."

Tetratherix was up 36 cents or 5.6 percent to \$6.74.

FLINDERS UNIVERSITY

Adelaide's Flinders University says it has found vanillin, or vanilla, "may provide the key to new cost-effective materials that will benefit chronic wound healing".

Flinders University said research at its Biomedical Nanoengineering Laboratory found that vanillin had "pronounced anti-oxidant, anti-inflammatory and anti-bacterial properties, making it a good candidate for wound-healing formulations".

The University said vanillin was the primary chemical component extracted from natural vanilla pods but could "also be synthetically produced from clove oil or rice".

Flinders University said apart from being a sensory additive, vanillin was "also a functional molecule, serving as a dynamic crosslinker and functional element in material design".

The University said its researchers had linked vanillin and "its chemical properties to biological activity and potential biomedical applications".

Flinders University said vanillin was a low-cost small molecule that offered "a clear advantage for industrial scale-up, formulation reproducibility, and supply chain robustness".

The University said the research, titled 'Vanillin as a bioactive component in biomedical formulations for chronic wound healing and tissue regeneration' was published in the International Journal of Pharmaceutics at: <https://pubmed.ncbi.nlm.nih.gov/42543076/>.

Flinders University's Prof Krasimir Vasilev said vanillin was "among the most widely used flavor compounds ... valued for its sensory attributes, chemical stability and long history of safety, and that can be transferred to other areas, such as medical uses".

"Owing to its amphiphilic molecular structure, vanillin can interact with reactive oxygen species, cellular membranes and polymeric matrices, providing a basis for its incorporation into functional formulations," Prof Vasilev said.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has feedback from the US Food and Drug Administration that positive results from its 'Healey' platform trial "could potentially support a traditional approval". Earlier this year, Neurizon said it had enrolled all 250 patients in the phase II/III 'Healey' platform trial of NUZ-001, formerly monepantel, for the treatment of amyotrophic lateral sclerosis (ALS) (BD: Jul 17, 2026).

Today, the company said it had written responses from the FDA to its type C meeting request for NUZ-001 and that the feedback provided "guidance on clinical development plan, potential regulatory pathways and use of biomarkers, and would inform preparation of a new drug application".

Neurizon said the FDA noted that the 'Healey' platform trial in which NUZ-001 was being evaluated was "a placebo-controlled study designed to assess clinically meaningful endpoints after 36 weeks of treatment, and that positive results could potentially support a traditional approval pathway".

The company said the FDA also noted that the 'Healey' trial served "as the single registrational study for a [new drug application], subject to meeting the requirement for substantial evidence of effectiveness, including supporting evidence alongside the study results".

Neurizon said the FDA "agreed with its approach to measuring plasma neurofilament light chain (NfL), a marker of nerve damage, and outlined the types of evidence that would be needed for NfL to support accelerated approval".

The company said the FDA noted that a strong scientific rationale would be required if the primary endpoint was not met and its regulatory strategy remained "focused on preparing a [new drug application] seeking traditional approval, with biomarker data from 'Healey', including NfL, intended to form part of the supporting evidence".

Neurizon said the FDA advised that it may resubmit a fast-track designation request considering the data available, with eligibility determined on review.

The company said it expected top-line results by July 2027.

Neurizon was up 0.3 cents or 3.6 percent to 8.7 cents with 1.85 million shares traded.

STARPHARMA HOLDINGS

Starpharma says its annual general meeting will vote to issue managing-director Cheryl Maley 961,219 performance rights.

Starpharma said the performance rights included Ms Maley's short-term incentive with a value of \$110,682 as well as a long-term incentive component valued at \$522,665.

The company said the short-term rights would vest on June 30, 2028 and the long-term incentive rights on September 30, 2029, subject to performance milestones related to product development, partnerships and finances.

Starpharma said the incentives were in addition to Ms Maley's \$614,900 yearly pay.

The company said the rights would align Ms Maley's interests with the interests of shareholders, ensure Ms Maley's remuneration was "competitive and aligned with market remuneration for comparable roles in the industry" and encouraged the achievement of the business' goals.

Starpharma said investors would vote on the remuneration report, the re-election of Robert Thomas, David McIntyre and Dr Russell Bassar as directors as well as the approval of the performance rights plan.

The meeting will be held online and at Jumar Bioincubator, Level 11, 655 Elizabeth Street, Melbourne on November 6, 2026 at 1pm (AEDT).

Starpharma was up 0.5 cents or 0.6 percent to 81.5 cents with 2.95 million shares traded.

AROA BIOSURGERY

Firstcape Group Ltd says it has reduced its substantial shareholding in Aroa from 30,421,199 shares (8.820%) to 26,825,670 shares (7.755%).

Wellington, New Zealand's Firstcape said that with Harbour Asset Management, BNZ Investments and Jarden Wealth, between August 29, 2024 and August 28, 2026 it sold 10,634,025 shares for \$6,617,459, or 62.2 cents a share, sold 7,009,996 shares for \$4,267,313, or 60.9 cents a share and transferred 28,500 shares for no consideration. Aroa was up half a cent or one percent to 50 cents.

CERYVYN THERAPEUTICS (FORMERLY OPTHEA)

Jagen Nominees Pty Ltd says it has increased its substantial shareholding in Ceryvyn from 147,205,459 shares (10.76%) to 170,358,334 shares (12.45%).

Melbourne's Jagen said that the shares were held by BHL Pension Fund Pty Ltd acting for the B Liberman Family and Boliber Pty Ltd.

In 2018, Jagen said it was an investment vehicle for Bori Liberman (BD: Dec 4, 2018).

Today, Jagen said that on October 2 and 5, 2026 it acquired 23,152,875 shares for \$223,975, or 1.0 cent a share.

Ceryvyn was unchanged at 1.2 cents with 9.5 million shares traded.