Biotech Daily

Tuesday September 16, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 28.5%; IMPEDIMED DOWN 8%**

*** CSL $758m OPTION FOR VARMX BLOOD COAGULATION**

*** ATMO 1st US GAS CAPSULE SALES**

*** ORTHOCELL REMPLIR FOR PROSTATE COMPLICATIONS**

*** RACE BISANTRENE PHOTO-ISOMER COMPOSITION PATENTS**

*** NYRADA: XOLATRYP MITOCHONDRIAL STABILIZATION, IN RATS**

*** NEXT SCIENCE COMPLETES OSARTIS $75m ASSET SALE**

*** NEURIZON REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ZELIRA TAKES M-D, DIRECTOR $225k LOAN**

*** WILLIAM GUECK TAKES 5% OF MESOBLAST**

*** GAIASO APPOINTS DR TRACEY BROWN CEO**

MARKET REPORT

The Australian stock market was up 0.28 percent on Tuesday September 16, 2025, with the ASX200 up 24.7 points to 8,877.7 points. Sixteen of the Biotech Daily Top 40 companies were up, 13 fell, 10 traded unchanged and one was untraded.

Avita was the best, up 42 cents or 28.5 percent to $1.895, with 4.9 million shares traded. Actinogen climbed 14.3 percent; Imugene improved 13.3 percent, Orthocell was up 7.3 percent; Clarity climbed 6.8 percent; Medical Developments rose five percent; Clinuvel and Polynovo were up more than four percent; Prescient and Pro Medicus rose more than two percent; Compumedics, Nanosonics, Neuren and Paradigm were up one percent or more; with Mesoblast, Resmed, SDI and Telix up by less than one percent.

Impedimed led the falls, down 0.3 cents or 7.7 percent to 3.6 cents, with 1.3 million shares traded. Cyclopharm and Medadvisor lost more than six percent; Atomo and Genetic Signatures fell more than four percent; Amplia and Immutep shed more than three percent; 4D Medical lost two percent; CSL, Dimerix, Nova Eye and Proteomics were down more than one percent; with Aroa, Cochlear and Imricor down by less than one percent.

CSL

CSL says it will pay up-to $US505 million ($A757.6 million) to buy the Leiden, Netherlands' Varmx BV and develop its blood coagulation treatment VMX-C001.

CSL said Varmx had developed VMX-C001, a potential "first-in-class recombinant Factor-X protein, administered as a rapid single-dose, intended to bypass FXa anti-coagulation activity and restore coagulation in patients experiencing severe bleeding or requiring urgent surgery".

The company said that it would make an upfront payment of $US117 million for the exclusive option to acquire the company, which it could exercise on receipt of phase III trial data, and that after that and certain milestones and regulatory clearances being met, it would pay $US388 million up to the launch of VMX-C001, plus further commercial milestones later.

CSL said it would fund Varmx's phase III trial evaluating VMX-C001 in patients taking FXa inhibitors, and would support late-stage product development, manufacturing and pre-launch commercial and medical affairs activities.

The company said more than 20 million patients worldwide take FXa inhibitors as a chronic anti-coagulation therapy, with about three percent of these patients experiencing severe bleeding or requiring urgent surgery.

CSL chief executive officer Dr Paul McKenzie said "CSL has a long history of working in haematology and bleeding disorders and partnering with Varmx strengthens our strategic ambition to deliver enduring patient impact".

"This new treatment will potentially address a clear and significant unmet medical need in a well-defined and growing patient population," Dr McKenzie said.

"It also fits with our strategy of seeking more external partners to help accelerate our clinical and commercial pipeline through investments in validated, clinical-stage opportunities," Dr McKenzie said.

"The pre-clinical and early clinical data are also very encouraging and led to the US Food and Drug Administration (FDA) granting fast track designation, recognizing VMX-C001's potential to address a critical unmet medical need," Dr McKenzie said.

CSL fell $2.57 or 1.3 percent to $201.91 with 1.1 million shares traded.

ATMO BIOSCIENCES

Atmo says its gas capsule system is reimbursed and available in the US, with early adoption at "leading gastroenterology centers" and successful initial patient ingestions.

In June, the Melbourne-based Atmo said it had US Food and Drug Administration 510(k) clearance to market and sell its ingestible, gas-sensing capsule for diagnosing gut motility disorders (BD: Jun 27, 2025).

Today, Atmo said the US launch of the capsule was a major milestone for its commercialization efforts that built on its mission to "improve outcomes for millions of people suffering from chronic and debilitating gastrointestinal conditions by offering a test that is accurate, patient-friendly, and clinically valuable".

Atmo chief executive officer Mal Hebblewhite said "we are delighted to see early validation of the Atmo Gas Capsule System in the US, with physicians recognizing the benefits it delivers in assessing motility disorders".

Mr Hebblewhite told Biotech Daily that Atmo had the common procedural terminology (CPT) code that had originally been available to the Medtronic predicate device, which was no longer available, with the US Centres for Medicare and Medicaid reimbursement set at $US1,477 ($A2,215) per procedure.

Atmo is a public-unlisted company.

ORTHOCELL

Orthocell says Australian urologists have used its Rempir nerve repair device to reduce post-surgical complications in nerve-sparing, robot-assisted radical prostatectomies.
Orthocell said Remplir had been used in about 40 surgical cases to help improve recovery of erectile function and urinary continence post-prostate cancer surgery.
The company said that up to 80 percent of men had erectile disfunction and up to 35 percent had urinary incontinence after radical prostatectomy due to peripheral nerve damage in the neurovascular bundle surround the prostate.
Orthocell said it was collating clinical data on the initial patients who underwent the surgeries and would release clinical data once available, and would also invest in further studies to build evidence and assist medical education initiatives to drive further adoption of Remplir in this market.
Orthocell chief executive officer Paul Anderson said “the use of Remplir in nerve-sparing robotic-assisted radical prostatectomy highlights the product’s versatility and superior performance in the protection and reconstruction of damaged peripheral nerves”.
“Surgeons across multiple specialties - including orthopaedics, plastic and reconstructive surgery, and now urology - are increasingly adopting Remplir to simplify procedures, minimize scarring, and improve functional recovery,” Mr Anderson said.
“This represents a significant step forward in Remplir’s organic expansion into broader peripheral nerve repair applications and has the potential to substantially increase the device’s global total addressable market,” Mr Anderson said.
Orthocell was up eight cents or 7.3 percent to $1.18 with 1.6 million shares traded.

RACE ONCOLOGY

Race says it has submitted three patent applications following its discovery of three photo-isomers with biological and anti-cancer activities in its bisantrene.
Race said the bisantrene isomers were generated during chemical synthesis, or by exposure to visible light and heat, with only one, named E,E-bisantrene or RCDS1, having “significant anti-cancer activity”.
The company said it filed patent applications covering the chemical structure, manufacture, formulation, storage and uses of the anticancer-related isomer, which would protect its intellectual property until 2045.
In 2021, Race said the US Patent and Trademarks Office had granted its sixth US patent for Zantrene, or bisantrene dihydrochloride, for cancer (BD: Oct 19, 2021).
Today, the company said composition of matter patents were “the most valuable form of intellectual property in the pharmaceutical industry” and offered the strongest protection for new drugs because they protected the chemical structure of the active pharmaceutical ingredient in the product.
Race chief executive officer Dr Daniel Tillett said “being able to generate new composition of matter [intellectual property] covering the active isomer of bisantrene fundamentally changes the commercial prospects of Race Oncology”.
“We now expect to have 20 years of the strongest [intellectual property] protection possible for the RC220 and RC110 formulations containing E,E-bisantrene,” Dr Tillett said.
“These discoveries highlight the commercial value of undertaking new preclinical research on clinically established pharmaceutical assets,” Dr Tillett said.
“I congratulate the entire Race preclinical team for their inspiration and extraordinary efforts in making this fundamental discovery and turning science into a valuable outcome for all our investors,” Dr Tillett said.
Race was up 50 cents or 27.8 percent to $2.30 with 1.4 million shares traded.

NYRADA INC

Nyrada says further analysis of its Xolatryp (NYR-BI03) traumatic brain injury study has confirmed it reduced mitochondrial calcium ion loading in the brain of rats.

In April, Nyrada said NYR-BI03 showed a “statistically significant level of neuroprotection” for models of penetrating traumatic brain injury ($p = 0.043$) in rats (BD: Apr 7, 2025).

At the time, the company said the study with the US Walter Reed Army Institute of Research and Sydney’s University of New South Wales included 28 test animals and was designed to “replicate the severe head injuries commonly sustained by military personnel”.

Today, Nyrada said the results provided “further pre-clinical evidence of Xolatryp’s mechanism of action in mitigating secondary brain injury”, showing that the drug helped preserve mitochondrial health by improving calcium handling, which protected the brain’s energy centres from reactive oxygen species-related damage.

The company said reactive oxygen species damage and calcium-drive mitochondrial damage occurred in both brain injury and myocardial ischemia reperfusion injury, giving Nyrada “increased confidence of Xolatryp’s benefits in treating myocardial ischemia reperfusion injury”.

Nyrada said the study results showed that mitochondria from Xolatryp-treated animals showed a “significant improvement” in calcium ion buffering ability compared to control, with an overall 11 percent improvement in mitochondrial function ($p = 0.035$ at 450 to 550 seconds, $p = 0.046$ at 550 to 650 seconds) in 10 rodents.

The company said the results supported its previous stroke and brain injury findings where treatment significantly preserved brain tissue compared to control.

Nyrada chief executive officer James Bonnar said that with “strong cardio-protection efficacy previously shown in a rodent [myocardial ischemia reperfusion injury] model, our focus is on translating this mechanism into patient benefit … [and the] mitochondrial data demonstrates a significant reduction in [calcium ion] loading, providing a coherent rationale for Xolatryp as a first-in-class adjunct at the point of reperfusion”.

Nyrada was up four cents or 16 percent to 29 cents with 3.1 million shares traded.

NEXT SCIENCE

Next Science says it has completed the sale of its assets, as well as those of its subsidiaries, to Munster, Germany’s Osartis GmbH for $US50 million ($A75 million).

Earlier this year, Next Science said it had an asset purchase agreement to sell “substantially all” of its assets and subsidiaries for $US50 million ($A76 million) to Milan, Italy’s Demetra Holding SpA (BD: Jul 1, 2025).

Later, the company said Demetra had assigned its acquisition of the company to its portfolio company Osartis GmbH, subject to shareholder approval (BD: Aug 19, 2025).

Today, Next Science said it had transitional agreements to provide services until December 31, 2025 and would convene a shareholder meeting to seek approval of the proposed method for the distribution of the net sale proceeds, with a notice of meeting expected to be dispatched in November 2025.

Next Science was unchanged at 14.5 cents with 1.5 million shares traded.

NEURIZON THERAPEUTICS

Neurizon has requested a trading halt pending an announcement regarding “the outcome of a proposed capital raising”.

Trading will resume on September 18, 2025 or on an earlier announcement.

Neurizon last traded at 14 cents.

ZELIRA THERAPEUTICS

Zelira says managing director Dr Oludare Odumosu and non-executive director Dr Donna O'Donnell will lend it $US150,000 ($A224,800) at 20 percent annual interest.
Zelira said Dr Odumosu would provide $US100,000 while Dr O'Donnell would provide $US50,000 through two loan notes, which would become convertible loan notes with a conversion price of the higher of 25.85 US cents and the 15-day volume weighted average price, prior to converting the note, subject to shareholder approval.
The company said the loan had a termination fee of 10 percent and a maturity date of September 16, 2026, with funds to be used for general working capital.
In July, Zelira said it had a $650,000 loan from London's Rocking Horse Capital Finance Co against its expected Federal Government Research and Development Tax Incentive, at 17 percent interest a year (BD: Jul 24, 2025).
Zelira was untraded at 38 cents.

MESOBLAST

The St Louis, Missouri-based William Gueck says he has become a substantial shareholder in Mesoblast with 64,171,900 shares or 5.01 percent of the company.
Earlier this month, Mesoblast said it had an up-to $US50 million ($A74.9 million) convertible note subscription option with Surgcenter's Gregory George and William Gueck (BD: Sep 4, 2025).
At the time, the company said Mr George and Mr Gueck were principals in the Baltimore, Maryland-based Surgcenter and Mesoblast investors, and would receive a commitment fee of $US100,000 and two million warrants over two million shares, or 200,000 Mesoblast American depositary receipts (ADRs), for entering in the convertible note option, and a further three million warrants should Mesoblast exercise the option.
Mesoblast was up two cents or 0.9 percent to $2.34 with 3.6 million shares traded.

GAIASO THERANOSTICS

Gaiaso says it has appointed Dr Tracey Brown as its chief executive officer.
Gaiaso said that Dr Brown was recognized "for transforming breakthrough science into real-world products, with a track record of clear strategy, collaborative leadership, and disciplined execution in resource-constrained, high-growth settings".
The company said that Dr Brown had "extensive international experience across oncology and radio-pharmaceutical development" and was previously employed by Telix, Anatara and Alchemia.
Gaiaso said Dr Brown co-founded Meditech Research, invented the Hyact oncology drug-delivery platform and built a substantial patent estate while leading the portfolio strategy.
The company said that Dr Brown began her career at Monash University, where she led the Hyaluronan Laboratory and held research and adjunct appointments.
According to her Linkedin page, Dr Brown held a Bachelor of Science from the Royal Melbourne Institute of Technology and a Doctor of Philosophy from Monash University.
Gaiaso is a private company.