Biotech Daily

Friday September 19, 2025

Daily news on ASX-listed biotechnology companies

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*** MCRAE BELOW 5% OF NEUROSCIENTIFIC**

*** BERGEN, NEW LIFE, EUGENE TABLIS TAKE 15% OF ADALTA**

MARKET REPORT

The Australian stock market was up 0.32 percent on Friday September 19, 2025, with the ASX200 up 28.3 points to 8,773.5 points. Eighteen of the Biotech Daily Top 40 companies were up, 14 fell, seven traded unchanged and one was untraded.

Amplia was the best, up 2.5 cents or 16.1 percent to 18 cents, with seven million shares traded. Nova Eye climbed 10 percent; Atomo was up 9.5 percent; Clarity and Telix climbed six percent or more; Paradigm was up 5.4 percent; Botanix, Pro Medicus, Proteomics and Starpharma were up four percent or more; Compumedics, Medical Developments and Orthocell were up more than three percent; Cynata, Impedimed and Mesoblast rose more than two percent; Nanosonics and Optiscan were up more than one percent; with Clinuvel, CSL and Resmed up by less than one percent.

Micro-X and Resonance led the falls, down 10.7 percent and 10.5 percent, to 7.9 cents and 3.4 cents, with 785,020 shares and 798,174 shares traded, respectively. Imugene lost 10.3 percent; Curvebeam fell 7.7 percent; 4D Medical and EBR shed more than six percent; Alcidion fell five percent; Aroa, Dimerix and Polynovo were down more than three percent; Imricor shed two percent; Avita, Emvision and Genetic Signatures were down more than one percent; with Cochlear down 0.6 percent.

DR BOREHAM'S CRUCIBLE: PRESCIENT THERAPEUTICS

By TIM BOREHAM

ASX code: PTX

Share price: 4.2 cents; **Shares on issue:** 1,051,514,543; **Market cap:** $44.2 million

Chief executive officer: James McDonnell

Board: Dr James Campbell (chair), Dr Ellen Feigal, Dr Allen Ebens, Dr Gavin Shepherd, Melanie Farris

Financials (year to June 30, 2025): interest income $225,611, loss of $7.3 million (previous $8.23 million deficit), cash of $6.9 million (down 34%)

Identifiable major shareholders: Anthony and Michelle Kittell 3.69%, David Kenley 1.96%, Dr Gavin and Catherine Shepherd 1.67%

As the Wise Man sayeth, one should giv-eth a task to a busy person if one want-eth it done well. Sadly-eth, that doesn't translate too well into the corporate biotech sphere.

Many drug developers proclaim they have 'multiple shots at goals' - more than one clinical program, that is - and are busier than a one-armed bricklayer.

The trouble is, they don't have Sam Kerr - now recovered from injury and back in form - or the funding to get past the goalie.

In the words of Precision Funds Management's Dermot Woods, companies also need to present scientific information in "semi understandable" form.

"It helps if [investors] can pronounce the name of a disease, or it has an action we can remember."

Cancer drug developer Prescient has picked up the simplicity-is-godly vibe, having frozen several cell therapy pursuits to focus on a single blood cancer program.

Not too long ago, Prescient highlighted its acquired assets in the sexy CAR-T space.

Now, it's gone DeLorean and Back to the Future with its more advanced legacy program, PTX-100, to treat the difficult blood cancer, cutaneous T-cell lymphoma (CTCL).

The CAR-T programs have been parked, so to speak.

"You only have so many resources and you need to manage them carefully," says Prescient's new CEO, James McDonnell.

"You need to fight for your cash and have a clear message about what you are going to do with it."

Clear path

While Prescient only has one shot at goal in biotech's penalty shoot-out, there's a clear trajectory into the back of the net.

Having reported "strong" phase Ib trial data, Prescient has embarked on a phase IIa/IIb effort for lead compound PTX-100 (see below).

Management hopes it can become a registration study pitched at regulatory approval - the World Cup of any drug development. The trial dosed the first patients in June.

Mr McDonnell says it's still early days, but "it means a lot to dose the first patient because everything we have done to get to that point is enormous".

The US Food and Drug Administration has bestowed orphan and fast track drug designation on PTX-100.

The Hand of Hopper (with apologies to Diego Maradona)

Prescient evolved from oncology house Virax Holdings, acquiring the 'old' part of its current portfolio, via the acquisition of Aktivate Therapeutics in October 2014.

The $2.3 million scrip deal was engineered by legendary biotech entrepreneur Paul Hopper. For those new to the planet, Mr Hopper was also involved in founding ASX-listed cancer plays Imugene, Chimeric, Radiopharm Theranostics and the acquired Viralytics.

Virax undertook a one-for-20 share consolidation and changed its name to Prescient.

Prescient's foundation programs were PTX-100 and PTX-200, which are not Peruvian airline codes but different disciplines of targeted therapies. A pathway inhibitor, PTX-100 has the ability to block oncogenic pathways called Ras and Rho (see below).

In May 2000, Prescient acquired its Omnicar CAR-T program, from the Ivy League institution University Pennsylvania. This august establishment is reputed to be the home of CAR-T therapy – and who are we to argue?

Mr McDonnell took over from former analyst and molecular biologist Steve Yatomi-Clarke, who had run the company since 2016.

It's no accident that Mr McDonnell has a background in haematological disorders. A registered pharmacist, he has held numerous leadership roles, including the head of global marketing at Pharmion, eventually acquired by Celgene Corporation for $2.9 billion.

More recently, he headed the Swiss mob Vifor Health's Australian operations, before and after the kidney specialist was taken over by CSL in 2022, for circa $17 billion.

Earlier he worked at the ASX-listed Chemgenex, which developed the chronic myeloid leukemia drug Omapro (omacetaxine), as did Prescient chair Dr James Campbell.

About CTCL

Cutaneous T-cell lymphoma (CTCL) is a rare type of cancer that begins in the white T-cells, which boost the immune system.

The T-cells become cancerous and accumulate in the skin, causing symptoms like red, scaly patches or bumps that can resemble eczema or psoriasis.

Unlike with most cancers, the treatment effects are evident with the naked eye.

Common types include mycosis fungoides, a slow-growing form, and the more aggressive Sézary syndrome.

In the US CTCL affects about 3,000 new cases a year and in the case of advanced patients, two-thirds will die within five years.

Mr McDonnell says many CTCL patients have undergone multiple unsuccessful therapies, with no more options.

“Only one third respond and only for an average six months, so there are a lot of relapsed and refractory patients out there.”

About the trial

After the FDA cleared the company’s investigational new drug (IND) application in December, Prescient established the first clinical site at the Epworth Freemasons’ haematology clinical trial unit, overseen by principal investigator Prof Miles Prince.

In late May, the company dosed the first patient, at a Perth site, and so far, the phase IIa trial has dosed four patients at three sites.

“This is a rare disease, so getting patient access is critical,” Mr McDonnell says. “These are significant cancer centres with a significant number of patients.”

The company expects to enrol up to 40 patients - 20 in the initial dose-ranging stanza. The trial targets 15 clinical sites: six in the US and three each in Australia, Italy and France.

The dose methodology is in keeping with the FDA’s desire for drug developers to find the most effective - rather than highest - dose. The first 40 patients will be dosed either 500 or 1,000 milligrams per square metre.

After 20 patients, a dose optimization committee will scrutinize the data.

The study is open label, which means the company can announce the results immediately. Naturally, the phase IIb study will go ahead with the optimal dose. The single-arm effort is expected to enrol about 75 patients who have failed two lines of previous therapy.

But this number could increase if the FDA requires a control group.

Ras-ing things up

What's all the fuss about? In terms of mechanism of action, PTX-100 disrupts the so-called Ras family pathway, which consists of 170 proteins with different purposes.

The 'razzes' are switches that attach to the cell membrane. In tumors, the switches stay on. They need to be turned off, like a dodgy power point that requires a $300 electrician's house call to fix.

As commissioned research house Pitt Street Research describes it, PTX-100 blocks a cancer growth enzyme known as geranyl-geranyl-transferase type 1 (GGT-I).

Yes, it does. Yes it does.

The process also disrupts oncogenic Ras pathways by inhibiting the activation of cancer cells known as Rho, Rac and Ral. The inhibition leads to apoptosis (death) of cancer cells.

"In some ways, PTX-100 isn't different from other cancer drugs in the sense that it is disrupting an aberrant cellular signalling pathway that prevents cells from dying," Pitt Street says. "PTX-100 can block multiple pathways that other inhibitors cannot."

Recognising this, the FDA in April granted fast-track designation to PTX-100, for adults with relapsed or refractory mycosis fungoides (the most common subtype of CTCL).

While Prescient is convinced PTX-100 ultimately works, Mr McDonnell says there's still a lot under the bonnet to understand.

Okay, but where's the evidence?

An earlier phase Ia trial of PTX-100 showed a 45 percent objective response rate (ORR).

Mr McDonnell says this was "way better than the 30 percent we were looking for".
This response also compares with a 36 percent ORR for current therapies, which also have a 36 percent severe adverse event rate. Only four percent of the PTX-100 patients had such side effects.

ORR measures the percentage of patients in a clinical trial whose cancer shows a significant decrease in size, or completely disappears after a treatment. One patient had a complete response - tumor disappearance - sustained for about two and a half years.

The patient duration on trial was 10.7 months, compared with 6.7 months for the standard-of-care.

The earlier trial covered two patient cohorts: those with CTCL and the harder peripheral T-cell lymphoma. Of the 11 responders, seven had CTCL.

"I would hope and expect our duration of therapy [for this cohort] is around the 12-month mark," Mr McDonnell says.

Finances and performance:

Prescient had $6.9 million of cash at June 30 and in July raised a further $9.8 million, in a $6.8 million share purchase plan and $3 million placement at 4.0 cents a share.

Mr McDonnell says management will keep an open mind on funding as the PTX-100 program progresses. Successfully completing phase IIa provides an opportunity to engage with potential funders and partners.

Over the last 12 months, Prescient shares have ranged between 3.7 cents (late November last year) and 5.9 cents (late January this year), peaking at 29 cents in September 2021.

Top marks to FDA

Mr McDonnell says the FDA was expeditious in accepting the company's IND, while the fast-track designation was - well - fast track. Fast-track status means the company doesn't have to wait for the end of the phase IIb trial to request a 'type B' guidance meeting.

Mr McDonnell says: "I would give them a good scorecard at the moment, but we need more information to get down to the nitty gritty."

This of course refers to the mayhem afflicting the agency in the early days of the President Donald Trump administration. Prescient plans a US facility to make the drug, but the FDA had favoured this approach dating well before Mr Trump's election.

Dr Boreham's diagnosis:

Drug developers need to strive for more simplicity in their programs, and need to communicate to investors more clearly as well. In his initial weeks, Mr McDonnell has undergone a blitzkrieg of investor briefings (and media interviews).

"The feedback has been quite positive," he says. "The central theme is that everything is clearer and directed. We have a clear destination, and we need to get there."

Mr McDonnell says beyond ascertaining that a drug candidate works, management must consider commercial aspects such market access, insurance coverage and what clinicians think of the therapy. He says the CAR-T program had no clear funding pathway and would have involved a clunky treatment pathway. "Nothing was easy".

In contrast, PTX-100 offers a clear pathway to approval.

"We just need to deliver on the results," Mr McDonnell says.

Indeed! Could anything be so simple?

Disclosure: Dr Boreham is not a qualified medical practitioner and does not possess a doctorate of any sort. Is that simple enough?

OPTISCAN IMAGING

Optiscan says its fully underwritten, pro-rata, one-for-four renounceable rights offer is expected to raise $17,617,831, including an underwritten $7,786,277 shortfall.
In August, Optiscan said it expected to raise $17,750,992 at 8.5 cents a share in a rights offer, fully-underwritten by shareholder Peters Investments Pty Ltd (BD: Aug 27, 2025).
Today, the company said eligible shareholders applied for 117,232,576 shares worth for $9,964,769, with 91,603,253 shares worth $7,786,277 allocated to the underwriter.
Optiscan was up 0.1 cents or 1.2 percent to 8.5 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says Scenesse, or afamelanotide 16mg, was effective in three vitiligo patients, with all three patients reporting “satisfaction with the therapy” and no safety issues.
Clinuvel said the three patients were treated at a hospital in La Reunion, France as part of its ongoing CUV105 study, and received seven Scenesse implants and up to 40 narrowband ultraviolet B (NB-UVB) phototherapy sessions.
In 2022, the company said it had approval for an up-to six-patient, ‘CUV104’ phase II study of Scenesse as a monotherapy in darker-skin vitiligo patients (BD: May 10, 2022)
In June, Clinuvel said a three-patient, phase II study of Scenesse monotherapy for vitiligo failed to show re-pigmentation of depigmented skin (BD: Jun 18, 2025).
Today, the company said the results, presented to the European Academy of Dermatology and Venereology conference in Paris, evaluated the three patients at the first follow-up visit, 14 weeks after treatment was completed, with results focusing on the extent and stability of re-pigmentation following treatment.
Clinuvel said the three patients had Fitzpatrick skin types IV and V and long-standing disease, with one having previously been resistant to topical treatments and another having relapsed following partial treatment.
Clinuvel head of global clinical affairs Dr Emilie Rodenburger said “Vitiligo patients receiving Scenesse treatment understand that temporary darkening of the entire skin surface is required to activate the pigment to reverse vitiligo”.
Clinuvel was up two cents or 0.2 percent to $11.54 with 494,713 shares traded.

ECHO IQ

Echo IQ says it is aware of media and market speculation on its US current procedural technology (CPT) code application for Echosolv AS but has no indication of the result.
According to Commsec data, Echo IQ fell as much as 5.5 cents or 22.0 percent to 19.5 cents after an ASX “pause in trading” ended.
Echo IQ said it presented to the American Medical Association CPT editorial panel meeting for a category III CPT code for Echosolv AS and “wishes to advise it has not received an indication of panel votes at this time”.
The company said the meeting results would be announced by the American Medical Association “in the next two to four weeks”.
Last year, Echo IQ said it had US Food and Drug Administration 510(k) clearance to market and sell Echosolv AS for detecting aortic stenosis (BD: Oct 8, 2024).
Today, Echo IQ said it would continue to focus on the ongoing deployment of Echosolv AS with hospital groups, strategic partners and clinics in the US and continue to progress US Food and Drug Administration clearance for Echosolv HF, new product development and licencing and partnership opportunities for Echosolv technology.
Echo IQ closed down five cents or 20 percent at 20 cents with 20 million shares traded.

QBIOTICS

Qbiotics says it has dosed the first three of up-to 40 patients in stage two of its phase IIa trial of tigilanol tiglate for advanced and metastatic soft tissue sarcoma.

In 2023, Qbiotics said it had treated the first of 10 patients in its open-label, single-arm, preliminary efficacy trial of intra-tumoral tigilanol tiglate for soft tissue sarcoma in the US (BD: Jun 13, 2023).

At that time, the company said tigilanol tiglate was “a small molecule targeting a range of solid tumors” and that the drug was registered and marketed as a cancer drug for animals under the trade name Stelfonta, in the US, Europe, the UK and Australia.

In 2024, Qbiotics said the trial showed tigilanol tiglate had exceeded “the primary endpoint for a promising response” and was safe (BD: Sep 17, Nov 19, 2024)

Earlier this year, the company said further data from the trial showed tigilanol tiglate had “rapid systemic clearance after intra-tumoral injection” (BD: Feb 17, 2025).

In June, Qbiotics said its 11-patient trial showed tigilanol tiglate led to eight of 10 evaluable soft tissue sarcoma patients having an objective response (BD: Jun 25, 2025).

Today, the company said the second stage, an expansion arm in up-to 40 additional patients, had both the original study objectives, as well as new primary objectives including evaluating the effect of tigilanol tiglate on objective response rate and overall disease control, and a “new exploratory objective” of evaluation of metabolites following a single intra-tumoral injection of tigilanol tiglate.

Qbiotics chief executive officer Stephen Doyle said “in this arm of the trial, we aim to build on the encouraging response rates observed in stage one and are particularly excited by the potential for tigilanol tiglate to re-sensitize patients to systemic therapies to which they were previously unresponsive”.

Qbiotics is a public-unlisted company.

ISLAND PHARMACEUTICALS

Island says it will have a type C meeting with the US Food and Drug Administration for its investigational new drug application for galidesivir for Marburg virus disease.

In July, Island said it had completed its up-to $US2.5 million ($A3.8 million) acquisition of the Durham, North Carolina-based Biocryst Pharmaceuticals’ galidesivir anti-viral program (BD: Jul 31, 2025).

Earlier this month, the company said it had requested a meeting with the US Food and Drug Administration (FDA) on Galidesivir for Marburg virus disease, as part of its investigational new drug application, with the type C meeting to “seek alignment with the regulator regarding the use of the animal rule for Galidesivir’s” as well as to provide feedback on any other required documentation, study design, quality control and priority review voucher potential (BD: Sep 1, 2025).

Today, Island said the FDA intended to provide it written feedback by November 12, 2025, prior to which Island would submit a full briefing package that included all relevant historical Galidesivir data.

The company said it was also continuing negotiations with “strategic counterparties” to progress an animal study to begin and be completed this year.

Island chief executive officer Dr David Foster said “securing this type C meeting with the FDA represents an important milestone in advancing Galidesivir towards approval”.

“The guidance from the regulator is expected to provide clarity on the potential to leverage the Animal Rule, as well as important insight into study design requirements and galidesivir’s eligibility for a [priority review voucher],” Dr Foster said.

Island was up seven cents or 19.2 percent to 43.5 cents with 3.6 million shares traded.

PYC THERAPEUTICS

PYC has requested a trading halt regarding “pending changes to the board and management of the company”.
Trading will resume on September 23, 2025 or on an earlier announcement.
PYC last traded at 89.5 cents.

ANTERIS TECHNOLOGIES GLOBAL CORP

Anteris says it has again adjourned its meeting to approve the ASX Listing Rule 7.1 waiver to September 29, 2025.
Earlier this month, Anteris said it had postponed its special meeting to provide shareholders “additional time to vote in order to facilitate broader participation”, having initially been scheduled for 5pm US Central Time on September 4 (BD: Sep 4, 2025).
Last week, Anteris said it postponed the meeting to approve the ASX Listing Rule 7.1 waiver, for a second time, again to “facilitate broader participation” (BD: Sep 12, 2025).
In August, the company said it had a “waiver from ASX Listing Rule 7.1 to issue new securities without obtaining security holder approval” (BD: Aug 8, 2025).
Anteris said ASX Listing Rule 7.1 restricted “listed entities from issuing securities in excess of 15 percent of their issued share capital without security holder approval over a 12-month period unless an exception applies”.
Today, the company said it adjourned the special meeting due to lack of a quorum, to September 29, 2025 at 8am (US CT) or September 29 at 11pm (AEST) and on-line.
Anteris fell 26 cents or 3.2 percent to $7.90.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Perth’s McRae Technology Pty Ltd says it has ceased its substantial shareholding in Neuroscientific, selling 3,500,000 shares for $612,500 or 17.5 cents a share.
In July, McRae said it held 19,122,262 shares (5.75%) and Biotech Daily calculates that McRae retains 15,622,262 shares or 4.7 percent (BD: Jul 30, 2025)
Neuroscientific was up 1.5 cents or 9.1 percent to 18 cents.

ADALTA

The Boca Raton, Florida-based Bergen Global Opportunity Fund LP says it has increased its holding in Adalta from 88,925,648 shares (6.73%) to 225,015,037 shares (15.41%).
Bergen said that with New Life Sciences Capital and Eugene Tablis between September 15 and September 17, 2025 they sold 2,799,500 shares and on September 16 acquired 138,888,889 shares for $250,000 or 0.18 cents a share.
In June, Adalta said that it raised $1,090,452 of a hoped for $1,300,000 at 0.3 cents a share, in a two-for-three rights offer; and later said it had placed $193,830 of the $209,548 shortfall to a single, unnamed investor (BD: May 1, Jun 3, 13, 2025).
Adalta was unchanged at 0.3 cents with 1.3 million shares traded.