



Biotech Daily

Wednesday September 2, 2026

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH EVEN: COMPUMEDICS UP 8%; SALUDA DOWN 8%**
- * **PROTAGONIST: FDA OKAYS PTG-300 FOR POLYCYTHEMIA VERA; \$1.6b**
- * **DIMERIX REQUESTS 'NON-DILUTIVE FUNDING' TRADING HALT**
- * **TELEX ENROLS PHASE III ILLUCCIX, GOZELLIX PRE-BIOPSY TRIAL**
- * **ONCOSIL FILES BILE DUCT CANCER DEVICE TO US MEDICARE**
- * **VITRAFY, CHARTER MEDICAL GUARDION FREEZER CONTRACT**
- * **ADALTA BZDS1901 MESOTHELIOMA CHINA SPECIAL ACCESS SCHEME**
- * **PRESCIENT DOSES 50% OF PHASE IIa PTX-100 BLOOD CANCER PATIENTS**
- * **TISSUE REPAIR RESUMES AUSTRALIA, NEW ZEALAND DIRECT SALES**
- * **RESMED UP-TO \$630m SHARE BUY-BACK**
- * **RECCE EGM DEFEATS ALL 6 RESOLUTIONS**
- * **BLACKROCK REDUCES TO 6% OF COCHLEAR**
- * **FIRETRAIL DILUTED TO 7% OF CURVEBEAM**
- * **PINNACLE INCREASES, DILUTED TO 7% OF CURVEBEAM**
- * **ILWELLA BELOW 5% OF CURVEBEAM**
- * **VANGUARD BELOW 5% OF CLINUVEL**

MARKET REPORT

The Australian stock market fell 0.97 percent on Wednesday September 2, 2026, with the ASX200 down 88.3 points to 8,978.4 points. Thirteen of the Biotech Daily Top 40 were up, 14 fell, 12 traded unchanged and one was untraded. The four Big Caps were mixed.

Compumedics was the best, up 2.0 cents or 7.8 percent to 27.5 cents, with 120,873 shares traded; followed by Paradigm, up 1.5 cents or 7.3 percent to 22 cents, with 3.2 million shares traded. Optiscan climbed 6.7 percent; Actinogen and Micro-X were up four percent or more; Telix rose 2.75 percent; Avita, Clinuvel, Cochlear, Emvision, Mesoblast, Proteomics and Resonance were up more than one percent; with CSL and Neuren up by less than one percent.

Saluda led the falls, down 3.5 cents or 7.7 percent to 42 cents, with 507,309 shares traded. Immutep, Imricor and Nova Eye lost more than three percent; Clarity, Orthocell, Pro Medicus and Resmed shed more than two percent; Aroa, Cyclopharm, EBR and Racura fell one percent or more; with 4D Medical, Artrya, Nanosonics and Polynovo down by less than one percent.

PROTAGONIST THERAPEUTICS

Brisbane's Protagonist says Takeda has US Food and Drug Administration approval for subcutaneous Mimrylo (rusfertide or PTG-300) for the blood cancer polycythemia vera. Protagonist said that approval was granted by the FDA on Friday US time; and triggered \$US275 million in milestones, 14-29 percent royalties, with up to an additional \$875 million "in potential future milestones".

Last year, Protagonist said its 293-patient, phase III trial of rusfertide for polycythemia vera met its primary endpoint ($p < 0.0001$) and all four secondary endpoints, earning it a \$US25 million (\$40.3 million) milestone payment from partner Takeda (BD: Mar 4, 2025). In a media release, the company said that Mimrylo was "the first and only hepcidin mimetic peptide therapy approved for the treatment of erythrocytosis in adults with polycythemia vera, offering a novel mechanism to maintain haematocrit control, meaningfully reduce phlebotomy burden, and improve fatigue".

Protagonist chief executive officer Dr Dinesh Patel said the approval was "a paradigm shifting approach to management of [polycythemia vera]".

"Mimrylo mimics the action of hepcidin, the body's natural master regulator of iron availability thereby controlling haematocrit levels and helping restore iron balance," Dr Patel said.

"Mimrylo was conceived 14 years ago with the idea that a mimetic of hepcidin, the body's primary regulator of iron homeostasis, could address the underlying biology of erythrocytosis in [polycythemia vera]," Dr Patel said.

"The approved label also reflects improvement in fatigue," Dr Patel said.

"This is Protagonist's second FDA approval in 2026, reflecting years of disciplined investment in the right type of innovative projects, and working with the right partners at the right time," Dr Patel said.

"With two approved products validating our peptide-centric drug discovery and development acumen and a strong financial foundation, the company is now focused on leveraging its expertise to advance the next generation of wholly-owned product candidates in IL-17, obesity, and beyond with the intent of addressing unmet needs of patients and creating long-term value for our shareholders," Dr Patel said.

In March, Protagonist said that it had FDA approval for Icotyde, or icotrokinra, for moderate to severe plaque psoriasis.

The company said that polycythemia vera was characterized by the excessive production of red blood cells (erythrocytosis), leading to elevated haematocrit which can increase blood viscosity, or thickness, which had the potential to result in life-threatening thrombotic events, including stroke, deep vein thrombosis and pulmonary embolism.

Protagonist said that patients with polycythemia vera might experience burdensome symptoms, including severe fatigue, pruritus (itching), difficulty concentrating and night sweats and patients experiencing uncontrolled haematocrit have a four times higher risk of cardiovascular death or major cardiovascular events compared to patients who achieve a haematocrit of less than 45 percent.

On the Nasdaq, on Monday US East Coast time, Protagonist closed at \$US147.75 (\$A206.85) with 567,300 shares traded.

DIMERIX

Dimerix has requested a trading halt "pending an announcement by the company in relation to non-dilutive funding arrangements".

Trading will resume on September 4, 2026, or on an earlier announcement.

Dimerix last traded at 29 cents.

TELIX PHARMACEUTICALS

Telix says it has enrolled all 350 patients in a phase III trial of its gallium-68-based Illuccix and Gozellix kits for pre-biopsy prostate cancer imaging.

Earlier this year, Telix said it dosed the first US patient in the open-label, phase III trial of Illuccix and Gozellix prostate specific membrane antigen (PSMA) positron emission tomography (PET) imaging for prostate cancer (BD: Jan 19, 2026).

At the time, the company said the study aimed to determine whether combining magnetic resonance imaging (MRI) with Illuccix or Gozellix could “improve diagnostic accuracy and reduce unnecessary biopsies compared to current standard practice”.

In 2022, Telix said it had US Food and Drug Administration approval for Illuccix; and last year, said the FDA approved ‘Gozellix’ (BD: Apr 4, 2022; Jun 12, 2025).

Today, the company said if the trial met its primary objectives, the data, alongside evidence from previous studies had “the potential to shift gallium-68 PSMA-PET beyond its current use in initial staging and secondary re-staging at disease recurrence and establish precision imaging as a critical step in initial diagnosis”.

Telix chief medical officer Dr David Cade said that “instead of asking how best to stage prostate cancer, clinicians may increasingly use advanced imaging to determine which men need to undergo biopsy in the first place”.

Telix was up 42 cents or 2.75 percent to \$15.69 with 1.9 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has applied for US Centers for Medicare & Medicaid Services (CMS) transitional pass-through payment status for its cholangio-carcinoma radiotherapy device. Last month, Oncosil said it had US Food and Drug Administration humanitarian device exemption approval for its radiotherapy device for the treatment of distal cholangio-carcinoma, a form of bile duct cancer (BD: Aug 17, 2026).

Today, the company said the CMS application was submitted on September 1, 2026 and sought separate, supplemental Medicare reimbursement for its device at a proposed price of \$US55,000 (\$A77,000) per dose.

Oncosil said it expected a US Centres for Medicare & Medicaid Services decision and an effective date for reimbursement by January 1, 2027, subject to approval.

The company said it would conduct a mandatory, multi-centre, prospective, 30-patient post-approval study at five academic medical centres, with a follow-up period of about 24 months from the last patient enrolled, with FDA consent to expand distribution expected following enrolment of the 30 patients.

Oncosil said the transitional pass-through payment status would provide supplemental Medicare reimbursement for the device for up-to three years from launch, “an important component of the company’s US commercialization strategy”.

The company said that, if approved, reimbursement was “expected to support adoption at the academic medical centres participating in the company’s mandatory FDA post-approval study, facilitating early clinical utilization ... while helping establish the reimbursement foundation for broader US payer coverage over time”.

Oncosil said that US reimbursement was “a critical near-term priority”.

Oncosil managing-director Nigel Lange said the submission was “the next critical step in our US commercialization strategy, building directly on last month’s ... approval”.

“Securing [transitional pass-through] status would give academic medical centres the reimbursement certainty they require to bring Oncosil to patients ... quickly and lays the foundation for broader US payer coverage as we scale,” Mr Lange said.

Oncosil fell six cents or 5.3 percent to a post-consolidation \$1.075.

VITRAFY LIFE SCIENCES

Vitrafy says it will install a Guardion cryo-preservation freezing unit with Lifechain software at Charter Medical Innovation Hub, for cell and gene therapy customers.

Vitrafy said the Winston-Salem, North Carolina-based Charter Medical would use its technology to support cryo-preservation and freeze-curve optimization studies.

The company said freeze-curve optimization was “a challenge in [the] cell and gene therapy process, with improvements in cell recovery critical to advancing clinical outcomes and reducing cost”.

Vitrafy said that its Guardion unit was designed to deliver controlled, reproducible freeze profiles across a wide range of cell lines, with Lifechain capturing processing data to deliver improved cryo-preservation protocols and outcomes.

Vitrafy said the agreement was its first in cell and gene therapy as well as its first in North America, which had thousands of ... registered contract manufacturers”.

The company said the agreement was for an initial six-months with deployment expected by July 2027 and no revenue to be generated over the initial term.

Vitrafy managing-director Brent Owens said the agreement was “a significant milestone as our first product deployment in cell and gene therapy, incorporating Vitrafy’s cryo-preservation hardware and Lifechain software platform from the outset”.

“Freeze-curve optimization across different cell lines is a real and unresolved problem for cell and gene therapy manufacturers, and one our ecosystem is built to solve,” he said.

“Charter Medical has supplied the advanced therapy sector for more than 30 years and works with the [contract development and manufacturing organizations] and therapy developers we are targeting, so this deployment puts our technology directly in front of those customers with a trusted market leader,” Mr Owens said.

Vitrafy was up 24 cents or 6.2 percent to \$4.10.

ADALTA

Adalta says co-development partner Shanghai Cell Therapy Group will supply BZDS1901 to mesothelioma patients in China under a special access scheme.

In January, Adalta said through its Adcella ‘East-to-West’ strategy it would develop Shanghai Cell Therapy’s BZDS1901 for mesothelioma outside China (BD: Jan 18, 2026).

Last month, the company said five of 10 mesothelioma patients in a China study treated with EW-001, formerly BZDS-1901, remained alive and on study, providing an overall response rate of 50 percent (BD: Aug 10, 2026).

Today, Adalta said BZDS1901 was a China version of EW-001, its lead chimeric antigen receptor (CAR)-T cell therapy containing the same engineered features.

The company said Shanghai Cell Therapy’s special access scheme approval allowed it eligible patients with advanced mesothelioma to receive BZDS1901 in China’s Hainan Boao Lecheng International Medical Tourism Pilot Zone.

Adalta said approval was granted after Hainan’s provincial health and medicines authorities assessed the evidence for BZDS1901’s safety and possible efficacy.

The company said it would not receive revenue from patients treated in Hainan and its rights to develop and commercialize EW-001 outside Greater China were unaffected.

Adalta managing-director Dr Tim Oldham said “an independent group of regulators has examined the BZDS1901/EW-001 safety and efficacy data and concluded that the therapy can be offered to patients outside a clinical trial”.

“That is a meaningful external endorsement of a product we have believed in from the outset,” Dr Oldham said.

Adalta was unchanged at 0.3 cents with 5.9 million shares traded.

PRESCIENT THERAPEUTICS

Prescient says it has dosed 20 evaluable patients in its phase IIa trial of PTX-100 for T-cell lymphoma, with a dose optimization committee review expected in December. Earlier this year, Prescient said it dosed the first of up-to 40 patients in the phase IIa trial of PTX-100 for relapsed and refractory cutaneous T-cell lymphoma, a type of blood cancer (BD: May 27, 2025).

Today, the company said patients were considered evaluable on completion of four treatment cycles.

Prescient said the dose optimization committee would “review safety and efficacy data from both dosing arms of the study to provide guidance on continuation of the study for further development”.

The company said enrolment continued towards the full 40-patient target.

Prescient managing-director James McDonnell said reaching the first dose optimization committee meeting reflected “strong execution by our clinical team and the sites supporting this study”.

“We look forward to the dose optimization committee’s review in December as we advance PTX-100 towards its next stage of development,” Mr McDonnell said.

Prescient was unchanged at 6.8 cents with one million shares traded.

TISSUE REPAIR

Tissue Repair says it has resumed direct distribution of its TR Pro+ for aesthetic wound repair in Australia and New Zealand alongside current medical distribution.

In 2024, Tissue Repair said the Australian Therapeutic Goods Administration approved its yeast-based Glucoprime TR Pro+ gel for wound-healing; and last year, said Perth’s Advanced Cosmeceuticals Pty Ltd would distribute TR Pro+ in Australia and New Zealand (BD: Jul 25, 2024; Jul 11, 2025).

Previously, the company said the active ingredient of its topical treatment for wound repair TR Pro+, then called TR987, was Glucoprime, invented by former Novogen and Noxopharm chief executive officer Prof Graham Kelly (BD: Nov 24, 2021).

Today, Tissue Repair said it would assume “direct responsibility for customer relationships, sales, ordering, and account management, as well as customer engagement related to business development opportunities, promotions, and education”. The company said that it did not “anticipate any interruption to customers’ ability to order TR Pro+”.

Tissue Repair chief executive officer Tony Charara said that Advanced Cosmeceuticals had been the company’s distribution partner in Australia and New Zealand since September 2025.

“Tissue Repair has determined that returning to a direct distribution model is the appropriate approach for the next stage of development of the TR Pro+ business,” Mr Charara said.

“Our immediate priority is to ensure continuity for existing customers and a smooth transition of customer relationships and ordering arrangements,” Mr Charara said.

“We look forward to engaging directly with our customers and supporting the continued development of the TR Pro+ business,” Mr Charara said.

In July, Tissue Repair said that it had applied to the ASX requesting its removal from the official list in accordance with Listing Rule 17.11, and to conduct a share buy-back (BD: Jul 23, 2026).

Tissue Repair was up 0.2 cents or 2.3 percent to nine cents.

RESMED

Resmed says it will open an up-to \$US450 million (\$A630 million) on-market share buy-back with New York's Citibank.

Resmed said it was conducting the share repurchase agreement following authorization for the repurchase of an aggregate of 20,000,000 shares of common stock, approved by its board of directors in February 2014; and would fund the buy-back with the proceeds from the sale of its Matrixcare business and existing cash reserves.

Earlier this year, Resmed said it sold its Matrixcare business for \$US490 million in cash to Frazier Healthcare Partners (BD: Jul 8, 2026).

Today, the company said it would pay Citibank \$US450 million on September 3, 2026 and expected to receive shares of common stock equal to 80 percent of \$US450 million divided by the closing price of the common stock on September 2, 2026.

Resmed said the final number of shares to be repurchased would be based on the average of the daily volume weighted average price during the term of the agreement, less a discount and subject to potential adjustments.

Resmed fell 91 cents or 2.7 percent to \$32.28 with 1.6 million shares traded.

RECCE PHARMACEUTICALS

Recce says its extraordinary general meeting has blocked all six resolutions relating to the issue of placement shares and share purchase plan options to directors.

Earlier this year, Recce said it had raised \$2.4 million at 40 cents a share in a share purchase plan, leaving a \$1.6 million shortfall and taking the total raised to \$6.4 million (BD: Jul 31, 2026).

At the time, the company said investors would receive one option for every two shares bought, exercisable at 60 cents each by June 30, 2027, with an additional 'piggyback' option for every two options exercised by the expiry date, exercisable at \$1.00 each by June 30, 2028 and subject to shareholder approval.

Today, Recce said the issue of the attaching options and piggyback options were defeated by 40,998,676 votes (80.76%), with 9,770,055 votes (19.24%) in favor.

The company said that the issue of attaching options and piggyback options to managing-director James Graham was defeated by 41,110,992 votes (59.91%), attaching options and piggyback options for its chair Dr John Prendergast and directors Dr Alan Dunton and Dr Justin Ward blocked by more than 54.49 percent of the meeting; with ratification of the prior issue of shares opposed by 54.81 percent of the meeting.

According to its most recent filing, Recce had 299,718,821 shares on issue, meaning that the votes against the issue of options to Mr Graham amounted to 13.72 percent of the company, sufficient to requisition extraordinary general meetings.

The company said it was "considering the options available to it following the failure to obtain shareholder approval".

Recce was unchanged at 36 cents.

COCHLEAR

Blackrock Group says it has reduced its substantial shareholding in Cochlear from 5,723,271 shares (8.21%) to 4,043,954 shares (5.59%).

New York's Blackrock said that between June 30 and Aug 31, 2026 it bought shares at prices ranging from \$111.61 to \$141.20 and sold shares at prices ranging from \$111.61 to \$141.20 as well as transferring shares in specie for no consideration.

Cochlear was up \$2.10 or 1.6 percent to \$136.45 with 461,927 shares traded.

[CURVEBEAM A.I.](#)

Firetrail Investments says its substantial 40,682,305 share-holding in Curvebeam was diluted from 8.52 percent to 6.74 percent of the company.

In a substantial shareholder notice signed by company secretary Terence Kwong, the Level 19, 307 Queen Street, Brisbane-based Firetrail said that it was diluted by the issue of 120,000,000 shares on August 28, 2026.

Yesterday, Curvebeam said it raised \$606,150 at 1.8 cents a share in a share purchase plan, leaving a \$393,850 shortfall and taking the total raised with a previous placement to \$5,606,150 (BD: Sep 1, 2026).

Curvebeam was unchanged at two cents.

[CURVEBEAM A.I.](#)

Pinnacle Investment Management says it has increased its holding in Curvebeam and been diluted from 34,362,059 shares (8.80%) to 40,682,305 shares (6.74%).

In a substantial shareholder notice signed by company secretary Terence Kwong, the Level 19, 307 Queen Street, Brisbane-based Pinnacle said that between August 6 and December 22, 2025 it bought 6,320,246 shares for \$601,717, or 9.5 cents a share and was diluted in a share issue on August 28, 2026 (see above).

[CURVEBEAM A.I.](#)

Sydney's Ilwella Pty Ltd says it has ceased its substantial shareholding in Curvebeam with the sale of 976,222 shares on August 12 for \$17,534, or 1.8 cents a share and a diluted due to a share issue on August 28, 2026 (see above).

Last year, Ilwella said its 30,370,856 share-holding in Curvebeam was diluted from 8.34 percent to 6.63 percent due to a placement (BD: Oct 9, 2025).

According to its most recent filing, Curvebeam had 733,846,192 shares on issue, meaning that Ilwella retained 4.00 percent of the company.

[CLINUVEL PHARMACEUTICALS](#)

Philadelphia, Pennsylvania's Vanguard Group says it has ceased its substantial shareholding in Clinuvel and retained 4.972 percent of the company.

Vanguard Group said that between August 11 and August 27, 2026 it bought shares at prices ranging from \$9.18 to \$9.70 and sold shares at \$9.18 and \$9.34.

Clinuvel was up 12 cents or 1.5 percent to \$8.36 with 307,736 shares traded.