



Biotech Daily

Monday September 14, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: COMPUMEDICS UP 20%; IMMUTEP DOWN 16%**
- * **TELIX: FDA APPROVES PIXCLARA FOR BRAIN CANCER GLIOMAS**
- * **ENTROPY: ALL 6 BINGE EATERS RESPOND TO PSILOCIN FOR 12 WEEKS**
- * **PROTEOMICS PROMARKER D, PROMARKER ESO 'CONTROLLED RELEASE'**
- * **IMAGION APPOINTS NANOCOMPOSIX CDMO FOR BREAST CANCER TRIAL**
- * **NOXOPHARM LUPUS EXTENSION TRIAL**
- * **DIMERIX MEXICAN COMPOSITION OF MATTER PATENT**
- * **AUDEARA TO LIST ON US OTCID**
- * **DORSAVI FURTHER EVALUATES RRAM FOR SENSORS**
- * **ARCHER STARTS QUANTUM TECHNOLOGY PILOT PROGRAM**
- * **COGSTATE 356k CEO RIGHTS, 33% DIRECTOR POOL HIKE AGM**
- * **AUSTRALIAN ETHICAL TAKES 11% OF ONCOSIL**
- * **RENERVE M-D DR JULIAN CHICK INCREASES, DILUTED TO 8.8%**
- * **BIOTRON LOSES 24-YEAR M-D DR MICHELLE MILLER**
- * **BLS: EDWARD MYER APPOINTS ANGUS WALKER ALTERNATE DIRECTOR**

MARKET REPORT

The Australian stock market was up 0.1 percent on Monday September 14, 2026, with the ASX200 up 8.7 points to 8749.9 points. Thirteen of the Biotech Daily Top 40 companies were up, 17 fell and 10 traded unchanged. All four Big Caps were up.

Compumedics was the best, up 4.5 cents or 20.0 percent to 27 cents, with 166,553 shares traded. Cyclopharm climbed 14.9 percent; Optiscan was up 6.7 percent; Starpharma and Telix improved more than four percent; Clinuvel climbed 3.4 percent; 4D Medical, CSL, EBR and Neuren rose two percent or more; Cochlear, Imricor, Nanosonics and Orthocell were up more than one percent; with Aroa, Pro Medicus and Resmed up by less than one percent.

Immutep led the falls, down 0.9 cents or 16.1 percent to 4.7 cents, with 35.7 million shares traded. Micro-X lost 5.3 percent; Alcidion, Dimerix, Prescient, Saluda and Syntara fell four percent or more; Clarity, Emvision, Nova Eye and Polynovo were down more than three percent; Atomo shed 2.9 percent; with Artrya, Imugene, Mesoblast, Racura and Resonance down by one percent or more.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has approved its new drug application (NDA) for Pixclara positron emission tomography for imaging brain cancer gliomas.

Telix said that the flore-tyrosine amino acid positron emission tomography (PET) Pixclara was “a radioactive diagnostic drug indicated for use with positron emission tomography to differentiate recurrent or progressive glioma from treatment-related change, in conjunction with other diagnostic evaluations, in adults and pediatric patients one month of age and older”.

The company said that positron emission tomography imaging with flore-tyrosine F 18 (FET-PET) was “recommended in international clinical practice guidelines for the imaging of gliomas, including [the US National Comprehensive Cancer Network] guidelines, but until now there has not been an FDA-approved product available in the US”.

In March, Telix said it had resubmitted its new drug application to the FDA for TLX101-Px, or Pixclara, for imaging glioma brain cancer (BD: Mar 16, 2026).

In 2024, Telix said it had filed an NDA for the imaging agent with the FDA, which had granted ‘priority review’ for the submission (BD: Aug 28, Oct 24, 2024).

Last year, the company said that in “a complete response letter” the FDA required “additional confirmatory clinical evidence” for Pixclara for glioma, and said the FDA ruled the application required additional confirmatory clinical evidence (BD: Apr 28, 2025).

Later, Telix said the FDA had agreed to an existing data analysis for its new drug application resubmission for Pixclara for glioma imaging (BD: Sep 9, 2025).

In March, the company said the resubmitted new drug application included the additional data requested by the FDA and it believed that “the additional data and statistical analysis ... appropriately addresses the ‘complete response letter’”.

Today, Telix said that gliomas were the most common form of central nervous system (CNS) cancer, accounting for about 30 percent of all brain and CNS tumors and 80 percent of all malignant brain tumors.

The company said that in the US, about 24,000 glioma cases were diagnosed each year, representing a significant unmet addressable need.

Telix precision medicine chief executive officer Kevin Richardson said that “FDA approval of Pixclara will enable broad access in the US to FET-PET imaging, which is already recognized in international clinical practice guidelines”.

“As the first FDA-approved PET imaging drug for glioma, Pixclara will provide physicians in the US with more certainty in their diagnoses and greater confidence in their treatment planning for patients,” Mr Richardson said.

American Brain Tumor Association chief executive officer Kelly Sitkin said the approval would “advance glioma care by enabling more precise monitoring, complementing the role of [magnetic resonance imaging]”.

Telix said that Pixclara (flore-tyrosine F 18) was an intra-venous positron emission tomography (PET) imaging drug for the differentiation of recurrent or progressive glioma from treatment-related change, in conjunction with other diagnostic evaluations, in adults and paediatric patients one month of age and older.

The company said that it comprised a small molecule-targeting compound labelled with a diagnostic radioisotope, fluorine-18.

Telix said after administration into the bloodstream, Pixclara targeted membrane transport proteins known as L-type amino acid transporters 1 and 2 (LAT1 and LAT2) and once bound, the energy emissions from the radioisotope could be detected by a PET scanner.

The company said that Pixclara (TLX101-Px) was the subject of a phase III registrational study for potential indication expansion for the diagnosis of brain metastases.

Telix climbed 67 cents or 4.3 percent to \$16.34 with 5.4 million shares traded.

ENTROPY NEURODYNAMICS

Entropy says all six treatment-resistant binge eating disorder patients in its phase II trial of TRP-8803 infused psilocin showed improvement in symptoms for the 12 weeks.

Entropy said the trial, with Swinburne University of Technology, showed that three of the six patients had “no binge-eating episodes during the entire 84-day follow-up period after completion of two TRP-8803 infusions”.

The company said that the response to TRP-8803 was “durable with weekly binge-eating episodes 73 percent below pre-treatment baseline at 12 weeks, substantially maintaining the 74 percent reduction at four weeks.

Entropy said that patients had a 50 percent reduction in anxiety, a 42 percent reduction in depression and a 61 percent improvement in quality of life.

The company said that a “durable response [was] achieved in a chronic, treatment-resistant population with a median [binge eating disorder] duration of 15 years with all patients having failed at least one previous [binge eating disorder] treatment”, with sustained treatment responses seen after two TRP-8803 infusions.

Entropy said that a second cohort would evaluate a shorter TRP-8803 infusion period, with topline results expected by the end of 2026.

The company said that the three patients with no binge-eating episodes throughout the 12-week (84-day) follow-up period had a “full clinical remission” which was “particularly significant given patients entered the study [averaged] 2.3 binge-eating episodes per week, a disease burden equivalent to 28 binge-eating episodes over the 12- week period”.

Entropy said that TRP-8803 “produced a powerful and reproducible psychedelic state across cohort 1, with nine of 12 treatment sessions reaching 10/10 intensity and a mean peak intensity of 9.4/10”

Previously, the company said that psilocin was the active psychedelic metabolite of psilocybin found in ‘magic mushrooms’ (BD: Jul 1, 2024).

Today, Entropy said that independent preliminary electro-encephalogram (EEG) analysis identified “large and reproducible changes in brain dynamics following TRP-8803 administration, including increased EEG complexity and substantial reductions in alpha activity across both treatment sessions”.

Entropy chief executive officer Jason Carroll said the 12-week results were “particularly encouraging”.

“These were patients who had lived with Binge Eating Disorder for as long as 20 years and who had previously failed treatment,” Mr Carroll said.

“Every patient maintained a clinically meaningful improvement at 12 weeks and weekly binge-eating episodes remained 73 percent below baseline,” Mr Carroll said.

“For us, durability is critical,” Mr Carroll said.

“We are not seeking to develop another medicine that patients need to take every day,” Mr Carroll said. “We are investigating whether a limited number of precision-controlled psychedelic treatments can produce a clinically meaningful benefit that persists long after dosing has finished.”

“What is particularly interesting is that the FDA’s recently finalized guidance for psychedelic drug development specifically identifies 12 weeks as an important efficacy assessment period for chronic psychiatric conditions,” Mr Carroll said.

“Our [binge eating disorder] program has independently generated 12-week follow-up data showing that the clinical response after two TRP-8803 infusions was substantially maintained,” Mr Carroll said.

“These are early data from a small study, but the regulatory direction and the clinical evidence we are generating are increasingly aligned,” Mr Carroll said.

Entropy was up 0.1 cents or 2.5 percent to 4.1 cents with 1.1 million shares traded.

PROTEOMICS INTERNATIONAL

Proteomics says a “controlled market release” of Promarker D and Promarker Eso is underway in Western Australia and the Northern Territory with distributor Healius.

Proteomics said it had an “exclusive pathology distribution agreement with Healius ... for all Promarker tests” (BD: Jul 22, 2026).

The company said that Healius was progressing to a national rollout with broader sales expected to follow by July 2027, subject to completion of implementation activities.

Proteomics said Australian pricing had been set at \$495 for Promarker D which provided a “risk assessment for diabetic kidney disease up to four years before clinical symptoms appear” and \$997 for Promarker Eso, which “assists in ruling out oesophageal cancer in patients with chronic reflux”; with the tests available initially on a private-pay basis.

The company said the Healius agreement provided it with access to a network of about 1,900 collection centres and established partner relationships; and was the first national commercial distribution partnership for the Promarker portfolio.

Proteomics managing-director David Morris said that Promarker D and Promarker Eso were ready for a controlled market release and “we continue to progress reimbursement strategies and advance Promarker Endo [which assists in the diagnosis of endometriosis] assay refinement and validation”.

“These activities remain important to the broader commercial development of the Promarker portfolio, and our focus remains on disciplined execution as we progress the commercialization of the portfolio,” Mr Morris said.

Proteomics was unchanged at 14 cents.

IMAGION BIOSYSTEMS

Imagion says that following its investigational new drug (IND) application to the US Food and Drug Administration Nanocomposix will resume nanoparticle manufacturing.

In June, Imagion said it had FDA approval for a 70-patient, phase Ib/II trial of Magsense for breast cancer (BD: Jun 2, 2026).

Today, the company said that the San Diego, California-based Nanocomposix was a “specialty nanoparticle contract development and manufacturing organization (CDMO).

Imagion said it would provide its “nanoparticle synthesis equipment, software and procedures for manufacturing the core particles to Nanocomposix ... to manufacture pharmaceutical grade material”.

The company said that partnering with the CDMO would keep its “operational costs low, avoiding fixed costs of investing in a manufacturing facility and staffing, while still allowing for the development of the technology towards potential commercialization”.

Imagion said developing manufacturing processes early could ensure specifications and shelf-life of the product were well characterized when submitting a new drug application (NDA), helping to avoid delays in the marketing authorization process; and “since the core nanoparticle is the base component of all Magsense imaging agents, implementing this program ... positions [it] well and will likely add value to any ... partnering transaction”.

Imagion’s head of US operations Ward Detwiler said that “establishing robust nanoparticle production capabilities is extremely important for our future”.

“The core particles are a key component of our proprietary Magsense technology and, therefore, essential to the long-term success of our business,” Mr Detwiler said.

Imagion said that Nanocomposix had previously shown its capabilities, having supported production of the Magsense HER2 imaging agent for the completed phase I study and the investigational product planned for use in the pending phase Ib/II study.

Imagion was unchanged at 0.8 cents with 1.8 million shares traded.

NOXOPHARM

Noxopharm says it will begin a 15-patient, SOF-SKN cutaneous lupus erythematosus (CLE) extension trial, with enrolment to begin in Melbourne, by April 2027.

Noxopharm said the Heracles first-in-human trial of SOF-SKN as a topical treatment was completed in healthy volunteers in January (BD: Jan 21, 2026).

The company said that lupus was an autoimmune disease than can affect different organs, and CLE was a sub-type that manifests in the skin.

Noxopharm said there was no targeted therapy for CLE, and a significant unmet need for targeted and well tolerated therapies, as well as the opportunity for orphan drug status.

The company said the extension study was “intended to assess the safety and tolerability of SOF-SKN in CLE patients, and to generate initial signals of clinical efficacy”.

Noxopharm said that each patient would receiving 14 days of daily topical dosing with SOF-SKN, plus a seven-day follow-up.

The company said it hoped to complete treatment, and report initial data by July 2027, with a full clinical data readout by the end of 2027.

Noxopharm said the data was intended to inform the design of its phase II trial in CLE patients, targeted by July 2028, subject to regulatory feedback and standard clinical and manufacturing requirements.

Noxopharm was up 0.3 cents or 4.2 percent to 7.5 cents.

DIMERIX

Dimerix said the Mexican Institute of Industrial Property has granted a composition of matter patent covering its recently acquired DMX-652.

In July, Dimerix said it would pay up-to \$US292 million plus royalties for Mission Therapeutics’ DMX-652 for acute kidney injury (BD: Jul 17, 2026)

Today, the company said that the patent, titled ‘N-cyanopyrrolidines with activity as USP30 inhibitors’ would provide protection for DMX-652 until Jun 3, 2041.

Dimerix fell one cent or four percent to 24 cents with 1.1 million shares traded.

AUDEARA

Audeara says it has begun the process to establish quotation of its ASX shares on the over-the-counter issuer designation (OTCID) tier of the US over-the-counter market.

The OTC Markets website said that the basic market was “for companies that publish baseline information, rather than meet the higher qualifications of our premium markets ... [which] provide ongoing financial disclosure and a management certification, and verify their company profile for US investors, brokers and regulators”.

Today, Audeara said that to expedite the process, it had appointed Viriathus Capital LLC as its non-exclusive financial advisor for an initial three-month engagement.

The company said that Viriathus would manage the OTCID quotation process, including eligibility review, preparation of the application, liaison with OTC Markets Group and the relevant market maker, and ongoing quotation requirements.

Audeara said that the listing expansion followed “a year of record group revenue and significant commercial progress across its core technology platforms”

Last month, Audeara said that revenue from sales of its hearing-health technologies including hardware, wholesale clinical distribution, white-label product development, engineering services and software licencing for the year to June 30, 2026 was up 17.5 percent to \$4,449,000.

Audeara was untraded at 2.2 cents.

DORSAVI

Dorsavi says it has begun an evaluation of its resistive random-access memory (RRAM) structures, assessing the energy required to update RRAM memory states.

Dorsavi said that the “targeted energy-efficiency evaluation” would generate device-level energy data to support the development of its low-power RRAM-complementary metal-oxide-semiconductor (CMOS) hardware.

Last year Dorsavi said it would test the resistive random-access memory (RRAM) technology for use in electro-myography (EMG) and electro-cardiography (ECG), licenced from the Singapore Nanyang Technological University to extend the battery life of its EMG and ECG-based wearable sensors, minimizing recharge cycles and improving usability in continuous monitoring (BD: Jun 12, Jul 8, 2025).

Today, the company said that the findings were intended to inform further optimization and subsequent reliability, array-level, compute-in-memory (CIM) and CMOS-integration evaluation as it progressed towards more integrated hardware capability.

Dorsavi said that “as memory and processing move closer to sensors, power, space and thermal capacity can become constrained, particularly where memory is updated frequently alongside sensing, local interpretation, communication and responsive action”.

The company said that physical artificial intelligence systems might benefit from hardware that retained and processed information close to where physical data was generated, rather than continuously transferring all raw data to a distant processor.

Dorsavi was up 0.2 cents or 9.1 percent to 2.4 cents with 11.1 million shares traded.

ARCHER MATERIALS

Archer says it is strengthening its partnership with IonQ and its customer pipeline development, with the launch of a national quantum commercial pilot program.

IonQ is based in College Park, Maryland.

Archer said it was “Australia's only listed pure-play quantum technology company” and the pilot program would give customers “access to the most powerful quantum hardware available to help solve complex real-world challenges spanning logistics, defence, healthcare and pharmaceuticals, beyond the reach of classical computational platforms”.

Archer chief executive officer Dr Simon Ruffell, said the company was “taking the work we have been developing with [the Commonwealth Scientific and Industrial Research Organisation] and running it on a commercial IonQ quantum computing platform, which will allow for more advanced testing and optimization”.

Archer was up half a cent or 2.8 percent to 18.5 cents.

COGSTATE

Cogstate will vote to issue chief executive officer Brad O'Connor 355,866 performance rights and increase the directors fee pool by 33.3 percent from \$750,000 to \$1,000,000.

Cogstate said Mr O'Connor's rights would vest pending revenue and earnings targets.

The company said that Mr O'Connor's total remuneration was \$US500,000 base salary, plus short-term incentives up to 150 percent of that base salary as well as a further long-term incentive of up to 150 percent of that base salary.

Cogstate said the annual general meeting would vote on the remuneration report and the election of Darryl Inns as a director.

The meeting will be held virtually and at Level 13, 664 Collins Street, Melbourne, on October 15, 2026 at 10am (AEDT).

Cogstate was up one cent or 0.3 percent to \$3.01.

ONCOSIL MEDICAL

Sydney's Australian Ethical says it has increased its substantial shareholding in Oncosil from 2,913,919 shares (9.43%) to 3,976,358 shares (10.83%).

Australian Ethical said that it bought 1,062,439 shares on August 13 and September 7, 2026, for \$1,019,003 or 95.9 cents a share.

Oncosil was up half a cent or 0.5 percent to 98 cents.

RENERVE

Renerve managing-director Dr Julian Chick says he has increased his substantial shareholding from 13,983,888 shares (9.85%) to 15,260,469 shares (8.81%).

The Melbourne-based Dr Chick said that between December 13, 2024 and September 11, 2026, with Violeta Traicevski and Viomaj Pty Ltd he bought 1,276,581 shares for \$134,457 or an average of 10.53 cents a share.

In July, Renerve says it has an up-to \$5 million convertible note with London's Riverfort Global Opportunities PCC, with an initial \$1.6 million draw-down (BD: Jul 9, 2026).

Renerve fell 0.4 cents or 5.4 percent to seven cents.

BIOTRON

Biotron says managing-director Dr Michelle Miller will step down "for personal reasons after 24 years of service to Biotron".

Biotron said its board thanked Dr Miller "for her leadership and significant contribution to the company since 2002 and acknowledges her role in advancing Biotron's strategic and clinical development".

The company said it had begun a search for new leadership effective immediately.

Biotron said that Dr Miller had agreed to remain available to assist with the transitioning to new leadership and to support the company on matters that may benefit from her long tenure as [chief executive officer].

Biotron was unchanged at 0.2 cents with 2.1 million shares traded.

BLS PHARMACEUTICALS (BREATHE LIFE SCIENCES, FORMERLY BIOXYNE)

BLS says that director Edward Myer has appointed Angus Walker as his alternate director.

BLS said it had approved the appointment effective from September 14, 2026.

The company said that Mr Walker would be able to attend and participate in board meetings in Mr Myer's place when required.

BLS said that Mr Walker was chief investment officer of MWP Partners, a Hong Kong-based investment management firm which he co-founded with Mr Myer.

BLS fell 1.5 cents or 1.3 percent to \$1.165.