



Biotech Daily

Tuesday September 15, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: CURVEBEAM, LUMOS UP 10%
- MICRO-X DOWN 17%**
- * **CURVEBEAM: FDA CLEARS BONE MINERAL DENSITY CT; HIRISE NEXT**
- * **FEDERAL RDTI, CGT CONSULTATION OPENS; AUSBIOTECH WEBINAR**
- * **AMPLIA, ANZGOG AMP945 OVARIAN CANCER TRIAL PROTOCOL**
- * **MAYNE LICENCES BLISSEL MENOPAUSE HORMONE THERAPY**
- * **LUMOS PROGRESSES FEBRIDX US COMMERCIALIZATION**
- * **EBR: US FDA STARTS PRE-APPROVAL INSPECTION**
- * **ANATARA RECEIVES \$318k FEDERAL R&D TAX INCENTIVE**
- * **HERAMED REQUESTS 'COMMERCIAL DEPLOYMENT' TRADING HALT**
- * **EPSILON, HELIX, PURO TO MAKE MARIJUANA NANO-EMULSION**
- * **REGAL FUNDS TAKES 14% OF ONCOSIL**
- * **DR DANIEL FURTNER REPLACES PARADIGM CMO DR DONNA SKERRETT**

MARKET REPORT

The Australian stock market fell 0.88 percent on Tuesday September 15, 2026, with the ASX200 down 77.4 points to 8672.5 points. Sixteen of the Biotech Daily Top 40 companies were up, 14 fell, nine traded unchanged and one was untraded.

Curvebeam and Lumos were the best, both up 10.0 percent to 2.2 cents and 11 cents, respectively, with 15.8 million and five million shares traded, respectively. 4D Medical and Telix climbed more than eight percent; both Paradigm and Syntara improved 4.2 percent; Avita was up 3.7 percent; Clarity, Emvision and Resmed rose more than two percent; Artrya, CSL, Nanosonics and Prescient were up more than one percent; with Aroa, Clinuvel, Neuren, Pro Medicus and Starpharma up by less than one percent.

Micro-X led the falls, down 0.3 cents or 16.7 percent to 1.5 cents, with 3.6 million shares traded. Imugene lost 11.3 percent; Optiscan fell 9.4 percent; Cyclopharm was down 7.4 percent; Actinogen and EBR lost five percent or more; Immutep fell four percent; Nova Eye, Proteomics and Saluda were down more than three percent; Dimerix and Mesoblast shed more than two percent; Orthocell fell 1.4 percent; with Cochlear and Imricor down by less than one percent.

CURVEBEAM AI

Curvebeam says the US Food and Drug Administration has given 510(k) clearance for its supine computed tomography (CT) technology for bone mineral density.

Curvebeam managing-director Greg Brown told Biotech Daily that doctors ordered a bone mineral density scan “to determine whether a patient has low bone density and is at increased risk of osteoporosis and fractures”.

“For a total joint replacement patient, understanding the quality of the bone into which the implant will be placed is also important,” Mr Brown said.

“It can help inform decisions such as whether to cement the joint and which implant to select,” Mr Brown said.

Mr Brown said radiologists used a dual energy x-ray (DXA) to measure how much mineral is in a patient’s bones, primarily to assess bone strength and fracture risk, which takes about 15 to 20 minutes process, but in the US it could “involve substantial waiting times”. In 2023, Curvebeam said its Hirise CT scanner could perform weight bearing CT scans, with the patient standing in a normal, weight bearing pose (BD: Aug 1, 2023).

Today, the company said that the FDA clearance established a foundation for broader bone mineral density software as a service and it would pursue FDA clearance to extend the technology to Hirise measurement of bone mineral density.

Curvebeam said the clearance was “an important regulatory milestone ... [in its] strategy to expand its advanced CT imaging capabilities into quantitative bone-health assessment, and over time develop a broader CT-based platform that can deliver anatomical, alignment and bone-quality information from a single examination”.

The company said the Hirise was “designed to provide weight bearing CT imaging of the lower extremity, providing the potential to combine assessment of the patient’s anatomy, alignment and bone quality within a single standing examination”.

Curvebeam said assessing bone mineral density using a standing CT examination “could provide an important additional clinical capability for orthopaedic applications, particularly where understanding bone quality ... is relevant to clinical decision-making”.

“Importantly, integrating [bone mineral density] into the CT examination has the potential to provide surgeons with additional quantitative information without requiring the patient to undergo a separate imaging examination,” the company said.

“This could support a more efficient practice workflow, with relevant anatomical and bone-health information available from the same imaging pathway used for orthopaedic assessment and surgical planning,” Curvebeam said.

Mr Brown said the FDA clearance was “a significant milestone for Curvebeam AI, being our first clearance of the two necessary steps to take our [software as a service] based bone health products to market”.

“Achieving our first FDA 510(k) clearance for CT-based [bone mineral density] establishes an important regulatory foundation for the company and demonstrates our ability to bring quantitative bone health capabilities through the FDA pathway,” Mr Brown said.

“Our next objective is to take this capability to the Hirise platform and pursue clearance for weight bearing CT [bone mineral density],” Mr Brown said. “This is particularly exciting because it aligns quantitative bone health assessment with the weight bearing imaging environment that is central to the Hirise proposition.”

Curvebeam said a study of more than 10,000 dual energy x-ray (DXA) examinations found the mean time from initial order to completion “increased from 79.1 days before the Covid-19 pandemic to 88.8 days during the pandemic, highlighting the potential for delays in access to conventional bone density assessment [and evidencing] the potential value of integrating [bone mineral density] assessment into existing CT imaging pathways”.

Curvebeam was up 0.2 cents or 10 percent to 2.2 cents with 15.8 million shares traded.

FEDERAL GOVERNMENT, AUSBIOTECH

The Federal Government has begun consultations on Research and Development Tax Incentive (RDTI) and Capital Gains Tax (CGT), with Ausbiotech holding a webinar. According to the Federal Treasury website, consultations on both matters opened on Friday September 11, 2026 and will close on Monday, September 28, 2026.

The Federal Government said one change to the announced legislation was that the Federal Research and Development Tax Incentive had “an extension for up to 15 years for eligible firms undertaking R&D activities related to therapeutic goods” from the previous 10 years (BD: May 13, Jun 9, 2026).

For more information go to: <https://consult.treasury.gov.au/c2026-792804> for the RDTI, and <https://consult.treasury.gov.au/c2026-801619> for the CGT.

Ausbiotech said that its members were “invited to attend a special member webinar to learn more about and discuss recently released draft legislation for changes to the Research and Development Tax Incentive (RDTI) and Innovative Business Capital Gains Tax Concession (IBCC).”

Ausbiotech said that the one-hour webinar would be held on September 17, 2026 at 11.30am (AEST) with registration at: <https://bit.ly/4r9eONW>.

AMPLIA THERAPEUTICS

Amplia says its 26-patient, phase II, Prrose trial will investigate narmafotinib with standard of care chemotherapy for advanced ovarian cancer.

Amplia said the clinical trial protocol had been finalized with the Australia New Zealand Gynaecological Oncology Group (Anzgog).

The company said that Australia and New Zealand ethics and site governance approvals would be submitted with the goal of opening trial sites by the end of 2026.

Amplia said it was “an important milestone toward study commencement”.

The company said the trial will explore the combination of its focal kinase (FAK) inhibitor narmafotinib, or AMP945, with standard-of-care chemotherapy, in women with high-grade serous ovarian cancer.

Amplia said the study would “focus on patients whose tumors demonstrate a poor response to chemotherapy prior to planned interval debulking surgery, a group with a significant unmet medical need”.

The company said that the study would be led by Monash Health’s Dr Gwo Yaw Ho and will be sponsored and coordinated by Anzgog.

Amplia managing-director Dr Chris Burns said it was “an important study for a patient population who currently have limited treatment options”.

Amplia was unchanged at 12 cents.

MAYNE PHARMA

Mayne has an exclusive five-year licence with Italfarmaco SA for the Australian rights to the menopause hormone therapy Blissel 50µg/g.

Mayne said that Blissel was an “ultra-low-dose estriol vaginal gel for the treatment of vaginal atrophy in post-menopausal women”.

The company said that Blissel complemented Nextstellis in its women's health portfolio. Mayne fell three cents or 1.0 percent to \$3.03.

LUMOS DIAGNOSTICS

Lumos says it is progressing US commercialization of its Febridx test to differentiate bacterial from viral respiratory infections at its top 100 urgent care groups target list. Earlier this year, Lumos said the FDA had granted a Clinical Laboratory Improvement Amendments (CLIA) waiver for Febridx finger-prick blood-test (BD: Mar 27, 2026). Today, the company said it was using a four-stage commercial framework to help track and communicate how accounts were advancing.

Lumos said that since its July updates, two additional unnamed top 100 US urgent care groups, committed to rolling out Febridx at more than 40 sites.

The company said that the two accounts comprised a large, integrated regional health system and a leading academic medical centre and health system.

Lumos chief executive officer Doug Ward said that "securing two further top 100 urgent care groups, both backed by major US health systems, is a clear signal that Febridx is earning a place in frontline respiratory care".

"Febridx is now deployed across 215 live sites, including 44 Wellstreet sites, with a further 405 sites in the evaluation stage," Mr Ward said.

"Just as importantly, they are following the same path we established with Wellstreet: pilot, validate, then expand," Mr Ward said.

Lumos was up one cent or 10 percent to 11 cents with five million shares traded.

EBR Systems

EBR says the US Food and Drug Administration has begun its pre-approval inspection of the manufacturing facility for its wireless cardiac pacing device for heart failure.

EBR said the inspection was at its factory in Santa Clara, California, which was "a key regulatory milestone" and it expected FDA approval by the end of the year.

EBR fell 1.5 cents or 5.8 percent to 24.5 cents with 1.8 million shares traded.

ANATARA LIFESCIENCES

Anatara says it has received \$318,402 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anatara said the incentive related to research and development expenditure for the year to June 30, 2026.

Anatara was untraded at 0.8 cents.

HERAMED

Heramed has requested a trading halt "pending an announcement ... regarding a material commercial deployment".

Trading will resume on September 17, 2026 or on an earlier announcement.

Heramed last traded at 3.3 cents.

EPSILON HEALTHCARE

Epsilon says with Helix Research Australia and Puro New Zealand it will establish an integrated, cannabinoid medicine development and manufacturing platform.

Epsilon said the group would cultivate, characterize, formulate, manufacture and develop the 'nano-emulsion' at its Southport, Queensland facility.

Epsilon was unchanged at 2.5 cents.

ONCOSIL MEDICAL

Sydney's Regal Partners Funds Management says it has increased its substantial holding in Oncosil from 2,858,562 shares (9.25%) to 5,070,702 shares (13.82%).

Regal said it sold shares from August 20, to September 10, 2026 and on September 10 bought 4,000,000 shares for \$4,000,000 or \$1.00 a share.

Last year, Oncosil said it completed its 400-to-one consolidation (BD: Jun 6, 2025).

Oncosil was up five cents or 5.1 percent to \$1.03.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed Dr Daniel Furtner as chief medical officer, replacing Dr Donna Skerrett, who continues as senior scientific advisor, effective September 16, 2026.

Paradigm said Dr Furtner had more than 20 years of experience in life sciences and healthcare, specializing in medical affairs, rheumatology, immunology and joint diseases. The company said that Dr Furtner was previously CSL's senior director of medical affairs for the Asia Pacific and had worked for Abbott/Abbvie and Janssen in Europe, Asia and Australia.

Paradigm said that Dr Furtner has led clinical studies and educational programs supporting patients, caregivers and nurses, with a focus on advancing rheumatology care in the Asia Pacific region.

The company said that Dr Furtner held a Doctor of Medicine from the Medical University of Vienna and a Master of Business Administration from Danube Business School in Krems, Austria.

Paradigm said that Dr Skerrett had been its chief medical officer since September 2019 and had "played a central role in the company's clinical and regulatory development".

The company said the Dr Skerrett had been "instrumental in the execution of the global phase III ... trial, which completed recruitment with 538 participants across the US, Australia, Hong Kong and Moldova".

Paradigm executive chair Paul Rennie said: "On behalf of the board and the entire Paradigm team, I would like to thank Donna for her outstanding contribution as chief medical officer".

"Since joining Paradigm in 2019, Donna has helped shape our clinical development strategy and has led our clinical team with an unwavering commitment to scientific rigor, patient safety and data quality," Mr Rennie said.

Paradigm was up one cent or 4.2 percent to 25 cents with 2.6 million shares traded.