



Biotech Daily

Monday September 28, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: PROTEOMICS UP 9%; MICRO-X DOWN 9%**
- * **ENLITIC \$1.15m MICHIGAN UNI IMAGING MIGRATION CONTRACT**
- * **MICRO-X \$1m US BAGGAGE SCANNER EXTENSION**
- * **EBR FDA INSPECTS SANTA CLARA FACTORY, APPROVAL THIS YEAR**
- * **MAYNE PAYS \$926k US CIVIL COMPLAINT SETTLEMENT**
- * **EMVISION RECEIVES \$4.3m FEDERAL R&D TAX INCENTIVE**
- * **PARADIGM REQUESTS 'DATA, FINANCES' SUSPENSION EXTENSION**
- * **MERCER TAKES 5% OF GENETIC SIGNATURES**

MARKET REPORT

The Australian stock market was up 0.17 percent on Monday September 28, 2026, with the ASX200 up 14.7 points to 8,679.7 points.

Eight of the Biotech Daily Top 40 companies were up, 23 fell, seven traded unchanged and two were untraded. All four Big Caps were up.

Proteomics was the best, up one cent or 8.7 percent to 12.5 cents, with 81,913 shares traded. Dimerix climbed 4.4 percent; Cochlear, CSL, Cyclopharm and Prescient rose two percent or more; Clinuvel, Resonance and Telix were up more than one percent; with Orthocell, Pro Medicus and Resmed up by less than one percent.

Micro-X led the falls, down 0.4 cents or 8.9 percent to 4.1 cents, with 2.8 million shares traded.

Artrya and Imugene lost more than six percent; Immutep, Imricor, Mesoblast and Racura were down more than five percent; Curvebeam and Lumos fell more than four percent; Clarity, Nova Eye and Optiscan were down more than three percent; Aroa, EBR, Emission, Neuren, Polynovo and Starpharma shed two percent or more; Actinogen, Medical Developments and Nanosonics were down one percent or more; with 4D Medical and Avita down by less than one percent.

ENLITIC

Enlitic says it has an \$US806,000 (\$A1,150,000) contract with University of Michigan Health-Sparrow for the migration of radiology and cardiology imaging studies.

Enlitic said the contract was its sixth imaging data migration project with University of Michigan Health and was expected to be completed within 12 months.

The company said the project included standardization of the University's historical imaging archive using its technology "within a large-scale healthcare data migration".

Enlitic said the project was the first use of its standardization and associated reporting in the University's "Sectra-based imaging environment, marking the first customer application of Ensignt alongside one of the world's leading enterprise imaging platforms".

According to Sectra's website, the Linköping, Sweden-based company provided medical imaging information technology and cybersecurity systems, managing more than 170,000,000 imaging examinations a year.

The company said the contract was "another significant example of a leading US healthcare provider using Ensignt to standardize imaging data as part of a major migration".

Enlitic said imaging data migration was "an important revenue channel for Enlitic and provide potential opportunities to expand the use of Ensignt across large healthcare organizations".

Enlitic managing-director Michael Sistenich said the contract showed "the commercial momentum we are building and the increasing opportunity to combine our migration and Ensignt capabilities".

"Importantly, it also marks our first active integration with a Sectra customer," Mr Sistenich said.

"With approximately 10,600,000 studies in scope, this is a significant real-world deployment of our technology at scale," Mr Sistenich said.

Enlitic fell 0.2 cents or 4.8 percent to four cents.

MICRO-X

Micro-X says it has a \$US765,000 (\$A1,050,000) contract extension with the US Department of Homeland Security "to mature the design of its ... CT baggage scanners". In 2021, Micro-X said it had US Government contracts worth up to \$US4.1 million for its computed tomography (CT) baggage screening scanner and self-screening portal; and later, said the Department had extended its \$7.25 million baggage scanner contract with a further \$21 million (BD: Sep 29, 2021; Jul 24, 2023).

Today, the company said the eight-month extension would fund the design, build and delivery of an upgraded version of its miniaturized CT baggage scanner, including improvements identified through the manufacture and testing of the existing prototypes and further maturing the design for manufacturing at scale.

Micro-X said it had built four prototype scanners to date based on the same initial design which had since been successfully evaluated and used to collect images from thousands of test bags.

The company said the extension "specifically funds Micro-X to implement and demonstrate the improvements identified through this testing".

Micro-X said developments would include increasing imaging speed to improve passenger throughput of the self-screening checkpoint, and the program would "incorporate design changes to simplify manufacture and enable more efficient production, as the early prototypes were not designed for volume manufacture".

Micro-X fell 0.4 cents or 8.9 percent to 4.1 cents with 2.8 million shares traded.

EBR SYSTEMS

EBR says it has completed US Food and Drug Administration inspection of its Santa Clara, California factory, with approval expected by the end of 2026.

Last year, EBR said the FDA approved its Wise cardiac resynchronization therapy (CRT) for left ventricular pacing; and (BD: Apr 14, 2025).

Today, the company said the inspection of its facility was connected to its pre-market approval supplement to add the facility as a manufacturing site for the Wise device.

EBR said following the inspection the FDA investigator issued a form FDA483 inspectional observations, listing two "routine" observations that it would address.

The company said the FDA's Center for Devices and Radiological Health would review the inspection record and make a final determination regarding the inspection classification and the pre-market approval supplement, with approval expected by 2027.

EBR said additional manufacturing equipment had been installed at the site "to support moving certain manual production processes toward automated assembly".

EBR managing-director John McCutcheon said completion of the inspection was "an important step in the approval process for our new Santa Clara manufacturing facility".

"The observations identified by the FDA are minor and we expect to address them during [the three months to December 31, 2026]," Mr McCutcheon said.

"The new facility remains an important part of EBR's manufacturing scale-up strategy and our broader US commercial execution plans for Wise," Mr McCutcheon said.

EBR fell half a cent or two percent to 24 cents with 1.7 million shares traded.

MAYNE PHARMA

Mayne says it will pay \$US650,000 (\$A926,000) to resolve the "civil complaint brought by the attorneys general of 49 US states and territories".

Mayne said the complaint was "one of the legacy civil actions that arose in response to an industry-wide investigation into the US generic pharmaceutical sector that was initiated in March 2016 by the US Department of Justice".

In 2016, the company said it was co-operating with a US Department of Justice investigation after receiving a subpoena seeking information into the marketing, pricing and sales of its generic products, particularly its Doryx doxycycline hyclate delayed-release tablets (generic) and potassium chloride powders (BD: Nov 4, 2016).

Later that year, Mayne said multiple US states had filed anti-trust proceedings in the US District Court of Connecticut against it and several other companies selling generic-branded medicines (BD: Dec 16, 2016).

In 2023, the company said the US Department of Justice dismissed its last pending criminal indictment of a different company regarding doxycycline (BD: Nov 30, 2023).

Today, Mayne said it would make a one-time payment of \$US650,000 in full and final settlement of the claims "without any admission of liability or wrongdoing of any sort".

The company said the decision to settle reflected "a pragmatic commercial judgement rather than any change in the company's view of the claims".

Mayne said resolving the states' action removed "a meaningful source of legal costs, management distraction and uncertainty", with its ongoing obligations under the settlement "limited and administrative in nature".

The company said it was "required to confirm to the nominated representative State attorney general that it maintains an antitrust compliance policy (which is in place today) and to provide annual notices describing the nature of and continued compliance with that policy for a period of two years".

Mayne Pharma was up two cents or 0.7 percent to \$2.83.

EMVISION MEDICAL DEVICES

Emvision says it has received \$4.3 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Emvision said the incentive related to research and development expenditure for the year to June 30, 2026, its "most active development year to date", including eligible activities related to its 'Emu' stroke scanner trial and first responder programs.

Emvision fell four cents or 2.3 percent to \$1.70.

PARADIGM BIOPHARMACEUTICALS

Paradigm has requested an extension to its voluntary suspension pending "its review of the interim analysis data from its phase III clinical trial ... and financial implications".

Last week, Paradigm said it halted its phase III trial of injectable pentosan polysulfate sodium or Zilosul for knee osteoarthritis following confirmation that the interim efficacy result "did not reach the pre-specified threshold required" (BD: Sep 23, 2026).

At the time, the company requested a voluntary suspension while it assessed the financial implications of the trial outcome and progressed discussions with Obsidian.

Paradigm last traded at 24.5 cents.

GENETIC SIGNATURES

Mercer Investments Australia says it has become a substantial shareholder in Genetic Signatures with 11,697,893 shares, or 5.150 percent of the company.

Melbourne's Mercer said that between June 15 and September 23, 2026 it bought shares at prices ranging from 5.89 cents to 7.78 cents a share and sold 7,745,224 shares on August 24, 2026 at 8.00 cents a share.

Genetic Signatures was unchanged at 7.8 cents.