



Biotech Daily

Wednesday September 30, 2026

Daily news on ASX-listed biotechnology companies

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- * ALCIDION: NORTHERN CARE NHS \$7.5m MIYA FLOW EXTENSION
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- * INVION \$400k CHAIR, DIRECTOR LOAN
- * CYNATA EXTENDS RDTI LOAN REPAYMENT TO NOVEMBER 30
- * RECCE 249N NOTICE CALLS FOR 'MEETING REQUESTS, DIRECTORS'
- * PINNACLE, FIRETRAIL DILUTED BELOW 5% OF CURVEBEAM
- * JAMES FRAYNE STARTS AS VITURA CFO; TOM HOWITT RESIGNS

MARKET REPORT

The Australian stock market was up 0.92 percent on Wednesday September 30, 2026, with the ASX200 up 80.0 points to 8,789.3 points. Eighteen of the Biotech Daily Top 40 companies were up, 11 fell, 10 traded unchanged and one was untraded.

Impedimed was the best, up 0.1 cents or 25 percent to 0.5 cents, with 11.0 million shares traded. Micro-X climbed 16.3 percent; Aroa and EBR were up more than seven percent; 4D Medical, Alcidion, Compumedics, Curvebeam, Proteomics and Starpharma were up four percent or more; Avita, Clinuvel and Orthocell rose more than two percent; CSL, Imricor, Nanosonics, Resmed and Saluda were up one percent or more; with Artrya, Neuren and Pro Medicus up by less than one percent.

Prescient led the falls, down 0.5 cents or 6.9 percent to 6.7 cents, with 2.5 million shares traded; followed by Actinogen, down 0.4 cents or 6.7 percent to 5.6 cents, with 10.6 million shares traded. Lumos lost 4.8 percent; Cochlear was down 3.3 percent; Imugene, Racura and Telix shed more than two percent; Emvision, Medical Developments and Resonance fell more than one percent; with Clarity and Polynovo down by less than one percent.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed FTI Consulting as its voluntary administrator and has continued its suspension from quotation.

Last week, Paradigm halted its 538-patient, phase III trial of injectable pentosan polysulfate sodium, or Zilosul, for knee osteoarthritis, citing the data safety monitoring board finding that the interim efficacy result “did not reach the pre-specified threshold required for the study to continue” (BD: Sep 23, 2026).

In 2015, Paradigm listed on the ASX to develop pentosan polysulfate sodium for bone marrow oedema and allergic rhinitis (BD: June 18, 2015).

Last week, Paradigm said it would assess its financial position and future operations, including potential trial wind-down costs, remaining contractual commitments, future funding requirements and its rights and obligations under its funding arrangements.

Today, the company said it appointed FTI Consulting’s Christopher Pattinson and Hayden White as administrators to conduct “an independent assessment of the company and its ongoing future viability, including an assessment of possible restructuring options”.

Paradigm said the decision followed discussions with Obsidian Global on “the financial implications of the interim clinical trial outcome and potential restructuring options”.

The company said it “required time to resolve the mismatch between current liabilities payable in the short term and the inherent long-term value of the intellectual property”.

Paradigm said it would work with Obsidian and stakeholders on a deed of company arrangement with the objective of restructuring its liabilities, preserving intellectual property and available clinical data, and assessing a viable path forward.

The company said it would continue analyzing the interim study data and review its clinical program, subject to the administrators’ assessment and available resources, to improve its understanding of the interim outcome, including the impact of missing data, and inform future development and commercial options.

Paradigm said it expected the clinical review and restructuring process to take at least eight weeks and expected to hold a first meeting of creditors on October 9, 2026.

Separately, the ASX said it determined Paradigm’s financial condition was not adequate to warrant continued quotation and extended the suspension under Listing Rule 17.3.

Paradigm was in a suspension and last traded at 24.5 cents.

CURRUS BIOLOGICS

Currus says the US Food and Drug Administration has cleared its investigational new drug application (IND) for an up-to 43-patient, phase I trial of CUR-001 for solid tumors. Melbourne's Currus said that the trial would investigate the chimeric antigen receptor (CAR) CUR-001 for mesothelin-positive advanced refractory.

The company said that CUR-001 combined its 'bispecific engagers of antigen presenting cells and T-cells' (Beat) antibody, CURB-001, with CURT-001, a peptide protein FLAG-tagged autologous CAR-T-cell therapy targeting mesothelin, a protein expressed at high levels across a range of solid tumors.

The company said that Beat was designed to activate CAR-T-cells in lymphoid tissue by engaging both the CAR-T-cells and professional antigen-presenting cells, helping to overcome the suppressive effects of the tumor micro-environment.

Currus Biologics chief executive officer Sam Cobb told Biotech Daily that the escalation phase Ia trial would enrol up to 16 cancer patients and the expansion phase would have up to 43 patients, including the initial 16.

In a media release the company said that this was "the first clinical program from [its] Beat platform, designed to overcome the barriers that have limited CAR-T-cell therapy in solid tumors.

Currus said the open-label basket study would recruit patients with mesothelin-positive advanced refractory solid tumors, with the first patient expected to be dosed in early 2027. The company said that Beat was "a proprietary, universal, bispecific antibody platform to unlock CAR-T-cell therapy for solid tumors".

Currus said that CAR-T-cell therapies had proved effective against blood cancers, but the impact in solid tumors, about 90 percent of all cancers, was limited.

"In solid tumors, CAR-T-cells face a highly immune-suppressive tumor micro-environment that drives exhaustion and restricts their ability to expand, persist and infiltrate tumor tissue effectively," the company said.

Currus said in pre-clinical models, this "enhanced CAR-T-cell expansion, persistence and tumor infiltration while generating epitope spreading and immunological memory".

Ms Cobb said that "receiving IND clearance from the FDA is a major milestone for Currus and an important step in bringing the Beat into the clinic".

"CUR-001 is designed to overcome key barriers that have limited the impact of CAR T-cell therapies in solid tumors, an area of significant unmet need," Ms Cobb said.

Currus is a private company.

ALCIDION GROUP

Alcidion says it has a \$7.5 million, three-year deal with Manchester, England's Northern Care Alliance NHS Foundation Trust for the use of its Miya Flow software.

Alcidion said under the expanded contract it would upgrade the existing Extramed Flow at Salford Royal Hospital to Miya Flow and add additional sites across the Trust.

In 2021, the company said it paid GBP5.3 million for Extramed, a UK provider of patient flow software with nine UK National Health Service (NHS) Trusts (BD: Apr 15, 2021).

Today, Alcidion said the contract included options to extend for a further two years and expand to additional modules, with \$4.5 million in revenue expected this year, including a six-month renewal of the Extramed subscription while Miya Flow is implemented.

Alcidion managing-director Kate Quirke said the expanded agreement would "see Miya Flow deployed more broadly across the Trust, replacing and upgrading the existing Extramed capabilities and supporting operational efficiency across multiple sites".

Alcidion was up half a cent or 4.8 percent to 11 cents with 2.8 million shares traded.

TELIX PHARMACEUTICALS

Telix says it has US Food and Drug Administration fast track status for its 'Bypass' program of gallium-68-based PSMA-PET for pre-biopsy prostate cancer imaging. Earlier this month, Telix said it enrolled all 350 patients in a phase III trial of its gallium-68-based Illuccix and Gozellix prostate specific membrane antigen (PSMA) positron emission tomography (PET) kits alone and in combination with magnetic resonance imaging (MRI) for pre-biopsy prostate cancer imaging (BD: Sep 2, 2026).

Today, the company said fast track was "a process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fill an unmet medical need, potentially accelerating patient access if approved".

Telix said it had "positively engaged with the FDA on a new drug application pathway and is planning its submission".

The company said "the [new drug application] pathway supports registration as a new product which, if approved, would broaden access to gallium-68 PSMA-PET imaging for a substantially larger patient population".

Telix said the biopsy of the prostate avoidance stratification (Bypass) study built on previous studies which showed that combining gallium-68 PSMA-PET imaging with MRI could "significantly improve detection of clinically significant prostate cancer while reducing unnecessary biopsies by almost 50 percent".

The company said 'Bypass' was not intended to replace biopsy when it benefitted the patient but aimed "to improve the diagnostic pathway by helping clinicians determine which patients would benefit from biopsy and where biopsy should be targeted".

Telix chief medical officer Dr David Cade said fast track designation reflected the FDA's "recognition of the potential for 'Bypass' to address an important unmet need in the prostate cancer diagnostic pathway".

"We believe gallium-68 PSMA-PET, used alongside MRI, could help physicians make more informed decisions before biopsy, improve diagnostic confidence and potentially reduce unnecessary invasive procedures for patients," Dr Cade said.

"This designation supports continued close engagement with the FDA as we advance 'Bypass' toward an [new drug application] submission," Dr Cade said.

Telix fell 43 cents or 2.7 percent to \$15.72 with 2.9 million shares traded.

BCAL DIAGNOSTICS

Bcal says clinical validation of its Breastest Plus 2 blood test shows sensitivity of 80.3 percent and specificity of 48.5 percent for stage zero to stage two breast cancer.

Bcal said the Breastest Plus 2 was developed "to provide women greater surety they do not have the disease ... [and that] a 'normal' test result supports reassurance".

The company said the test was "not a diagnosis" and, as with other screening tests, further assessment was needed to confirm a result.

Bcal said the test was validated in women aged more than 30 years old, with 61.9 percent of the cancers detected in the study stage zero or stage one.

The company said the results supported the test's clinical use, with commercialization expected in November 2026 beginning in Sydney, Melbourne and Brisbane.

Bcal did not disclose the number of patients tested during the clinical validation.

Bcal chief executive officer Annie Arnett said Breastest Plus 2 was "a significant advance in Bcal's offering to the market, expanding patient eligibility and clinician access, and strengthens our position to deliver earlier breast-health assessment to a larger population of Australian women".

Bcal was up 0.9 cents or 11.1 percent to nine cents.

INOVIQ

Inoviq says an independent review confirms study evidence supporting the biological relevance of its Exo-ovarian cancer (OC) test and it will continue to develop the test. Earlier this year, Inoviq fell as much as 54.1 percent, following the announcement that 1,200 samples in an expanded study of its Exo-ovarian cancer (OC) test were deemed unsuitable due to significant quality variability (BD: Jul 1, 2026).

Today, the company said Dr Mathew Moore from the Irvine, California-based diagnostics organization Researchdx was commissioned to conduct a review of the findings and found that its assessment “accurate, reproducible and appropriately interpreted”.

Inoviq said the review found that pre-analytical sample collection and handling differences “were the largest identified source of study variability”.

The company said that the samples used “contained substantially lower measurable [micro] RNA biomarker levels than the earlier ... study”.

Inoviq said “the reduced amount of quantifiable biomarker data prevented meaningful evaluation of the Exo-OC algorithm across the full ... cohort”.

The company said the review recommended that the Exo-OC program focus on “optimizing tumor-specific [extra-cellular vesicle] capture to increase signal-to-noise ratio, refining the biomarker panel and implementing consistent sample collection protocols before further clinical evaluation”.

Inoviq said it would begin assay optimization before conducting clinical verification in an independent cohort, with laboratory validation expected by July 2028 prior to US commercialization of Exo-OC as a laboratory developed test.

Inoviq chair Peter Gunzberg said that the company was “very disappointed that the poor quality of the biobank samples led to the discontinuation of the OC2200 study”.

“However, the thorough review, including Dr Moore's report, validates the company's technical assessment and gives us additional confidence that we understand the key factors that contributed to the OC2200 study outcome,” Mr Gunzberg said.

“Importantly, the review confirmed that these factors are addressable through assay optimisation and standardised sample collection protocols,” Mr Gunzberg said.

“The board believes that notwithstanding the ... results, our science is sound and we now continue to advance the Exo-OC test towards commercialization in the US with an enhanced understanding of what is required to succeed,” Mr Gunzberg said.

Inoviq was unchanged at 16.5 cents.

IMAGION BIOSYSTEMS

Imagion says it has Advarra Inc central institutional review board ethics approval to begin its phase Ib/II trial of Magsense Her2 imaging for breast cancer in the US.

Earlier this year Imagion said that it had US Food and Drug Administration investigational new drug approval for a 70-patient, phase Ib/II trial of its Magsense human epidermal growth factor receptor-2 (HER-2) imaging agent for breast cancer (BD: Jun 2, 2026).

Today, the company said that central institutional review board approval was “a significant milestone and clears a key ethics and regulatory requirement prior to patient enrolment”.

Imagion said the Columbia, Maryland-based Advarra's review confirmed that the study protocol, informed consent process and participant safeguards meet US ethical and regulatory standards for clinical research involving human participants.

The company said with its clinical trial partners it would finalize site activation activities, including site contract execution, investigator training, and patient recruitment planning, with first patient enrolment expected following first site activation.

Imagion was unchanged at 0.75 cents with 1.6 million shares traded.

VITRAFY LIFE SCIENCES

Vitrafy says it has partnered with the Milwaukee, Wisconsin-based Versiti Blood Health Inc to develop its cryo-preservation ecosystem for platelets.

Vitrafy said Versiti was a non-profit blood network and the partnership would contribute resources to advance development of its cryo-preservation ecosystem for no-wash platelet cryo-preservation within Versiti's platelet workflows.

The company said Versiti was Vitrafy's third US civilian blood partnership, following the previously announced partnerships with Vitalant and Hoxworth Blood Center, both of which were focused on red blood cells (BD: Jun 2, Jul 23, 2026).

Vitrafy said blood products supplied under the partnership would support verification and validation activities for its cryo-preservation freezer for currently approved cryo-preserved blood products, such as plasma.

The company said its partnerships were "directed at completing US medical device listing for Vitrafy's cryo-preservation freezer, targeted for 2026-'27".

Vitrafy said Versiti intended to explore the application of its cryo-preservation ecosystem to other blood products, including red blood cells.

The company said it would place two cryo-preservation units at Versiti's facility in Milwaukee, with the units to be provided without charge and non-revenue generating.

Vitrafy said it would fund certain verification and validation services undertaken by Versiti on its behalf related to the US Food and Drug Administration medical device listing process currently underway.

Vitrafy was up 57 cents or 16.6 percent to \$4.00 with 272,433 shares traded.

VECTUS BIOSYSTEMS

Vectus says the US Food and Drug Administration has granted a pre-investigational new drug type B meeting for VB0004 in idiopathic pulmonary fibrosis (IPF).

Vectus said VB0004 was its first-in-class oral vasoactive intestinal peptide (VIP)-mimetic and natriuretic peptide receptor C (NPR-C)-agonist in development and that it had completed a phase Ia clinical study in healthy volunteers showing favorable safety.

In 2022, the company said its phase I, dose-escalation, safety, tolerability and pharmacokinetics trial of VB0004, had 'no significant adverse side effects (BD: Sep 14, 2022).

Today, Vectus said regulatory activities were underway to establish development in the US and the FDA's responses were expected by mid-November 2026.

The company said with its US regulatory agent Cardinal Health Regulatory Services it would finalize and submit its meeting package to the FDA.

Vectus was unchanged at 11 cents.

CLEO DIAGNOSTICS

Cleo says it has filed two provisional patent applications in Australia to protect intellectual property related to its pre-surgical ovarian cancer test.

A spokesperson for the company told Biotech Daily that the patents, titled 'Protein Biomarkers for Detecting Malignant Gynecological Cancer', if granted, would protect its intellectual property until 2046.

Cleo said it intended "to file an international application under the Patent Cooperation Treaty within the 12-month priority period".

The company said both patent filings related to candidate biomarker combinations and their application to the early detection of ovarian cancer.

Cleo was up half a cent or 1.8 percent to 28.5 cents.

MAYNE PHARMA

Mayne Pharma says Mumbai's Sun Pharmaceutical Industries has agreed to resolve the US patent infringement litigation relating to Imvexxy, with no financial penalty.

In 2024, Mayne said it filed a patent infringement lawsuit against Sun Pharmaceutical Industries Ltd in the US District Court for the District of New Jersey (BD: Jul 25, 2024).

At the time, the company said the suit alleged "infringement by Sun Pharma of all 20 Orange Book listed patents relating to [its] Imvexxy, estradiol vaginal inserts".

Today, Mayne said the settlement provided an agreed pathway for potential future entry of a Sun Pharma generic product on October 21, 2032, or earlier under certain circumstances, subject to court approval of the settlement terms.

The company said the settlement did not include any financial payment or upfront monetary consideration between the parties.

Mayne chief executive officer Aaron Gray said resolving the litigation was "an important step in protecting the value of Imvexxy".

"The agreed pathway strengthens our longer term planning for Imvexxy within our menopause portfolio as part of our overall women's health business," Mr Gray said.

"We will continue to actively manage and defend our [intellectual property] estate and execute on access and patient support initiatives to maximise the product's patent life and long-term contribution," Mr Gray said.

Mayne Pharma was up nine cents or 3.2 percent to \$2.92.

ANTEOTECH

Anteotech says it has received \$1,905,639 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Anteotech said the incentive related to expenditure during the year to June 30, 2026.

Anteotech fell 0.1 cents or 6.25 percent to 1.5 cents with 21.2 million shares traded.

IMMUTEP

Immutep says it has received \$856,669 from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

Immutep said the incentive followed Ausindustry's approval of its advance overseas finding for eligible research and development expenditure undertaken outside of Australia for the year to June 30, 2025.

The company said the incentive was in addition to its Australian activities and French tax incentive through its subsidiary Immutep SAS for expenditure on activities in the EU.

Immutep said the funds would be used for the development of 'efti' and IMP761.

Immutep was unchanged at 3.4 cents with 6.7 million shares traded.

INVION

Invion says it has a \$400,000 loan at 8.0 percent yearly interest from executive chair Prof Thian Chew and director Alan Yamashita for working capital requirements.

Invion said Prof Chew and Mr Yamashita had provided \$200,000, each, with the loan repayable within four months from each advance.

The company said the lenders could elect to convert all or part of the outstanding amounts into shares at five cents each, a 26 percent premium to the 30-day volume weighted average price, subject to shareholder approval.

Invion fell 0.1 cents or 2.6 percent to 3.7 cents.

CYNATA THERAPEUTICS

Cynata says it has extended the maturity date of its Research and Development Tax Incentive loan from September 30 to November 30, 2026.

Earlier this year, Cynata said following two negative trial results all employees, would be made redundant, with a reduced board to evaluate future options (BD: Jul 6, 2026).

Today, the company said it had suspended or terminated outsourced activities “to the maximum extent possible, whilst preserving the company’s intellectual property” and it had a \$600,000 loan secured against its expected \$1.7 million Federal Government Research and Development Tax Incentive for the year to June 30, 2026.

Today, Cynata said it had submitted its Tax Incentive claim and tax return for 2025-'26, with the incentive expected “imminently”, when the loan and interest would be repaid.

Cynata was unchanged at 1.1 cents.

RECCE PHARMACEUTICALS

Recce says it has a Corporations Act (2001) section 249N notice calling for members to express opinions, form an advisory council and appoint directors.

Recce said the section 249N notice from substantial shareholder Gavin William Brown included a resolution to amend the company’s constitution to allow members in general meetings “to express an opinion or make a request or recommendation to the directors”. The company said the notice called for an advisory council, independent of directors and executives, to conduct a review within 60 days on clinical programs, commercialization, capital structure, board and executive structure and remuneration, and consulting.

Recce said the notice included nominations for Dr Paul MacLeman, Dr Jurgen Michaelis, Amos Meltzer and Diana Forsyth for election as directors at the annual general meeting. The company said it was reviewing the nominations against the requirements of its constitution and the ASX Listing Rules.

Recce fell one cent or 3.1 percent to 31.5 cents.

CURVEBEAM A.I.

Both Firetrail Investments and Pinnacle Investment Management say they were diluted below the five percent substantial threshold in Curvebeam.

The Brisbane-based companies’ secretary Terence Kwong filed the notices.

Earlier this month, Curvebeam said it raised \$1.75 million in its shortfall offer, taking the total raised with the placement and share plan to \$7.36 million (BD: Sep 18, 2026).

Curvebeam was up 0.1 cents or 4.55 percent to 2.3 cents with 5.8 million shares traded.

VITURA HEALTH

Vitura says James Frayne has begun as chief financial officer, effective from today, with Tom Howitt resigning as interim chief financial officer.

Earlier this year, Vitura said it appointed Mr Frayne as its chief financial officer and Trudy Adams as head of strategy and technology (BD: Jul 22, 2026).

Vitura was up 0.1 cents or 5.3 percent to two cents.