Biotech Daily

Monday July 13, 2026

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH DOWN: IMMUTEP UP 10%; PROTEOMICS DOWN 12%**

*** CRYOSITE UNAUDITED REVENUE UP 18% TO $17m; PROFIT UP 21% TO $2m**

*** ORTHOCELL RECORD REVENUE UP 43% TO $13.2m**

*** CLINUVEL WINS CANADA SCENESSE EPP APPROVAL**

*** PATRYS RETURNS DEOXYMAB TO YALE FOR 50% ROYALTIES**

*** IMMUTEP: 'TACTI-004 TRIAL PATIENTS HAD DIFFERENT IMMUNE PROFILES'**

*** ONCOSIL, CYCLOTEK VALIDATE PANCREATIC CANCER DEVICE PRODUCTION**

*** PARADIGM $5m OBISIDIAN NOTE DRAW-DOWN; TOTAL $24m**

*** ISLAND, TEXAS BIOMED 2nd GALIDESIVIR DOSE OPTIMIZATION STUDY**

*** BOTANIX: US ALLOWS SOFDRA PATENT**

*** BIOTRON: EMA 'SEDRX HYBRID MARKETING AUTHORIZATION UNSUITABLE'**

*** CLEO TO START OVARIAN CANCER TEST VALIDATION**

*** ACTINOGEN PHASE IIb/III XANAMEM ALZHEIMER'S RESULTS 'IN NOVEMBER'**

*** VECTUS APPOINTS CARDINAL HEALTH US REGULATORY AGENT**

*** ECHO IQ DIRECTOR STEVEN FORMICA DILUTED BELOW 5%**

*** FIDELITY (FMR LLC) REDUCES TO 10% OF SALUDA**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Monday July 13, 2026, with the ASX200 up 2.5 points to 8,808.5 points. Eleven of the Biotech Daily Top 40 companies were up, 22 fell and seven traded unchanged.

Immutep was the best, up 0.5 cents or 9.8 percent to 5.6 cents, with 90.1 million shares traded. Impedimed climbed 9.1 percent; Botanix, Mesoblast and Prescient were up more than four percent; Paradigm rose 2.9 percent; Pro Medicus was up one percent; with 4D Medical, Clarity, Emvision, Orthocell and Polynovo up by less than one percent.

Proteomics led the falls, down 2.5 cents or 12.2 percent to 18 cents, with 198,598 shares traded. Lumos lost 8.2 percent; Avita, Cyclopharm and Imugene were down more than six percent; Curvebeam fell 5.9 percent; Resmed and Resonance were down more than four percent; Amplia and Micro-X lost three percent or more; Artrya, Atomo, Dimerix, EBR, Imricor and Saluda shed more than two percent; Alcidion, CSL and Telix were down one percent or more; with Aroa, Clinuvel, Cochlear, Nanosonics, Neuren and Starpharma down by less than one percent.

CRYOSITE

Cryosite says unaudited revenue for the year to June 30, 2026 was up 18.4 percent to $16.7 million, with net profit after tax up 21.05 percent to $2.3 million.
Last year, Cryosite said revenue for the year to June 30, 2025 was up 11.9 percent to $14,116,000, with net profit after tax up 2.4 percent to $1,884,000 (BD: Aug 22, 2025).
Today, the company said revenue was from sales and contracts for its ambient, cold, frozen and ultra-frozen storage and distribution systems for pharmaceutical and biological products, with earnings before interest, taxation, depreciation and amortization (Ebitda) up 26.5 percent to $4.3 million, compared to the prior corresponding period.
Cryosite said that “earnings again grew faster than revenue, as capacity utilization of our Ferndell Street headquarters accelerated and margins continued to expand”.
The company said that revenue for the three months to June 30, 2026 was about $1,500,000 million, with Ebitda of $400,000.
Cryosite said with its Ferndell Street cool room expansion completed and Adderley Street facility build-out progressing well, its focus for 2026-’27 was “converting this additional capacity into client activity”.
Last year, the company said it had acquired its 100-104 Adderley Street West, Auburn warehouse “more than doubling” its national storage capacity (BD: Nov 27, 2025).
Cryosite was untraded at $1.25.

ORTHOCELL

Orthocell says record revenue for the year to June 30, 2026 was up 43.1 percent to $13.2 million, compared to the previous corresponding period.
Last year, Orthocell said revenue for the year to June 30, 2024 was up 36.4 percent to $9,226,963 with net loss after tax up 19.3 percent to $8,566,640, which did not include revenue from Remplir sales in the US (BD: Aug 29, 2025).
Today, the company said that record revenue for the three months to June 30, 2026 rose 39.2 percent to $3.8 million, compared to the prior corresponding period, driven by continued adoption of its Remplir peripheral nerve repair device in Australia and commercial traction in the US, as well as sales of its Striate+ for dental bone regeneration.
Orthocell said total overseas revenue from Remplir sales accounted for more than nine percent of total three-monthly revenue and would continue to expand.
Orthocell managing-director Paul Anderson said the record result reflected “the successful execution of Orthocell’s global commercialization strategy, with strong momentum across Australia and early scale-up in the US”.
“US surgeon adoption and hospital engagement continue to build, and we expect this to be a key driver of revenue growth as our distribution footprint expands,” Mr Anderson said.
“In parallel, we are progressing toward anticipated regulatory approval for Remplir in the UK and EU, which will unlock one of the largest peripheral nerve repair markets globally,” Mr Anderson said.
“During the quarter, we also commenced the US regulatory program for a tendon repair application based on our collagen technology platform,” Mr Anderson said.
“This represents a natural extension of our regenerative medicine portfolio, leveraging our existing manufacturing capability and commercial infrastructure to address a significant unmet clinical need,” Mr Anderson said.
The company said it had a three-month cash burn of $3,684,000, with cash and cash equivalents of $9,389,000 as well as $34,700,000 in term deposits, maturing within 12 months at June 30, 2026.
Orthocell was up half a cent or 0.6 percent to 85 cents with 1.75 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says Health Canada has granted a notice of compliance allowing it to market Scenesse for phototoxicity prevention in adults with erythropoietic protoporphyria (EPP).
In 2024, Clinuvel said its new drug submission for Scenesse, or afamelanotide, for EPP had been accepted for review by Health Canada; and later, said Health Canada had requested additional time and information to review (BD: Jan 19, Oct 16, 2025).
Today, the company said that it had a network of specialty centres in North America to treat EPP patients following US Food and Drug Administration approval.
In 2019, Clinuvel said that the FDA had approved Scenesse for EPP (BD: Oct 9, 2019).
Today, the company said five centres were already trained and accredited in Canada and had treated EPP patients with Scenesse under special access arrangements.
Clinuvel chief scientific officer Dr Dennis Wright said Health Canada had “taken a long time to arrive at this positive outcome”.
“Data from our global programs, including considerable data from post-marketing experience, were used to demonstrate the safety and clinical benefit of Scenesse in EPP, where the mechanism-of-action is well understood,” Dr Wright said.
“The major benefit of the drug is its proven long-term and consistent safety profile. Other drugs in development for EPP lack these data. “I thank our team for this momentous outcome and their tenacity for ensuring eligible patients may get access to this therapy,” Dr Wright said.
Clinuvel fell five cents or 0.5 percent to $10.22 with 166,560 shares traded.

PATRYS

Patrys says it will licence the deoxymab intellectual property to New Haven, Connecticut’s Yale University and will receive 50 percent of commercialization revenue.
In 2017, Patrys said that it had licenced the rights to develop and commercialize technology linking the anti-DNA antibody 3E10, or deoxymab, to nanoparticles from Yale University (BD: Jun 13, 2017).
Today, Patrys said Yale University would responsible “for a majority of the future research and development costs” associated with deoxymab and that it would continue supporting on-going clinical research through external collaborations, including the on-going vasculitis pre-clinical research of DX1 and DX3 with Monash University.
The company said it would assign “all relevant deoxymab intellectual property rights and associated assets to the University” which would provide a University-supported framework and establish a more capital-efficient and development-focused pathway.
Patrys said future payments included cash and non-cash consideration, equity interests, licencing income, royalties, milestone payments and other commercial considerations.
Nucleicon founder and deoxymab lead inventor Dr James Hansen said his “research career has been dedicated to developing deoxymab and uncovering its unique mechanisms of action”.
“I am incredibly excited to now have the opportunity to continue advancing this transformative antibody towards its full potential as a novel therapeutic that I believe will fundamentally change how we treat multiple diseases,” Dr Hansen said.
Patrys chief executive officer Dr Samantha South said the transaction was “an important strategic milestone for Patrys and the deoxymab platform”.
“This agreement preserves the company’s involvement and exposure to potential future commercial success, while materially reducing the capital required to continue advancing the asset internally,” Dr South said.
Patrys was unchanged at four cents.

IMMUTEP

Immutep says that patients in its discontinued ‘Tacti-004’ trial had “markedly different immune activation profile[s]” compared with previous studies including ‘Insight-003’.

Earlier this year, Immutep fell as much as 92.9 percent on news that the up-to 756-patient, ‘Tacti-004’ phase III trial of eftilagimod alfa (or ‘efti’), with chemotherapy for first line non-small cell lung cancer had been discontinued (BD: Mar 13, 2026).

Today, the company said in the ‘Tacti-004’ futility analysis of 173 evaluable patients, the objective response rate in the overall patient population receiving standard-of-care plus efti was 42.9 percent compared with 55.1 percent in patients receiving standard-of-care plus placebo.

Immutep said that preliminary immune monitoring data generated from ‘Tacti-004’ showed “patients treated with efti exhibited a markedly different immune activation profile compared with that observed in previous studies” based on analyses of absolute lymphocyte counts and circulating monocyte counts in blood.

The company said that the findings contrasted with observations from about 600 patients treated with eftilagimod alfa in five earlier studies as well as observations from the ‘Insight-003’ trial.

Last year, Immutep said that its 51-patient, phase I ‘Insight-003’ trial of eftilagimod alfa, with Keytruda and chemotherapy showed a 60.8 percent response rate and 90.2 percent disease control rate for first-line non-small cell lung cancer

(BD: May 15, 2025).

Today, the company said that mature results showed 47 of 51 evaluable patients (92.2%) in its ‘Insight-003’ trial of efti for lung cancer had no or low PD-L1 expression, meaning tumor proportion scores of more than 50 percent, compared to 68 percent in historical benchmarks.

Immutep said that patients with tumor proportion scores of more than 50 percent for whom PD-L1 inhibitor-based therapies typically performed sub-optimally, and were over-represented in the phase I ‘Insight-003’ trial compared with historical benchmarks.

The company said the ‘Tacti-004’ analysis, which included all recruited and evaluable patients who received a minimum of 12 weeks of treatment, remained ongoing, with additional results expected by October 2026.

Immutep said it would “continue to analyse this data as part of its ongoing root cause analysis of a range of potential factors, including manufacturing, and will share the outcome of that analysis as soon as it becomes available”.

Immutep managing-director Marc Voigt said that the company was “encouraged by the mature overall survival data from ‘Insight-003’ in first-line non-squamous [non-small cell lung cancer], which continue to compare favorably with historical benchmarks, particularly given the high proportion of patients in this study with no or low PD-L1 expression”.

“The observed median overall survival of 30.9 months especially in patients with no or low PD-L1 expression reinforces our confidence in efti’s potential to enhance anti-tumor immune responses, including in patient populations that have historically experienced less favorable outcomes,” Mr Voigt said.

“At the same time, we are completing a comprehensive root cause analysis of ‘Tacti-004’ to better understand the factors underlying the outcome of that trial and their implications for the potential future development of efti,” Mr Voigt said.

“Importantly, the differences observed in the immune activation profile between ‘Tacti-004’ and prior studies are providing valuable insights to inform our strategy as we evaluate efti’s potential path forward,” Mr Voigt said.

Immutep was up half a cent or 9.8 percent to 5.6 cents with 90.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says with Cyclotek it has completed three manufacturing validation cycles of its phosphorous-32 radiation device for locally advanced pancreatic cancer.

Oncosil said it had begun a dedicated Australian manufacturing program in partnership with the Macquarie Park, Sydney-based Cyclotek, and had invested about $2.1 million in production equipment.

Earlier this year, the company rose as much as 66.6 percent to 65 cents on news of Australian Therapeutic Goods Administration approval for its phosphorous-32 radiation device for locally advanced pancreatic cancer in addition to gemcitabine-based chemotherapy (BD: May 20, 2026).

Today, Oncosil said Cyclotek provided manufacturing facilities and operational production services, while Oncosil retained ownership of specialized production equipment and manufacturing processes used to produce its device.

The company said the manufacturing capability included validated production processes and specialized equipment designed to manufacture the device efficiently, safely and in accordance with quality and regulatory requirements, including International Organization for Standardization (ISO) 13485, TGA and US Food and Drug Administration.

Oncosil managing-director Nigel Lange said the company expected to begin commercial production “during the second half of 2026 following … the regulatory approval process”.

"The successful completion of our manufacturing validation program is a significant operational milestone for Oncosil,” Mr Lange said.

“Through our strategic partnership with Cyclotek, we have established a scalable Australian manufacturing capability that combines the efficiency of an experienced manufacturing partner with ownership of our specialized production equipment and proprietary manufacturing process,” Mr Lange said.

“Importantly, completing manufacturing validation substantially de-risks a key component of our commercial strategy by demonstrating that we have a validated production capability ready to support future market demand, subject to regulatory approval,” Mr Lange said.

Oncosil was up eight cents or 6.1 percent to $1.40.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has drawn-down $US3 million ($A4.6 million) under its Obsidian Global convertible note facility, taking the total to $US20 million ($A24.5 million).

Last year, Paradigm said that it had a $US27 million draw-down equity facility with New York’s Obsidian Global Partners LLC to support its phase III knee osteoarthritis trial, with an initial $US7 million drawn-down (BD: Jun 1, 2025).

Later, the company said it had drawn-down a second tranche of $US5 million under the convertible note facility with Obsidian Global; and earlier this year, said it had drawn-down a third tranche of $US5 million (BD: Nov 17, 2025).

Today, Paradigm said that the additional funds would be used for working capital to support its phase III trial, following completion of enrolment in the study.

The company said about $US7 million remained available under the facility, providing “continued financial flexibility to support phase III execution, interim analysis preparation and broader commercial readiness activities.

Paradigm said it continued “to maintain disciplined capital management, ensuring expenditure remains aligned with operational progress”.

Paradigm was up half a cent or 2.9 percent to 17.5 cents with 4.6 million shares traded.

ISLAND PHARMACEUTICALS

Island says the Texas Biomedical Research Institute will conduct a second dose optimization study of galidesivir to support Animal Rule efficacy study design.
Last year, Island said it completed its up-to $US2.5 million acquisition of the Biocryst Pharmaceuticals' galidesivir program (BD: Jul 31, 2025).
Later, the company said the US Food and Drug Administration confirmed the Animal Rule pathway, which allowed anti-viral drug approval based on animal data when human trials were unethical or not feasible, was appropriate for the development of galidesivir for Marburg virus disease (BD: Nov 17, 2025).
In December, Island said it had a master service agreement with the San Antonio-based Texas Biomedical Research Institute for pre-clinical studies of galidesivir in non-human primates at one of four biosafety level 4 facilities in the US (BD: Dec 17, 2025).
Today, the company said in the second study Texas Biomed would evaluate galidesivir in 12 non-human primates infected with the Angola strain of Marburg virus, with preparation activities expected to begin this year and the challenge and treatment phase in 2027.
Island said the agreement secured access to a second cohort of animals should additional optimization work be required, "materially de-risking the program, while providing operational flexibility and maintaining development momentum" towards beginning a planned pivotal Animal Rule efficacy study.
Island was up three cents or 6.7 percent to 48 cents with 1.655 million shares traded.

BOTANIX PHARMACEUTICALS

Botanix says the US Patent and Trademark Office has issued a notice of allowance for a US patent relating to the drug substance for Sofdra, or sofpironium bromide.
Botanix said the patent, titled 'Crystalline Form of Sofpironium Bromide and Preparation Method Thereof' would protect its intellectual property until May 2040.
The company said the allowed claims were directed to proprietary aspects of sofpironium drug substance technology used in the commercial manufacture of Sofdra.
Botanix was up 0.1 cents or 4.2 percent to 2.5 cents with 19.4 million shares traded.

BIOTRON

Biotron says the European Medicines Agency has indicated that a hybrid marketing authorization application is an unsuitable regulatory pathway for its Sedrx anaesthetic.
Last year, Biotron said it had completed its acquisition of Sedarex and its alfaxalone-based Sedrx anaesthetic for 500,000,000 consideration shares at 0.3 cents a share, valuing it at $1.5 million (BD: Oct 15, Dec 11, 2025).
Today, the company said the EMA had indicated the hybrid marketing authorization application pathway was not suitable for Sedrx "due to the proposed reference medicinal product … Althesin which is no longer on market and hence not available for comparable bridging studies that would be required".
Biotron said the hybrid marketing authorization was "a specific pathway where the marketing application relies on a mixture of existing data for a previously approved drug supplemented with new clinical data".
The company said the EMA response had "provided a clear direction for the next stage of development of Sedrx" and it would focus on a clinical and regulatory program aligned with current EMA expectations, including planning the pivotal clinical trial required to support a marketing authorization application.
Biotron fell 0.05 cents or 20 percent to 0.2 cents with 16.5 million shares traded.

CLEO DIAGNOSTICS

Cleo says it has completed the final development and preparation activities required for analytical validation of its ovarian cancer blood tests.

Earlier this year, Cleo said it achieved its recruitment target of 514 blood samples collected for its pivotal US trial of its presurgical ovarian cancer test (BD: Mar 31, 2026).

Today, the company said it could begin data collection ahead of a US Food and Drug Administration submission, with future activities focused on clinical data generation to support the regulatory filing.

Cleo said it had commissioned three additional Ella instruments, which had arrived at its Melbourne facility to be used to test the samples and generate the "first major analytical dataset supporting the company's planned FDA 510(k) submission".

In February, the company said it had selected the Minneapolis, Minnesota-based Bio-Techne's Ella automated platform as the immuno-assay instrument for its ovarian cancer blood test (BD: Feb 18, 2026).

Today, Cleo said that it expected analytical validation and clinical validation to be completed this year, with clinical trial testing, analysis and results as well as FDA submission and approval by July 2027.

Cleo fell 2.5 cents or 4.9 percent to 48.5 cents.

ACTINOGEN MEDICAL

Actinogen says it expects to report top-line results from its 247-patient, phase IIb/III trial of Xanamem for mild to moderate Alzheimer's disease "in November 2026".

Last month, Actinogen said the data monitoring committee recommended continuing the Xanamem trial unchanged (BD: Jun 18, 2026)

Today, the company said it presented screening efficiency and baseline population characteristics from the trial in a poster, titled 'Screening and baseline characteristics of a phase IIb/III randomized, placebo-controlled trial of emestedastat in mild to moderate AD' at the Alzheimer's Association International Conference in London, England held from July 12 to 15, 2026.

Actinogen was unchanged at 4.4 cents with eight million shares traded.

VECTUS BIOSYSTEMS

Vectus says Cardinal Health Regulatory Services will act as the primary point-of-contact for all US Food and Drug Administration regulatory activities for VB0004.

Vectus said the Dublin, Ohio- based Cardinal Health would prepare all FDA-facing communications, interactions and submissions on behalf of the company, including the orphan drug designation request, pre-investigational new drug communications and applications for VB0004 in idiopathic pulmonary fibrosis.

The company said Cardinal Health was "a leading US regulatory affairs consultancy with deep expertise in FDA submissions and drug development strategies".

Vectus chief executive officer and chief technology officer Dr Tara Speranza said the appointment was "an important milestone in establishing a clear regulatory pathway".

"Its extensive experience in regulatory strategies and submissions will be invaluable as we advance preparations for our US development program," Dr Speranza said.

"This represents another important step toward bringing our first-in-class oral therapy to patients living with [idiopathic pulmonary fibrosis], where there remains a significant unmet medical need," Dr Speranza said.

Vectus was up 1.5 cents or 9.4 percent to 17.5 cents.

ECHO IQ

The Perth-based Echo IQ director Steven Formica says he was diluted below the five percent substantial threshold in the company on July 7, 2026.
Earlier this year, Mr Formica said he became a substantial shareholder in Echo IQ with 33,016,667 shares, or 5.01 percent (BD: Apr 10, 2026).
Earlier this month, Echo IQ said it had “firm commitments” to raise $110 million at $1.45 a share, an 8.8 percent discount to the last traded price (BD: Jul 1, 2026).
According to its most recent filing, Echo IQ had 736,724,779 shares on issue, meaning that Mr Formica retained about 4.5 percent of the company.
Echo IQ fell 4.5 cents or 2.7 percent to $1.615 with 3.85 million shares traded.

SALUDA MEDICAL

Fidelity Management and Research (FMR) LLC says it has reduced its substantial shareholding in Saluda from 2,962,857 shares (11.75%) to 2,588,987 shares (10.27%).
The Wilmington, Delaware-based FMR said that it bought 2,100 shares on December 11, 2025 at $1.5067 a share and sold shares between January 5 and July 9, 2026 at prices ranging from 37.23 cents a share to $1.4186 a share.
Saluda fell 1.5 cents or 2.9 percent to 50 cents.