Biotech Daily

Wednesday July 9, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: BOTANIX UP 17%; CYNATA DOWN 9%**

*** US PRESIDENT TRUMP 200% PHARMACEUTICAL TARIFF 'LITTLE IMPACT'**

*** TELIX: CMS GRANTS GOZELLIX HCPCS CODE**

*** ORTHOCELL RECEIPTS UP 51% TO $5.15m**

*** MONASH A1R-TARGETING DRUG CANDIDATE FOR NERVE PAIN, IN-VITRO**

*** QUEENSLAND UNI NANOBODY 'NEUTRALIZES' HENIPAVIRUSES, IN-VITRO**

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*** CLARIFICATION: NOVA EYE MEDICAL**

*** ISLAND UP-TO $3.8m FOR BIOCRYST'S GALIDESIVIR ANTI-VIRAL**

*** TRUDELL DILUTED TO 13% OF ADHERIUM**

*** JENCAY TAKES 8% OF MEDADVISOR**

MARKET REPORT

The Australian stock market fell 0.61 percent on Wednesday July 9, 2025, with the ASX200 down 52.1 points to 8,538.6 points. Seventeen of the Biotech Daily Top 40 were up, 15 fell, seven traded unchanged and one was untraded. The Big Caps were mixed.

Yesterday's 53.2 percent worst, Botanix, was today's best, up 2.5 cents or 17.2 percent to 17 cents, with 175.2 million shares traded. Avita climbed 7.9 percent; Alcidion, Telix and Universal Biosensors were up five percent or more; Clarity and Genetic Signatures improved more than four percent; Medadvisor was up 3.8 percent; Medical Developments, Neuren, Prescient and Syntara rose more than two percent; Nanosonics was up 1.3 percent; with Aroa, Clinuvel, Cochlear, Dimerix, Pro Medicus and SDI up by less than one percent.

Cynata led the falls, down 1.5 cents or 9.1 percent to 15 cents, with 10,063 shares traded. 4D Medical and Optiscan lost eight percent or more; Nova Eye was down 7.4 percent; Proteomics shed 6.2 percent; Curvebeam fell four percent; Cyclopharm was down 3.4 percent; Amplia, Imugene, Micro-X and Paradigm shed more than two percent; EBR was down 1.3 percent; with CSL, Emvision, Mesoblast, Orthocell and Resmed down by less than one percent.

EDITORIAL: US PRESIDENT DONALD TRUMP PHARMACEUTICAL TARIFFS

Prospective 200 percent tariffs on Australian pharmaceutical exports to be levied by US President Donald Trump are not expected to have a significant impact.

Mr Trump was reported on Australian Broadcasting Corporation Radio saying he would introduce 200 percent tariffs in one year to 18 months.

“We’re going to give people about a year, a year and a half, to come in, and after that they’re going to be tariffed, if they have to bring the pharmaceuticals into the country, the drugs and other things into the country, they’re going to be tariffed at a very, very high rate like 200 percent,” Mr Trump said.

Mr Trump does not face a Presidential election until 2029, but there will be an election in November 2026 for the entire US House of Representatives and one third of the US Senate.

Last year, **CSL** said that $US7,294 million ($A11,156.4 million) of its $US14,800 million revenue, or 49.3 percent, came from the US.

CSL said revenue for the year to June 30, 2024 rose 11.2 percent to a record $US14,800,000,000 with net profit after tax up 20.4 percent to a record $US2,642,000,000 (BD: Aug 13, 2024).

Today, a CSL spokesman told Biotech Daily the President’s remarks were off-the-cuff “and we still don’t have the formal detail”.

CSL said it would “continue to monitor the situation, closely”.

The spokesman told Biotech Daily the company had “an extensive network of blood collection centres in the US, a little under 350 [centres] and the bulk of plasma products used in the US are processed at our US manufacturing facility in Kankakee, Illinois”.

“The same with vaccines,” the spokesman said. “The bulk of vaccines sold in the US are produced at our Holly Springs facility in North Carolina,” the spokesman said.

Neuren managing-director Jon Pilcher told Biotech Daily that his company did not “export any product”.

In 2023, Neuren said North America partner Acadia Pharmaceuticals had US approval for Daybue, or trofinetide, for Rett syndrome (BD: Mar 13, 2023).

In May, Neuren said US sales of Daybue by Acadia for the three months to March 31, 2025 were up 11 percent to $US84.6 million ($A131 million), compared to the prior period with its royalties for the three months up 17 percent to $13.5 million (BD: May 8, 2025). Today, Mr Pilcher said: “Acadia has it made by a third party and has years of stockpile in the US, so I don’t envisage any impact.”

“Of course, we are paid as a percentage of sales, so if there was any impact it would not be on us,” Mr Pilcher said.

A spokesman for **Mesoblast** referred Biotech Daily to a previous statement that "Mesoblast believes that its allogeneic cellular products, including Ryoncil and Revascor, will not be subject to the tariffs" (BD: Apr 4, 2025).

"Mesoblast develops allogeneic products based on its proprietary remestemcel-L and rexlemestrocel-L mesenchymal lineage stromal and precursor cell platform technologies," the company said at that time.

"Its allogeneic cellular products derived from these platforms are manufactured from US donors in the US and designated as US origin products," Mesoblast said.

Orthocell managing-director Paul Anderson told Biotech Daily that Remplir was not a pharmaceutical product.

"We sit within the medical device category and as a result we see no need to manufacture within the US," Mr Anderson said.

"All products are manufactured within Australia and have price parity with similar products in the US unlike the pharmaceuticals," Mr Anderson said.

"So, we are on pretty solid ground," Mr Anderson said.

LTR Pharma executive chair Lee Rodne told Biotech Daily: "We will manufacture in the US for North American sales so we don't expect to be impacted by the tariffs."

In March, LTR said it was developing a second vardenafil-based nasal spray for erectile dysfunction, called 'Roxus', and the US Food and Drug Administration "broadly endorsed" its Spontan development plans (BD: Mar 26, 2025).

Vardenafil is marketed by Bayer as Levitra for erectile dysfunction.

Starpharma chief executive officer Cheryl Maley told Biotech Daily: "Starpharma does not currently manufacture in the US, and does not foresee any impact at this stage."

Acrux managing-director John Warmbrunn told Biotech Daily: "We are in the fortunate position that all our current income generating products are sourced from the US".

"Some other partners have well-developed plans for reshoring to the US, so we believe we are covered," Mr Warmbrunn said. "We are frustrated that the tariffs may limit our future choices as the best, or only, choice of manufacturer for many specialized topical products are often outside the US."

According to the Washington DC-based law firm **Covington & Burling**: "There have been several legal challenges to President Trump's imposition of tariffs under the International Emergency Economic Powers Act of 1977. Three cases filed in the US Court of International Trade and the US District Court for the District of Columbia have resulted in decisions invalidating the IEEPA tariffs, and those decisions are now on appeal."

David Langsam
Editor

TELIX PHARMACEUTICALS

Telix says the US Centers for Medicare & Medicaid Services (CMS) has granted a permanent healthcare common procedure coding system code (HCPCS) for Gozellix.
Earlier this year, Telix said the US Food and Drug Administration had approved its new drug application for TLX007-CDx, or 'Gozellix', with gallium-68 for the positron emission tomography (PET) scanning of prostate-specific membrane antigen (PSMA)-positive lesions in men with prostate cancer (BD: Mar 21, 2025).
In June, the company said Gozellix had an "enhanced formulation, with an extended 'hot' shelf-life of up-to six hours [compared to Illucix and] offers a greater level of patient access and convenience through an extended transportation distance and clinical administration window". (BD: Jun 12, 2025).
Today, Telix said the CMS and commercial health insurers would recognize the HCPCS Level II code A9616 assigned for reimbursement of Gozellix, effective from October 1, 2025, and believed the code would "support clinical adoption of Gozellix and expanded access to PSMA-PET imaging".
According to the US CMS Medicare Claims Processing Manual, the HCPCS was "adopted as the code set for use in Health Insurance Portability and Accountability Act (HIPAA) transactions, for reporting outpatient procedures, items, and services".
The manual said "the HCPCS originated from the American Medical Association's (AMA) Physicians' Current Procedural Terminology, Fourth Edition" (CPT-4)".
Telix said the assignment of the code was "a significant milestone supporting provider billing and reimbursement for Gozellix, and a further step toward receiving Transitional Pass-Through (TPT) payment status".
Telix Precision Medicine chief executive officer Kevin Richardson said the code was "a significant step forward in Telix's mission to improve access to precision medicine imaging for prostate cancer patients across the US, regardless of their location".
"It is also an important enabler for commercial scale-up and reimbursement of Gozellix in the US as we bring our next-generation PSMA PET imaging agent to market," Mr Richardson said.
Telix was up $1.35 or 5.6 percent to $25.39 with 2.1 million shares traded.

ORTHOCELL

Orthocell says receipts from customers for the year to June 30, 2025 were up 50.8 percent to $5,148,000, compared to the prior corresponding period.
Last week, Orthocell said revenue for the year to June 30, 2025 was up 35.9 percent to a record $9.19 million, compared to the prior period (BD: Jun 30, 2024; Jul 1, 2025).
Today, the company said receipts from sales of its bioresorbable collagen membrane Striate+ dental bone and tissue repair and Remplir nerve repair were up 37.0 percent for the three months to June 30, 2025 to $1,337,000.
Orthocell managing-director Paul Anderson said it was "important to stress, our record result for June quarter was achieved prior to a contribution from Remplir in the US".
"We've seen excellent take-up of Remplir in our existing markets, most notably Australia," Mr Anderson said. "We feel this is an endorsement of the market access model that we expect to replicate on a far larger scale in the US."
In April, the company said it had US Food and Drug Administration 510(k) clearance to begin commercial distribution of Remplir in the US (BD: Apr 4, 2025).
Today, Orthocell said it had a cash burn of $3,541,000 for the three months, with cash and equivalents of $28,620,000 at June 30 2025 compared to $20,601,000 at June 30, 2024.
Orthocell fell half a cent or 0.4 percent to $1.22 with 888,988 shares traded.

MONASH UNIVERSITY, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Monash University says it has found drug candidates targeting A1R, in-vitro, which may lead to treatments for conditions including nerve pain and ischemia-reperfusion injury.

Monash University said a study led by the Monash Institute of Pharmaceutical Sciences conducted with Sweden's Uppsala University "focused on the discovery of drug-like candidates to target the adenosine A1 receptor (A1R) subtype".

The University said A1R was distributed in the brain and heart, played a role in communication between neurons and was part of the G-protein-coupled receptor (GPCR) family, the largest drug target class, which included Cobenfy for schizophrenia and semaglutide, marketed as Ozempic and Wegovy, for diabetes and obesity.

Monash University said "health conditions triggered by tissue stress benefitted from A1R activation, and thus this receptor has been identified as a promising target for ischemia-reperfusion injury and chronic neuropathic pain".

The University said neuropathic pain, or nerve pain, was often linked to inflammation in the peripheral and central nervous systems and ischemia-reperfusion injury was tissue damage that occurred when blood flow was restored to an area that had been deprived of oxygen, such as after a heart attack.

Monash University said the successful development of drugs targeting A1R "remained challenging due to unwanted effects, both on-target, such as slowing heart rate, and off-target, caused by interactions with other adenosine receptor subtypes".

Monash University said the research, titled 'Structure-based discovery of positive allosteric modulators of the A1 adenosine receptor' was published in the peer-reviewed journal the Proceedings of the National Academy of Sciences, with the full article available at: https://www.pnas.org/doi/10.1073/pnas.2421687122.

The University said its researchers used a combination of technologies to discover a set of 'subtype-selective A1R positive allosteric modulators', or PAMs, which "target A1R and enhance its activity without affecting other adenosine receptors".

Monash University said "unlike traditional agonists that fully activate A1R and often cause side effects like slowed heart rate, these PAMs act like a 'dimmer switch' rather than an on/off switch, subtly enhancing the receptor's response only when and where it is naturally active, offering more precise control with fewer on-target effects".

The University said the research "paves the way for potential new treatments for neuropathic pain, ischemia-reperfusion and other diseases linked to tissue stress and inflammation, without accompanying side effects".

Monash University said the researchers hoped the study would "lay the groundwork for future clinical trials and the development of safer, more targeted therapeutics for conditions involving A1R signaling".

Monash Institute of Pharmaceutical Sciences researcher and study co-first author Dr Anh Nguyen said the research was "a pivotal advance in A1R-targeted drug development".

"When the new drug candidates we've discovered bind to A1R they are able to modulate neuron activity in such a way that unwanted side effects, such as cardiac reactions, are no longer a hindrance," Dr Nguyen said.

"This has been a significant hurdle in the development of drugs targeting A1R, so we are very excited by this discovery and its potential to enable safer, more effective treatments for a range of conditions," Dr Nguyen said.

Co-lead author Dr Lauren May said a deeper pharmacological understanding of GPCRs, combined with technological advancements, had "collectively transformed the potential of this incredible family of drug targets which, in recent years, has led to new classes of life-changing drugs for millions of people around the world".

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says the DS90 nano-body may “neutralize” the henipaviruses Nipah and Hendra, which have no approved vaccine or cure, in-vitro.
The University of Queensland said it had confirmed DS90 could bind successfully to the proteins in Nipah and Hendra viruses and block their ability to enter cells, using cryogenic electron microscopy to examine the process.
The University said DS90 was among a series of nano-bodies isolated by researchers at Valdivia’s Austral University of Chile from the immune cells of an alpaca.
The University of Queensland said the research, titled ‘A nanobody-based therapeutic targeting Nipah virus limits viral escape’ was published in Nature Structural and Molecular Biology at: https://www.nature.com/articles/s41594-025-01598-2.
The University of Queensland said the researchers combined the DS90 nano-body with a developmental anti-body therapy that was used as a last resort treatment for people infected with Hendra and Nipah.
The University said Hendra virus was first identified in Brisbane in 1994 and had infected people via horses and flying foxes in eastern Australia, with Nipah virus outbreaks in people occurring almost annually in Bangladesh and occasionally in other Asian countries where it is carried by bats.
University of Queensland researcher Dr Ariel Isaacs said a nano-body was “one-tenth the size of an antibody and being that small it can access hard-to-reach areas of a virus to block infection”.
“Nano-bodies are also easier to produce and more stable at higher temperatures than traditional antibodies, so we are very excited about the potential of our discovery to lead to new treatments,” Dr Isaacs said.
“Excitingly, we demonstrated that the combination of DS90 with the m102.4 anti-body, which is made at [the University of Queensland], prevents Nipah virus from mutating and evolving,” Dr Isaacs said.
“This is a powerful technique to prevent new deadly variants emerging,” Dr Isaacs said.
“Other nano-bodies have been approved for use as cancer treatments and it is now exciting to see that nano-bodies can also be used to neutralize viruses,” Dr Isaacs said.
“The next step will be to translate our findings into a therapeutic to be clinically ready in case of an outbreak of Hendra in Australia or Nipah in Asia,” Dr Isaacs said.

ANATARA LIFESCIENCES

Anatara says the Japan Patent Office has granted a standard patent protecting its gastro-intestinal reprogramming, or Garp, product.
Anatara said the patent, titled ‘Gastrointestinal Health Composition’ would protect its intellectual property until October 9, 2040.
The company said it was continuing to progress in-vivo studies of its unnamed anti-obesity compound, whose mechanism of action involved the stimulation of glucagon-like peptide-1 (GLP-1) with New South Wales’ University of Newcastle, in mice.
Anatara said the anti-obesity project was “designed to develop an oral complimentary medication to assist weight reduction and sustaining weight control in conjunction with other contemporary treatments and approaches” and was expected to take six months.
The company said it had provided $350,000 for the completion of the proof-of-concept studies and would “determine further steps on the outcomes of these initial studies”.
Anatara was unchanged at 0.6 cents.

CLARIFICATION: NOVA EYE MEDICAL

Last night's edition reported Nova Eye revenue for the year to June 30, 2025 up 23.5 percent to a record $28.8 million, compared to the previous corresponding period.
The publication said that revenue for the year to June 30, 2024 was up 37.0 percent to $23,325,000, with net loss after tax reduced by 42.5 percent to $8,790,000.
In fact, the company said it expected revenue to continue to increase for 2025-'26, and in an accompanying presentation said "breakeven" was expected by the end of 2025.
Biotech Daily apologizes for any confusion.
Nova Eye fell one cent or 7.4 percent to 12.5 cents.

ISLAND PHARMACEUTICALS

Island says it has exercised its right to acquire the galidesivir anti-viral from Durham, North Carolina's Biocryst Pharmaceuticals for up-to $US2.5 million ($A3.8 million).
Last year, Island said it had paid Biocryst $US50,000 ($A75,109) for a 12-month exclusive period in which it could acquire galidesivir molecule which had exhibited anti-viral activity against Ebola, Zika, yellow fever and Marburg (BD: Sep 11, 2024).
Today, the company said that following due diligence, it gained "considerable confidence in the galidesivir anti-viral program" which would complete in about 30 days.
Island said it would pay Biocryst an acquisition fee of $US500,000 to acquire the rights, title and interest in the program.
The company said it would pay a further $US500,000 on completing a phase II clinical trial and $US1,000,000 on approval of a new drug application in the US, or equivalent, or $US1.5 million if no phase II trial was required.
Island said it would pay Biocryst royalties of five-to-10 percent on net sales and 25 percent of the sale of any priority review voucher following US Food and Drug Administration approval, with priority review vouchers valued at $US100 million to $US150 million.
Island said galidesivir had "robust clinical trial data, with the completion of phase I studies in healthy volunteers including single ascending dose and multiple ascending dose intra-muscular administration studies, as well as intravenous single ascending dose studies".
The company said the data package included a "non-human primate study in Marburg, which will provide a strong foundation for pending clinical trial requirements associated with the … FDA Animal Rule" and its initial work would develop galidesivir as a treatment for Marburg.
Island managing-director Dr David Foster said the company was "very pleased to acquire galidesivir".
"The acquisition provides Island with a second asset, which has a longstanding clinical development history and data of early-stage success in multiple RNA viruses, many of which do not have approved therapies," Dr Foster said.
"The decision to move directly through to an acquisition followed an in-depth due diligence process, which has given us considerable confidence", Dr Foster said.
"This has included a comprehensive review of datasets and collaboration with our leading consultants to define a potential path forward for approvals," Dr Foster said.
"The company is now focused on engaging with the FDA to ascertain the potential to leverage the Animal Rule, which could mean that the company may only be required to undertake one additional successful animal study in Marburg, prior to a new drug application," Dr Foster said.
"If so, a successful animal study could result in approval, which in turn may provide access to a priority review voucher," Dr Foster said.
Island was up two cents or 13.8 percent to 16.5 cents with 3.9 million shares traded.

ADHERIUM

London, Ontario's Trudell Medical says its 178,776,885 share-holding in Adherium has been diluted from 19.90 percent to 12.89 percent due to the issue of shares.
In June, Adherium said it hoped to raise up-to $4 million at 0.5 cents a share in a partially-underwritten institutional and retail entitlement offer (BD: Jun 24 2025).
Adherium was unchanged at 0.6 cents.

MEDADVISOR

Jencay Capital Pty Ltd says it has increased its substantial shareholding in Medadvisor from 43,247,079 shares (7.24%) to 52,389,949 shares (8.39%).
The Sydney-based Jencay Capital said that it bought 9,142,870 shares between April 9 and July 7, 2025 for $588,677, or 6.4 cents a share.
Medadvisor was up 0.2 cents or 3.8 percent to 5.5 cents with 1.3 million shares traded.