

Biotech Daily

Wednesday September 10, 2025

Daily news on ASX-listed biotechnology companies

- * ASX UP, BIOTECH EVEN: IMUGENE UP 9%; BOTANIX DOWN 18.5%
- * PACIFIC EDGE: US CXBLADDER TRIAGE PLUS \$2k REIMBURSEMENT
- * DORSAVI, SELECT MEDICAL 5-YEAR US DISTRIBUTION DEAL
- * FIREBRICK RECEIVES \$250k FEDERAL R&D TAX INCENTIVE
- * 'MARITAL ASSETS DIVISION' GIVES JESSIMINE JANSEN 7.6% OF VITURA
- * EX-VITURA DIRECTOR GUY HEADLY REDUCES TO 8%
- * BIO-MELBOURNE 'WOMEN IN LEADERSHIP' NEXT WEDNESDAY
- * AUSBIOTECH CONFERENCE 'EARLY BIRD' TICKETS CLOSE FRIDAY

MARKET REPORT

The Australian stock market was up 0.31 percent on Wednesday September 10, 2025, with the ASX200 up 26.9 points to 8,830.4 points. Seventeen of the Biotech Daily Top 40 companies were up, 16 fell, six traded unchanged and one was untraded.

Imugene was the best, up 2.5 cents or 9.3 percent to 29.5 cents, with 4.7 million shares traded.

Clarity and Emvision climbed more than seven percent; Genetic Signatures was up 5.7 percent; Micro-X and Telix improved more than four percent, Curvebeam, Mesoblast, Nova Eye and Prescient were up more than three percent; Aroa and Immutep rose more than two percent; Optiscan and Polynovo were up more than one percent; with Clinuvel, Cochlear, CSL, Nanosonics, Orthocell and Resmed up by less than one percent.

Botanix led the falls, down 2.5 cents or 18.5 percent to 11 cents, with 70.8 million shares traded.

Medadvisor lost 10.2 percent; Imricor retreated 9.4 percent; Amplia was down 6.1 percent; 4D Medical and Impedimed were down five percent or more; Starpharma fell four percent; Actinogen and Dimerix were down more than three percent; EBR shed 2.6 percent; Avita, Medical Developments, Paradigm and SDI were down more than one percent; with Cyclopharm, Neuren and Pro Medicus down by less than one percent.

PACIFIC EDGE

Pacific Edge says the US Centers for Medicare and Medicaid Services have proposed a \$US1,328.32 (\$A2,013) 'Gapfill' reimbursement price for Cxbladder Triage Plus. In April, Pacific Edge said the US Centers for Medicare and Medicaid Services (CMS) have proposed a draft 'gap-fill' price for Cxbladder of \$US1,018, following local coverage determination changes by its Medicare administrative contractor Novitas halting US Medicare coverage of its Cxbladder urine test, which became effective on April 24, 2025 (BD: Apr 28, 29, 2025).

At the time, the company said that Novitas priced Triage Plus at \$US1,588 and due to its agreements with multiple contractors, the price provided by Palmetto was the de facto median price, because Palmetto's pricing was used in 28 of the 50 US states.

Today, Pacific Edge said it was preparing to submit a reconsideration request for Triage Plus once its 'Drive' study results were published after peer review.

The company said the \$US1,328 price was a "meaningful increase" compared to the \$US760 CMS price of its existing test and the \$US1,018 draft price proposed in April. Pacific Edge said the final price was subject to 60 days' notice and comment but was not expected to change, and expected to become effective from January 1, 2026. Pacific Edge chief executive officer Dr Peter Meintjes said the company was "very pleased".

that [US Molecular Diagnostic Services Program] has recognized the novelty of Triage Plus in their pricing determination with an increase to \$US1,328 and that CMS has recommended this as a final price".

"We have invested significant resources in Triage Plus ... a multimodal test that combines DNA and RNA workflows with the outputs analyzed by a novel algorithm that provides dramatic performance improvement over existing tests and can be used on a broader patient population to assist clinicians to manage their haematuria patients as high, intermediate or low risk," Dr Meintjes said.

"The resources needed to develop, validate and operate Triage Plus commercially are substantial, thus necessitating a higher price, but importantly when Triage Plus' performance characteristics are used in our existing budget impact model, we observe that the improved performance characteristics has the potential for even greater savings to the Medicare system by reducing more unnecessary procedures and allowing clinicians to spend more time and clinical resources on those who need it most," Dr Meintjes said. Pacific Edge was up half a cent or 3.85 percent to 13.5 cents.

DORSAVI

Dorsavi says Select Medical will sell its US Food and Drug Administration-approved bodyworn motion analysis products at more than 1,900 shops, in a five-year agreement. Dorsavi said it had worked with the Mechanicsburg, Pennsylvania-based Select Medical for 18 months in a development pilot program to "ensure the technology met therapists' needs" including collecting data to assist in the rehabilitation of injured athletes and "return to play" assessments.

The company said its products would be available to buy at Select Medical outpatient physical therapy centres this month.

Dorsavi chief executive officer Andrew Ronchi said "we are delighted to have this opportunity to work with Select Medical".

"They are one of the largest providers of outpatient rehabilitation clinics in the US, and we are thrilled that our technology will have an opportunity to play a pivotal role in patient assessment and rehabilitation," Mr Ronchi said.

Dorsavi was up half a cent or 11.1 percent to five cents with 52.9 million shares traded.

FIREBRICK PHARMA

Firebrick says it has received \$250,000 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program. Firebrick said the incentive related to expenditure for the year to June 30, 2025. Firebrick fell 0.1 cents or 1.4 percent to seven cents.

VITURA HEALTH

Jessimine Charles Kiritea Jansen says she has become a substantial shareholder in Vitura with 50,101,072 shares or 7.57 percent of the company.

The Gold Coast, Queensland-based Ms Jansen said that on June 6, 2025 she acquired 42,575 shares for \$2,910 or 6.8 cents a share, and on September 8, 2025 acquired 45,447,693 shares for no consideration as part of a "financial separation agreement". A substantial shareholder notice signed by Ms Jansen said that former Vitura director "Guy Rothwell Headley was considered an associate due to our marital relationship at the time of the financial separation" and the 45.5 million shares were acquired "as part of the division of assets following the separation, and we are now legally separated with no ongoing association for the purposes of this disclosure". Vitura was unchanged at 6.7 cents.

VITURA (FORMERLY CRONOS AUSTRALIA)

Former Vitura director Guy Headley says he has reduced his holding from 100,202,157 shares (15.26%) to 50,101,079 shares (7.57%).

The Gold Coast, Queensland-based Mr Headley said that on February 25, 2025 he was diluted by the issuing of shares to Code4 Cannabis for the acquisition of Canview, and on September 9, 2025 transferred 45,447,693 shares off-market "due to financial agreement" (see above).

Last year, Vitura said it would pay Code4 Cannabis \$2.5 million and 5,787,037 shares, worth about \$500,000, for a copy of the Canview platform (BD: Oct 24, 2024).

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says its Women in Leadership awards launch will be held at its Bioforum, next Wednesday, September 17, 2025.

The Network said the 'Leading through uncertainty' forum was supported by the Victoria Government and would "feature a panel of some past awardees and sector leaders". The Network said the panel would discuss "how vision, passion, courage, collaboration and diverse experience translate into moving the health technologies sector, including driving investment, manufacturing strength and global patient impact further".

The Bio-Melbourne Network said the panel would be chaired by Allens partner Caroline Ryan and include Ego Pharmaceuticals head of scientific and operations Dr Jane Oppenheim, WEHI head of business development Dr Anne-Laure Puaux and Medicines Development for Global Health head of regulatory Dr Danielle Smith.

The Network said it was the eleventh year of the Women in Leadership awards, which "honor, celebrate and recognize women who lead in their fields, have made outstanding contributions to advancing the sector, ... take strategic risks and drive innovation". The Network said Bioforum tickets were \$95 for members and \$195 for non-members, with online tickets available at \$25 for members and \$45 for non-members. For more information and Bioforum tickets go to: https://tinyurl.com/mt4b3d85.

AUSBIOTECH

Ausbiotech says discounted early bird tickets to its 2025 conference in Melbourne from October 21 to 24, 2025, will close on September 12.

Last month, Ausbiotech said its 2025 conference would include more than 250 speakers in more than 60 sessions "exploring the issues and innovations shaping the future of biotech, both here in Australia and around the world", and 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 (BD: Aug 20, 2025). Registration and ticket prices are available at: https://ausbiotechic.com/register/.