



Biotech Daily

Wednesday September 16, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: CURVEBEAM UP 14%; COMPUMEDICS DOWN 13%**
- * **FDA OPENS EXPEDITED IND PILOT PROGRAM**
- * **CERETAS DELIVERS 2 PROTOTYPE COMPONENTS; \$693k BRANDON MILESTONE**
- * **EBR, FDA: WISE SAFETY LABELLING UPDATED FOR 'VISIBILITY'**
- * **EMVISION: 1st RESPONDER STROKE SCANNER USED ON 10 PATIENTS**
- * **ENA DOSES 2nd COHORT IN PHASE IIa INNA-051 RESPIRATORY TRIAL**
- * **UNSW: 'SODIUM BUTYRATE REPAIRS OPIOID DAMAGE IN BABY RATS'**
- * **TETRATHERIX: OPTIMATRIX REDUCES POST-OP EYE PRESSURE IN RABBITS**
- * **HERAMED: LEE HEALTH EXPANDS DEAL, 12-MONTH USE OF HERACARE**
- * **CAMBIUM PLACEMENT RAISES \$7.1m; \$3.75 ROCKFORD RDTI LOAN**
- * **ADHERIUM: 3rd LOAN FROM TRUDELL FOR \$1.3m; TOTAL \$4.7m**
- * **ANTEOTECH REVISES \$5.4m NET LOSS AFTER TAX TO \$4.9m**
- * **RYDER TAKES 17% OF LUMOS**
- * **CHEN TSUNG CHI, TREASURE CENTURY, APEX BELOW 5% OF CAMBIUM**
- * **ZHENG YANG DILUTED TO 38% OF CAMBIUM**
- * **CYNTEC DILUTED TO 8% OF CAMBIUM**
- * **MELBOURNE UNI: PROF GRAEME CLARK SHARES \$90k HONDA PRIZE**

MARKET REPORT

The Australian stock market was up 0.28 percent on Wednesday September 16, 2026, with the ASX200 up 24.0 points to 8696.5 points. Thirteen of the Biotech Daily Top 40 companies were up, 20 fell, five traded unchanged and two were untraded.

Curvebeam was the best for the second day in a row, up 0.3 cents or 13.6 percent to 2.5 cents, with 17.1 million shares traded. Impedimed improved 10 percent; Immutep was up 4.4 percent; Nova Eye and Proteomics climbed more than three percent; Dimerix, Saluda and Starpharma rose more than two percent; Nanosonics, Prescient, Racura and Resmed were up more than one percent; with Artrya, Cochlear, CSL and Emvision up by less than one percent.

Compumedics led the falls, down 3.5 cents or 13.0 percent to 23.5 cents, with 46,583 shares traded. Syntara fell eight percent; Micro-X lost 6.7 percent; 4D Medical, Actinogen, Botanix and Telix were down five percent or more; Clarity, Cyclopharm and Lumos fell four percent or more; Aroa was down 3.6 percent; Clinuvel, Imugene and Orthocell shed more than two percent; Imricor, Medical Developments, Mesoblast and Neuren were down one percent or more; with Avita, Polynovo and Pro Medicus down less than one percent.

US FOOD AND DRUG ADMINISTRATION

The US Food and Drug Administration says its expedited investigational new drug (IND) pilot program will partner drug companies with researchers to for drug development.

The FDA's website said the aim of the pilot program was "to accelerate the time it takes from identifying a drug to initiating a first-in-human clinical trial, by partnering drug companies with qualified research institutions that have scientific expertise to support efficient development of [investigational new drug] applications".

The Administration said that, compared to shorter timeframes in China and Australia, first-in-human trials could take up-to two years to complete in the US "threatening America's leadership in scientific innovation".

The FDA said "accelerating clinical trial timelines and eliminating regulatory hurdles to maintain American leadership in global medical innovation ... [was a] core priority for the [President Donald] Trump Administration".

The Administration said the research institutions selected for the program would bring "specialized and substantial scientific expertise to the IND application preparation process" which would allow it to review and accept individual components on a rolling review during the pre-IND phase, rather than waiting for all components to begin.

The Administration said it would accept applications until October 30, 2026.

CERETAS

Ceretas says it has delivered two prototype components for its portable ultrasound Alzheimer's disease therapy, completing a Brandon Biocatalyst \$692,578 milestone.

Last year, Ceretas said it raised \$1 million in seed funding to develop its ultrasound therapy for neurological illnesses such as Alzheimer's disease (BD: Feb 21, 2025).

Last month, the company climbed as much as 132 percent on its July 23, \$8 million initial public offer (IPO) at 25 cents a share for its portable ultrasound Alzheimer's disease therapy (BD: Aug 3, 2026).

Today, Ceretas said that in July 2025 it was awarded a \$2.4 million grant to fast-track development of its ultrasound device through the Cureator Plus Dementia and Cognitive Decline program under the Federal Government's Medical Research Future Fund (MRFF) Biomedtech Incubator initiative, delivered by Brandon Biocatalyst.

The company said the work contributed to two important components of its device, including the development of a fully functional in-house image-guided neuro-navigation (IGN) system prototype, which precisely targeted certain regions of the brain and would replace the off-the-shelf IGN currently used, reducing the number of operators required from two to one, improving usability and reducing cost of goods.

Ceretas said the second component was a lift assist device that helped the operator place the ultrasound probe accurately and steadily on the patient's head.

The company said that the device was designed in collaboration with Melbourne's Planet Innovation.

Ceretas said that it completed the milestone on schedule, with fully functional prototypes of both components delivered and accepted by Brandon Biocatalyst, triggering the final, non-dilutive funding tranche, expected in the coming weeks, with the broader development program on-track for completion by July 2027.

Ceretas chief executive officer Dr Rachel de las Heras said "completion of fully functional prototypes of the proprietary IGN software and lift assist device marks an important development and optimization milestone".

"Both will significantly improve usability," Dr de las Heras said.

Ceretas climbed 7.5 cents or 8.1 percent to \$1.00.

EBR SYSTEMS

EBR says it has submitted updated pacing risk warning and mitigation labelling for its Wise System to the US Food and Drug Administration.

In July, EBR said an event involving ventricular fibrillation in two patients implanted with its Wise leadless pacemaker was not related to its device, and the Food and Drug Administration (FDA) would review the events, and later said its final internal assessment concluded the death of a patient and complications in another were “an isolated event related to a disclosed risk that can be mitigated when following recommended ... [echocardiogram] procedures per the device labelling and training” (BD: Jul 24, 31, 2026). Last week, EBR said the FDA agreed that no immediate field corrective action or recall against its Wise system was warranted (BD: Sep 9, 2026).

Today, the company said it would submit a “changes being effected” pre-market approval supplement to the FDA by January 2027, a proactive initiative to update the commercial labelling for its Wise System designed to “elevate the visibility and prominence of mitigation strategies” to prevent known complications within the device labelling. EBR said the submission provided a streamlined regulatory pathway for labelling improvements, allowing safety enhancements to be implemented without requiring prior FDA approval.

The company said it had met with the FDA, during which it addressed FDA questions, and said it was “pleased” with the collaborative interaction, with both parties aligned on “ensuring patient safety”.

EBR chief executive officer John McCutcheon said “this proactive labelling update ensures that the clinical mitigations we have developed are clearly visible and top-of-mind for implanters, empowering them to mitigate complication before they occur”.

EBR was unchanged at 24.5 cents with 2.8 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it completed the 10 patient, first stage study of its First Responder portable brain scanner on pre-hospital mobile stroke units in road vehicles.

Emvision said 10 participants were enrolled across the Melbourne mobile stroke unit operating from the Royal Melbourne Hospital, with six scans performed in residences, three in ambulances and one at a workplace, with a mean scan time of 6.7 minutes.

The company said there were no device-related adverse events reported and operator feedback was “strong on the aspects that matter most for clinical use”, including scanner operation being rated as “easy” in 100 percent of operator responses, with securing the device rated positively in 90 percent of cases and packaging and preparation rated positively in 80 percent of cases.

Emvision said development of the production equivalent of its First Responder units was “well advanced”, with these systems lighter than the prototypes used in its field studies and designed to surpass its Emu brain scanner in diagnostic performance.

The company said it had an agreement with the Australian Stroke Alliance to work on securing non-dilutive research and translational funding for pre-hospital stroke diagnosis.

Emvision chief executive officer Scott Kirkland said “this study shows the First Responder scanner can be easily deployed where strokes occur, at the scene, and via the road”.

“Operators found it easy to use and patients found it unobtrusive,” Mr Kirkland said.

“What we learned has already shaped the next- generation production equivalent First Responder which is even lighter, simple to operate and engineered to better the diagnostic performance of the Emu,” Mr Kirkland said.

Emvision was up one cent or 0.6 percent to \$1.735.

ENA RESPIRATORY

ENA says it has begun dosing the first of up-to 900 patients in the second part of its phase IIa study of its INNA-051 anti-viral nasal spray for respiratory virus in young adults.

In May, the company said it had dosed the first part of the up-to 1,100-patient phase IIa study of its INNA-051 dry powder nasal spray for common respiratory viruses, which would assess the safety, tolerability and efficacy of up to three months' treatment with INNA-051 and its impact on the incidence, duration and severity of symptomatic infections caused by common respiratory viruses, including influenza, respiratory syncytial virus, rhinovirus and coronaviruses, and would continue to the second part (BD: May 12, 2026). Today, ENA said it would dose participants in the second part of the trial for three months at five sites in the US, with recruitment targeting patients in crowded households, university housing residents, military personnel in barracks, childcare centre workers and those living with, or caring for, children aged under 10 years, attending school or daycare. ENA consultant medicine development lead Dr Ruth Tal-Singer said "complications from respiratory viral infections ... [placed] a huge burden on patients and healthcare systems". "By boosting the body's natural host defence pathways, we believe INNA-051 could offer new hope to millions of vulnerable patients worldwide and we look forward to adding to the clinical evidence of its potential through this study," Dr Tal-Singer said. ENA is a private company.

THE UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says the gut supplement sodium butyrate can help repair opioid-related health and behavioral damage in baby rats.

The University said the offspring of pregnant rats given methadone showed behavioral and health issues similar to those in babies exposed to opioids before birth, while the pups of rats simultaneously treated with sodium butyrate showed "marked improvements".

The University said sodium butyrate was a compound naturally produced in the gut when dietary fibre was broken down and that, in some tests, the rat pups "performed as well as pups that had never been exposed to methadone".

The research, titled 'Sodium butyrate rescues long-term neurodevelopmental deficits following perinatal methadone exposure', was published in *Translational Psychiatry* and is available at: <https://www.nature.com/articles/s41398-026-04435-2>.

The University of New South Wales' Prof Kelly Clemens said opioids impacted "multiple internal systems in both a pregnant mother and her baby, including the brain, as well as the gut, where they disrupt the microbiota".

"Beyond the immediate withdrawal symptoms seen after birth, growing evidence suggests that opioid exposure in-utero can lead to subtle but lasting developmental challenges, including difficulties with attention, anxiety, learning, and impulse control," Prof Clemens said. "The animal studies are the first to show that butyrate can repair damage across a broad spectrum of these outcomes."

"Butyrate appears to counteract some of the effects of opioids across multiple systems in both the mother and her baby ... [but], these interactions are complex, and introducing the supplement could potentially disrupt the balance in otherwise healthy systems," she said. The University said 26 pregnant rats were divided into groups, with about half receiving methadone from mid-pregnancy through to birth and early nursing, and about half given sodium butyrate, either alone or alongside methadone.

The University said pups and mothers exposed to methadone showed "significant disruptions in their microbiota and the genetic codes needed to produce butyrate" but that sodium butyrate supplements "reversed some of these disruptions".

TETRATHERIX

Tetratherix says a rabbit study of its Optimatrix platform polymer for cataract surgery reduced post-operation intraocular eye pressure to pre-operative levels.

Tetratherix said that Optimatrix was a fully-synthetic, water-based product developed from its proprietary polymer platform and was designed to hold the front chamber of the eye open during surgery, with collapsed chambers risking damage to the cornea and making the operation harder.

The company said Optimatrix was delivered to surgeons as a liquid to be injected into the front chamber of the eye and then transformed by the patient's own body heat into a clear, cohesive gel that held the chamber open and stable through the operation.

Tetratherix said that Optimatrix could be simply removed, with cooled saline returning it to liquid form for washing away.

The company said that the rabbits in its study underwent a cataract operation in both eyes, with Optimatrix compared to a balanced salt solution procedure, and that every animal's eye treated with Optimatrix showed pressure lower than in the salt solution-treated eye, including some within six hours of surgery.

Tetratherix said that the washing step was required "because material left behind is the principal cause of a rise in intraocular eye pressure in the hours after surgery, this is the most common early complication of cataract surgery".

The company said that "with Optimatrix, even with 100 percent of the product remaining inside the eye, pressure was back at pre-operative levels within six hours in the treated eyes and had not risen again by 48 hours".

Tetratherix said that by 24 hours the Optimatrix eyes "returned to their pre-operative pressure" and sat "well below" the salt solution group, which remained elevated.

The company said that its formal pre-clinical study was underway, following engagement with the US Food and Drug Administration, and that it intended to commercialize Optimatrix.

Tetratherix chief technology officer Dr Ali Fathi said surgeons were forced by ophthalmic visco-surgical devices (OVDs) to solve the same problem at the end of every case:

"remove the applied product completely or risk a spike in eye pressure for the patient".

"We set out to help surgeons reduce that risk," Dr Fathi said.

Tetratherix was up 17 cents or 2.7 percent to \$6.51.

HERAMED

Heramed says Lee Health has approved a 12-month commercial deployment of its Heracare heart rate monitor, following the completion of a six-month pilot program.

Last year, Heramed said it would conduct a \$US115,000 pilot program of its Heracare foetal heart monitor with the Fort Myers, Florida-based Lee Health (BD: Nov 27, 2025).

At the time, the company said the pilot program was scheduled to begin in December 2025, with key performance indicators including patient engagement, virtual visits, remote monitoring and electronic medical records integration.

Today, Heramed said the initial work for the next 200 patients would cost \$US317,000, including licences, monitoring kits, implementation fees, hospital software integration, logistics fees and device and application support, with four maternity care plans on offer.

The company said the deployment built on results from the pilot program, including 92 percent virtual adoption and a 100 percent likelihood to recommend, and once the initial 200 licences were exhausted, additional licences and device kits would be ordered in mutually agreed increments of 20, 50, 100 or larger cohorts.

Heramed was up 0.6 cents or 18.2 percent to 3.9 cents with 14.6 million shares traded.

CAMBIUM BIO

Cambium says it has firm commitments to raise \$7.1 million through an institutional placement of 14,791,667 shares at 48.0 cents each.

Cambium said the price was a 4.3 percent premium to its closing price on September 15. Cambium said that, together with a \$3.75 million loan from Rockford RDF Pty Ltd to “pre-finance” its Federal Research and Development Tax Incentive, it had a total funding package of \$10.85 million for the phase III trial of Elate Ocular for moderate to severe dry eye disease, with funds also going towards general working capital.

The company said that the \$3.75 million Rockford facility was “executed on August 5, 2026” but did not announce the loan at the time.

Cambium was up one cent or 2.2 percent to 47 cents.

ADHERIUM

Adherium says it has taken a \$1.3 million, unsecured loan from major shareholder Trudell Medical, combined with its previous loans for \$4.7 million.

Adherium said the loans would be combined into a single \$4,671,025 facility, with interest charged at 12.0 percent a year, to be repaid by August 31, 2027.

The company said it previously drew down \$US1.65 million (\$A2.31 million) in June and \$1.0 million in August of this year (BD: Jun 29, Aug 18, 2026).

Today, Adherium said the loan would provide working capital.

Adherium was untraded at 8.5 cents.

ANTEOTECH

Anteotech says that it has revised its loss after income tax for the year to June 30, 2026 to an expected \$5,375,654 instead of the previously reported \$4,928,074.

Anteotech said the adjustment related to the accounting treatment of the “lease make-good provision” for its Brisbane premises, which it had recognized in its preliminary report but which in the revised statements had been recognized as “an adjustment to the carrying amount of the related right-of-use asset”.

The company said the adjustment was “non-cash” and had no effect on its cash position, cash flows or the amount or timing of any obligation to any third parties.

Anteotech said diluted loss per share was revised from 0.17 cents to 0.19 cents, while net tangible assets were revised from 0.36 cents to 0.35 cents.

Anteotech was unchanged at 1.9 cents with 2.1 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

The Sydney-based Ryder Capital says it has increased its substantial shareholding in Lumos from 135,895,593 shares (14.73%) to 161,671,446 shares (16.65%).

Ryder Capital said that between June 19 and September 15, 2026 it bought and sold shares, with the single-largest purchase an option exercise on September 15 of 26,098,017 shares for \$1,826,861 or 7.0 cents a share.

Lumos fell half a cent or 4.55 percent to 10.5 cents.

CAMBIUM BIO

Cambium says Chen Tsung Chi, Treasure Century Group and Apex Metro have been diluted and ceased their substantial shareholdings, in late-lodged shareholder notices. The Taipei, Taiwan-based Mr Chi said his 1,222,665 shareholding was diluted on October 16, 2025 and March 17, 2026 by the issue of shares, while the Mahe, Republic of Seychelles' Treasury Century Group said its 999,002 holding was diluted on July 12, 2024 on December 12, 2024 and August 29, 2025 by the issue of shares. The Apia, Samoa-based Apex said it was diluted on July 12, 2024 and April 5, 2025 by the issue of shares, and the release of shares from voluntary escrow. Cambium said the delay in lodgement was due to "an administrative oversight".

CAMBIUM BIO

Cambium says Zheng Yang Biomedical and Yu-Hung Sebastian Tseng Cyntec had their 11,280,229 shares diluted from 41.26 percent to 38.32 percent. A notice signed by Zheng Yang Biotechnology Co (ZYBT) chair Yu-Hung Sebastian Tseng said the company's 10,826,136 shareholding was diluted from 39.61 percent to 36.78 percent, while his own 454,093 shareholding was diluted from 1.66 percent to 1.54 percent, both by the issue of shares on July 24, 2026. Cambium said the delay in lodgement was due to "an administrative oversight".

CAMBIUM BIO

The Taipei, Taiwan based Cyntec Co Ltd said that its 238,435,861 shares (19.99%) were reduced and diluted to 2,384,359 shares (8.10%). In a substantial shareholder notice signed by director Jing-Hong Tsai, Cyntec said its holding was reduced by the 100-to-one share consolidation and by the issue of shares. Cambium said the delay in lodgement was due to "an administrative oversight".

THE UNIVERSITY OF MELBOURNE, COCHLEAR

The University of Melbourne says Prof Graeme Clark, inventor of the cochlear ear implant commercialized by Cochlear, has been co-awarded the 2026 Honda Prize. The University of Melbourne said Prof Clark was the second Australian to receive the award since its establishment in 1980, and would share the JPY10,000,000 (\$90,307) prize with joint-winner Dr Ingeborg Hochmair, an Austrian-based electrical engineer who co-founded Med-El, which specialized in hearing implants and devices. A media release from the University said both researchers had independently "spearheaded the research and development, clinical application and worldwide adoption of the multi-channel cochlear implant, commonly known as the bionic ear". The University's interim vice-chancellor Prof Glyn Davis said "we are enormously proud of Prof Clark, who worked tirelessly for decades to develop and refine the multichannel cochlear implant, achieving major advances in scientific understanding along the way". Cochlear was up 81 cents or 0.6 percent to \$137.24 with 263,553 shares traded.