Biotech Daily

Tuesday May 13, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: CLARITY UP 15%; UNIVERSAL BIOSENSORS DOWN 8%**

*** FEDERAL INDUSTRY, INNOVATION, SCIENCE, HEALTH, TRADE MINISTERS**

*** AUSBIOTECH, ATSE WELCOME APPOINTMENTS**

*** TELIX 'LOW LIKELIHOOD OF TRUMP DRUG ORDER IMPACT'**

*** QUEENSLAND UNI WINS $1.25m FOR QED-203 PROSTATE CANCER**

*** POLYNOVO: 'NOVOSORB TREATS 3 DIABETES PATIENTS FOR 3 YEARS'**

*** OPTISCAN, MAYO ADVANCE ROBOTIC ENDO-MICROSCOPE**

*** NEUREN, FDA OKAY PHASE III NNZ-2591 PHELAN-McDERMID ENDPOINTS**

*** PENGANA DILUTED TO 5.6% OF ENLITIC**

MARKET REPORT

The Australian stock market was up 0.43 percent on Tuesday May 13, 2025, with the ASX200 up 35.5 points to 8,269.0 points.

Twenty-two of the Biotech Daily Top 40 companies were up, 10 fell, seven traded unchanged and one was untraded. All four Big Caps were up.

Clarity was the best, up 34 cents or 15.3 percent to $2.56, with 5.6 million shares traded. Polynovo climbed 14.4 percent; EBR was up 10.8 percent; Paradigm improved 8.1 percent; Syntara was up 7.9 percent; Compumedics and Mesoblast were up more than five percent; Imugene, Nanosonics, Optiscan and Pro Medicus improved four percent or more; Telix was up 3.6 percent; Alcidion, CSL, Neuren and Resonance rose more than two percent; 4D Medical, Aroa, Clinuvel, Cochlear, Cyclopharm and Medadvisor were up one percent or more; with Avita, Emvision, Resmed and SDI up by less than one percent.

Yesterday's 8.3 percent best, Universal Biosensors, led the falls, down 0.4 cents or 7.7 percent to 4.8 cents, with 194,706 shares traded; followed by Actinogen, down 0.2 cents or 7.4 percent to 2.5 cents with 12.2 million shares traded. Prescient lost 3.9 percent; Botanix, Curvebeam and Dimerix shed more than two percent; Amplia, Orthocell and Proteomics were down more than one percent; with Medical Developments down by 0.8 percent.

FEDERAL GOVERNMENT

Prime Minister Anthony Albanese has released his ministerial appointments with Senator Tim Ayers replacing Ed Husic as Minister for Industry, Innovation and Science.
On his website, Mr Albanese said he intended to “recommend to the Governor-General the following makeup of my ministry”.
Mr Albanese said Mark Butler continued as Minister for Health and Ageing as well as the Minister for Disability and the National Disability Insurance Scheme (NDIS).
The website said Senator Don Farrell continued as Minister for Trade.
Mr Albanese said that Dr Andrew Charlton had been appointed Cabinet Secretary and Assistant Minister for Science, Technology and the Digital Economy.
The website said that Dr Anne Aly had been appointed the Minister for Small Business.
Mr Albanese said that Richard Marles would continue as Deputy Prime Minister and Minister for Defence, with Senator Penny Wong as Minister for Foreign Affairs, Dr Jim Chalmers as Treasurer and Senator Katy Gallagher as Minister for Finance and Minister for the Public Service.

AUSBIOTECH

Ausbiotech says it welcomes the Federal Government’s appointments.
Ausbiotech chief executive officer Rebekah Cassidy said the ministry presented “an opportunity for renewed focus and bold leadership in unlocking the full potential of Australia’s life sciences sector, which is a critical national asset for productivity, health security and improved health outcomes for all Australians”.
The organization thanked the outgoing Minister for Industry and Science Ed Husic, and his office, for establishing the Strategic Examination of Research and Development and advocated for early-stage innovators through the Industry Growth Program.
“Mr Butler is an advocate for a whole-pipeline approach for our sector, from discovery to start-up, clinical trials, manufacturing, export, access and reimbursement,” Ms Cassidy said.
“We welcome his ongoing support for Australia’s life sciences sector and look forward to continuing our collaboration with him and his office to strengthen the nation’s health innovation ecosystem, from bench to bedside,” Ms Cassidy said.
Ms Cassidy welcomed Senator Tim Ayres as Minister for Industry and Innovation, and Minister for Science, and Dr Andrew Charlton as Assistant Minister for Science, Technology and the Digital Economy.
Ms Cassidy called for “the establishment of a National Life Sciences Council to serve as a strategic partnership between industry and government”.

AUSTRALIAN ACADEMY OF TECHNOLOGICAL SCIENCES AND ENGINEERING

The Australian Academy of Technological Sciences and Engineering (ATSE) says it urges the ministry to conduct a strategic examination of research and development.
The Academy said it welcomed the appointed ministers and would work with Senator Ayres and Dr Charlton “to open doors to innovation-led national growth”.
ATSE chief executive officer Kylie Walker said the Academy was “ever ready to support evidence-based decision-making … [and] look forward to working with the Ministry to develop Australia’s workforce through the Elevate boosting diversity in [science, technology, engineering and mathematics] program, and to support Australia’s growing international research and development collaboration through the Global Science and Technology Diplomacy Fund”.

TELIX PHARMACEUTICALS

Telix says a US Government 'Executive Order' to implement a 'most-favored nation' policy on drug pricing has "a low likelihood of material impact to Telix's business".

In an email and announcement on its website, not released to the ASX, Telix cited the 'Delivering Most-Favored-Nation Prescription Drug Pricing To American Patients', Executive Orders signed by US President Donald J Trump on May 12, 2025, US time.

Mr Trump said the US "has less than five percent of the world's population and yet funds around three quarters of global pharmaceutical profits".

"This egregious imbalance is orchestrated through a purposeful scheme in which drug manufacturers deeply discount their products to access foreign markets, and subsidize that decrease through enormously high prices in the United States," Mr Trump said.

"Americans will no longer be forced to pay almost three times more for the exact same medicines, often made in the exact same factories," Mr Trump said.

"My Administration will take immediate steps to end global freeloading and, should drug manufacturers fail to offer American consumers the most-favored-nation lowest price, my Administration will take additional aggressive action," Mr Trump said.

"To the extent consistent with law, the Secretary of Health and Human Services [Robert F Kennedy] shall facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers that sell their products to American patients at the most-favored-nation price," Mr Trump said.

He said that within 30 days, Mr Kennedy and his officials would "communicate most-favored-nation price targets to pharmaceutical manufacturers to bring prices for American patients in line with comparably developed nations".

Mr Trump said agencies would "undertake enforcement action against any anti-competitive practices identified within such report", including through the Sherman Antitrust Act and the Federal Trade Commission Act.

Telix said that "based on currently available information, there is a low likelihood of material impact to [its] business".

Telix said that "due to their complex supply chain and just-in-time manufacturing requirements, radio-pharmaceuticals differ from traditional pharmaceutical products [and its] US pricing strategy reflects its focus on providing ready-to-inject radioactive doses delivered through locally-based nuclear pharmacy distributors".

"The localized production makes international pricing comparisons challenging to benchmark," the company said.

Telix said it generated the majority of its revenue from sales of Illuccix in the US, and "value in our US market for access and pricing strategy, including US government accounts, is a key focus for our business".

Telix said it intended to commercialize TLX250-CDx, or Zircaix, and TLX101-CDx, or Pixclara, in the US ahead of expansion into other global markets in turn setting effective and pharmaco-economically defensible pricing policies and "continues to invest heavily in its US-based manufacturing and distribution footprint to more quickly and cost-effectively bring these innovative and novel precision medicine products to US patients.

Telix managing-director Dr. Christian Behrenbruch said that "radio-pharmaceuticals represent a novel and emerging class of oncology treatments, driven by a precision medicine approach".

"We remain actively engaged with lawmakers, policymakers, and regulatory agencies to educate these stakeholders on the unique and complex nature of these innovative drugs," Dr Behrenbruch said. "Telix is committed to supporting American healthcare policy that continues to advance care and promote broad patient access."

Telix was up 89 cents or 3.6 percent to $25.36 with 2.8 million shares traded.

UNIVERSITY OF QUEENSLAND

The University of Queensland says it has a $1.25 million grant from the US Critical Path Institute to develop its QED-203 therapy-resistant prostate cancer treatment.
According to its website, the Tucson, Arizona-based Critical Path Institute was founded by the US Food and Drug Administration and was “a non-profit organization that is dedicated to improving and streamlining the process of drug development”.
The University said the QED-203 drug was based on research by its Prof Greg Monteith and was being developed by its Queensland Emory Drug Discovery Initiative (QEDDI), the small molecule drug discovery arm of commercialization company Uniquest.
The University said QED-203 “had a unique mode of action that aimed to improve the survival and quality of life of those with [metastatic castration-resistant prostate cancer] when they had exhausted all available treatment options”.
QEDDI’s Dr Brian Dymock told Biotech Daily that QED-203 targeted transient receptor potential vanilloid 6, or TRPV6, which was found on the surface of prostate cancer cells and, when blocked, could block the influx of calcium into the cells.
Dr Dymock said calcium was required for cancer cells to survive, and that blocking its influx could stop the cancer from growing.
Dr Dymock said the researchers had found that QED-203 showed “strong anti-tumor activity” and safety in early in-vivo testing in mice, and the funding would be used for anti-toxicity studies and efficacy studies in rats and dogs.

POLYNOVO

Polynovo says a three-patient study with Beta Cell Technologies shows pancreatic islets transplanted using Novosorb BTM have survived and functioned for three years.
In 2017, Polynovo said it was exploring the use of its Novosorb biodegradable temporizing matrix (BTM) wound treatment for hosting pig islets of Langerhans for type 1 diabetes with the Adelaide-based Beta Cell Technologies Pty Ltd (BD: May 12, 2017).
At that time, the company said that when Novosorb was infiltrated with dermal cells and blood supply, it potentially provided an accessible site for the injection and generation of islet cells, enabling renewed insulin production in people with type 1 diabetes.
Today, Polynovo said a proof-of-concept study showed “survival and function of human pancreatic islets transplanted into an alternative neo-vascularized site within the skin using Novosorb BTM to create a cell-supporting vascular bed”.
The company said the trial of three patients with type 1 diabetes who had received islet cells after kidney transplant, with Novosorb BTM supplied to Beta Cell at no cost.
Polynovo said the study was presented to the joint congress of the European Society for Paediatric Endocrinology and European Society of Endocrinology by Beta Cell director Prof Toby Coates on May 12, 2025 in Copenhagen, Denmark.
The study concluded that the pre-vascularized Novosorb BTM was safe and supported human islet cell survival in an intra-cutaneous transplant outside of the liver.
Polynovo chair David Williams said the results were “very exciting … and a red-letter day potentially creating a new and distinct silo for the Polynovo business, one in wound care and related uses, and another in cell delivery”.
“It goes without saying we are extremely excited about the use of Polynovo as a delivery device in cell therapies,” Mr Williams said.
Mr Williams said Prof Coates and Novosorb BTM developer Prof John Greenwood had “articulated the properties of our technology that should make it attractive to other cell therapy companies”.
Polynovo was up 21 cents or 14.4 percent to $1.67 with 5.55 million shares traded.

OPTISCAN IMAGING

Optiscan says it has made “significant advancements” in its 24-month development plan with the Mayo Clinic for an endo-microscopic imaging system for robotic surgery.

Last year, Optiscan said it would develop a digital confocal laser endo-microscopic imaging system for robotic surgery with Rochester, Minnesota’s Mayo Clinic, initially focusing on robotic-assisted breast cancer surgery (BD: May 13, 2024).

In 2024, Optiscan said it would use its “engineering expertise in digital endo-microscopic hardware and software with Mayo Clinic’s know-how in robotic surgery and patient care”.

Today, Optiscan said it had worked with Mayo Clinic robotic breast surgeon Dr Mara Piltin “to understand robotic-assisted surgical workflows and the most ideal way of incorporating endomicroscopic imaging systems within varied surgical settings”.

The company said it had identified hardware and software requirements of a standalone imaging system that had “the highest level of autonomy from the robotic surgical systems” and able to be integrated with as many robotic systems as possible.

Optiscan said an imaging stream from a prototype device was connected to a surgical robotic platform at the Mayo Clinic and had been verified as compatible with all imaging features such as picture-in-picture visualization.

The company said the prototype showed “the feasibility of providing intra-operative microscopic imaging to complement standard camera views to surgeons, using the same interfaces they currently use during precision surgery”.

Optiscan said that with the Mayo Clinic it had developed prototype imaging probe accessories that allowed for the integration of endo-microscopic probes with a “wide range of surgical instruments designed to perform specific actions during a surgery”.

The company said further development milestones included: defining system requirements, needs, regulatory considerations, commercial opportunities and constraints; development and feasibility testing; reviewing system requirements; and, concept selection, prototyping and benchtop testing, and project review.

Optiscan said it had begun prototyping and pre-clinical testing, with the next phase of work taking place at the Mayo Clinic’s Florida campus.

Optiscan managing-director Dr Camile Farah said the company was “thrilled with the outcomes delivered to date from our collaboration with the Mayo Clinic”.

“Just 12 months on from Optiscan signing a know-how-agreement with this prestigious US medical care organization, both groups have materially progressed an imaging system for use in robotic surgery,” Dr Farah said. “Harnessing the core strengths of both groups, all target deliverables at the 12-month anniversary of the agreement have been met.”

Optiscan was up half a cent or 4.55 percent to 11.5 cents.

NEUREN PHARMACEUTICALS

Neuren says with the US Food and Drug Administration it has confirmed the primary endpoints for its phase III trial of NNZ-2591 for Phelan-McDermid syndrome.

Last month, Neuren said it had a meeting with the FDA to discuss the primary endpoints for the trial (BD: Apr 14, 2025).

At that time, the company said the primary endpoints for the double-blind, placebo-controlled, 13-week study would be a change from “receptive communication” baseline in the Vineland Adaptive Behavior scales (VABS-3) and the Phelan-McDermid Syndrome assessment of change overall score (PMSA-C).

Today, Neuren said it remained “on-track to commence the phase III trial mid-year 2025, subject to FDA review of the final version of the trial protocol”.

Neuren was up 31 cents or 2.6 percent to $12.33 with one million shares traded.

ENLITIC

Sydney's Pengana Capital Group says its 40,474,040 share-holding in Enlitic was diluted from 7.03 percent to 5.61 percent on May 9, 2025 through the issue of shares.

Last week, Enlitic said it had "firm commitments" to raise $10 million in a non-underwritten placement of Chess depository interests (CDIs) at four cents each, a 21.2 percent discount to the 15-day volume weighted average price, with one attaching option for every two CDIs issued (BD: May 5, 2025).

Enlitic fell 0.1 cents or 2.9 percent to 3.3 cents.