



Biotech Daily

Monday May 12, 2025

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: UNIVERSAL BIOSENSORS UP 8%; BOTANIX DOWN 13%**
- * **FEDERAL \$953k FOR MONASH, MIPS DEMENTIA**
- * **WEHI 'BLOCKS CELL DEATH FOR NEURO-DEGENERATIVE DISEASES'**
- * **VITURA EXPECTS 2024-'25 \$138m REVENUE, COSTS DOWN 3%**
- * **POLYNOVO: TGA CLEARS NOVOSORB 4mm, 6mm**
- * **ORTHOCELL REMPLIR HONG KONG APPROVAL**
- * **OSTEOPORE, KELYNIAM SIGN 3-YEAR US CARNIO-FACIAL DEAL**
- * **RADIOPHARM HIGHER RAD204 CANCER DOSE OKAY**
- * **CLEO TESTS OVARIAN CANCER DIAGNOSTIC PROTOTYPE**
- * **BOTANIX PLEADS 'SCHULTZ, TRUMP' TO ASX 17% PRICE FALL QUERY**
- * **GZ TAKES 16.5% OF ATOMO**
- * **JM FINANCIAL, NO PLAN B INCREASE, DILUTED TO 15% OF IMEX**
- * **TRYPTAMINE JANSSEN, NTOUMENOPOULOS UP; DAVIES OUT**
- * **AMPLIA PROMOTES CLINICAL ADVISOR DR JASON LICKLITER TO CMO**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Monday May 12, 2025, with the ASX200 up 2.3 points to 8,233.5 points. Nine of the Biotech Daily Top 40 companies were up, 26 fell and five traded unchanged.

Universal Biosensors was the best, up 0.4 cents or 8.3 percent to 5.2 cents, with 890,143 shares traded. Atomo climbed 6.25 percent; Micro-X improved 4.9 percent; Actinogen, Impedimed and Medadvisor were up three percent or more; Genetic Signatures rose 2.6 percent; with 4D Medical, Mesoblast and Pro Medicus up by one percent or more.

Botanix the falls (see below), down six cents or 12.9 percent to 40.5 cents, with 60.85 million shares traded. Cyclopharm and Neuren were down more than nine percent; Avita, Clarity and Telix lost eight percent or more; Curvebeam and Dimerix were down more than seven percent; EBR and Syntara shed six percent or more; Cynata and Resonance were down five percent or more; Optiscan fell 4.35 percent; Clinuvel, Compumedics, Emvision, Medical Developments, Nanosonics and Nova Eye were down three percent or more; Orthocell shed 2.9 percent; Alcidion, Amplia, Aroa, CSL, Immutep and Paradigm were down more than one percent; with Cochlear, Polynovo and Resmed down by less than one percent.

MONASH UNIVERSITY, MONASH INSTITUTE OF PHARMACEUTICAL SCIENCES

Monash University says the Federal Government's Medical Research Future Fund has provided \$953,751 to study human brain cells for potential dementia treatments.

Monash University said the grant would allow the Monash Institute of Pharmaceutical Sciences to "‘light up’ human brain cells to observe activity and, ultimately, pinpoint new drug-like compounds with longer-term potential of translating to new medicines to manage symptoms associated with dementia".

The University said dementia was a "broad term used to describe a group of neuro-degenerative conditions characterized by gradual impairment of brain function which can greatly impact quality of life".

Monash University said neuroscience drug discovery had "high failure rates which is in part due to relying on poor model systems for human brain disorders".

The University said Monash Institute of Pharmaceutical Sciences researchers would "address this challenge by developing new methods to ‘light up’ human brain cells to measure the real-time activity of proteins directly linked to dementia".

Monash University said its researches would use fluorescent chemical probes, or glowing dyes, on lab-grown brain cells derived from human cells.

The University said the research would study changes in tau, a protein in the brain implicated in dementia and other neuro-degenerative diseases, and amyloid, which was often found in people with Alzheimer's disease.

Monash Institute of Pharmaceutical Sciences research and program lead investigator Prof Karen Gregory said effective and safer medicines were needed to manage the different symptoms experienced by people living with dementia.

"Our goal is to create new and improved human brain cell-based models to reliably and more rapidly identify novel drug candidates with the best chance of becoming future new medicines," Prof Gregory said.

"The [Medical Research Future Fund] grant will enable us to develop a range of methods including using [messenger] RNA delivery of fluorescent biosensors to measure real-time activity from different locations inside human brain cells," Prof Gregory said.

THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

The Walter and Eliza Hall Institute says it has found a molecule that selectively blocks cell death and may lead to therapies for neuro-degenerative conditions.

WEHI said that its National Drug Discovery Centre screened more than 100,000 chemical compounds and "identified one that was effective at stopping cells from dying by interfering with a well-understood cell death protein".

The Institute said the molecule targeted Bcl-2-associated X, or the BAX protein, which killed cells by damaging mitochondria.

WEHI said that "while drugs that trigger cell death are transforming treatment of certain cancers, the development of cell death blockers, that could be similarly game-changing for neuro-degenerative conditions, has proven challenging".

The Institute said the study showed "the potential to identify drugs that block cell death and may open a new avenue to find much-needed disease-modifying drugs for neuro-degenerative conditions such as Parkinson's [disease] and Alzheimer's [disease]".

WEHI said the research was supported by the Bodhi Education Fund and the National Health and Medical Research Council (NHMRC).

The Institute said the study, titled 'Differential regulation of BAX and BAK apoptotic activity revealed by small molecules' was published in Science Advances, with the full article available at: <https://www.science.org/doi/10.1126/sciadv.adr8146>.

VITURA HEALTH

Vitura says it expects revenue for the year to June 30, 2025 to be up 11 percent to about \$138 million, with operational expenditure reduced by about three percent.

Last year, Vitura said revenue from sales of its medical marijuana and psychedelic products and vapes for the year to June 30, 2024 was \$123,870,868, with net profit of \$3,512,278 (BD: Aug 29, 2024).

Today, the company said it expected a 20 percent increase in earnings before interest, tax, depreciation and amortization (Ebitda) and a three percent reduction in operational expenditure “notwithstanding the increased costs attributable to the businesses acquired by Vitura during the year”.

In November, Vitura said it would pay \$750,000 and relinquish \$3.8 million of debt to acquire half of marijuana dispensary Releaf Group through its Flora joint-venture with Crisci Group (BD: Nov 20, 2025).

Earlier this year, the company said it bought Brisbane’s Livelihood Health Pty Ltd and its medical marijuana telehealth consultation brand Candor Medical for \$5.9 million (BD: Feb 20, 2025).

Today, Vitura said increased revenues had followed the integration of the Candor and Releaf businesses as well as the signing of additional suppliers and “a number of other sales-related initiatives”.

Vitura chief executive officer Geoff Cockerill said the company had undergone a 12-month strategy reset “under a renewed leadership team [and was] ... encouraged to see the benefits of our hard work starting to emerge”.

“We’ve got the fundamentals of the business back on track and we’re looking forward to continuing that momentum into the near and mid-term future,” Mr Cockerill said.

“The team is focused on leveraging the company’s current momentum to deliver a positive finish to 2024-’25, setting the foundations to execute well against the company’s strategy into 2025-’26 and beyond,” Mr Cockerill said.

Vitura was up 0.2 cents or 2.8 percent to 7.4 cents.

POLYNOVO

Polynovo says it has Australian Therapeutic Goods Administration clearance for its four-millimetre and six-millimetre versions of Novosorb MTX.

Earlier this year, Polynovo said it had clearance for up-to six-millimetre thick Novosorb MTX in the US, with further indications, as well a two-millimetre version in Australia and India (BD: Mar 19, 2025).

At that time, the company said Novosorb MTX used the Novosorb BTM technology without a sealing membrane, developed for use in indications where the membrane was not required.

Today, Polynovo said the additional 4.0mm and 6.0mm versions of Novosorb MTX would be included on the Australian Register for Therapeutic Goods, allowing the products to be marketed and sold in Australia.

Polynovo chair David Williams said he was “very happy about this, especially for plastic surgeons who sometimes need more than 2.0mm to achieve effective wound management outcomes”.

Polynovo acting chief executive officer Robyn Elliott said the availability of Novosorb MTX in various thicknesses would “provide surgeons with even more options for reconstruction of complex wounds”.

Polynovo fell half a cent or 0.3 percent to \$1.46 with 2.4 million shares traded.

ORTHOCELL

Orthocell says the Hong Kong Department of Health has approved the sale of its Remplir collagen-wrap for nerve repair.

Last month, Orthocell said it had US Food and Drug Administration 510(k) clearance to begin commercial distribution of Remplir in the US (BD: Apr 4, 2025).

Later, the company said it had Thai Food and Drug Administration approval to begin sales of Remplir, with expected submissions to the European Union and UK regulators "in the next six-to-12 months" and approval pending in Canada (BD: Apr 28, 2025).

Today, Orthocell said the approval was received about a month after the regulatory submission, showing "the quality of the product, the clinical data and its growing global recognition" (BD: Apr 10, 2025).

The company said that it expected to appoint a specialist distributor in Hong Kong. Orthocell managing-director Paul Anderson said the company was "now building a strategically valuable portfolio of approvals for Remplir, spanning the Asia Pacific region and North America".

"We've experienced rapid growth in 2025 in the number of countries in which Remplir is approved and our focus is moving towards converting those approvals into sales," Mr Anderson said.

Orthocell fell four cents or 2.9 percent to \$1.34 with 2.5 million shares traded.

OSTEOPORE

Osteopore says it has a three-year distribution deal with the Canton, Connecticut-based Kelyniam Global Inc for its cranio-facial implants in the US.

Osteopore said Kelyniam was a medical device manufacturer that produced custom cranial and cranio-facial poly-ether-ether-ketone (PEEK) implants in 24-to-48 hours, "for rush and expedited cases" using 3-dimensional printing, and it expected "the first purchase to follow promptly after the agreement is signed".

Osteopore did not disclose commercial terms of the deal.

Osteopore was up 0.1 cents or 7.1 percent to 1.5 cents with 2.5 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has data and safety monitoring committee approval to increase the dose in its phase I trial of lutetium-177 RAD204 for cancers to 60 millicuries (mCi).

Last year, Radiopharm said it had dosed the first of up-to 21 patients in its phase I, dose-escalation, study of RAD204 for lung cancer (BD: Jul 10, 2024).

Later, the company said it had extended the trial to 23 patients with programmed death-ligand 1 (PD-L1)-expressing solid tumors including non-small cell lung cancer, breast, melanoma, head and neck and endometrial cancer (BD: Nov 19, 2024).

Today, Radiopharm said the safety committee reviewed the first four-patient cohort, treated with 30mCi of RAD204, and confirmed there was "positive safety, pharmacokinetic and bio-distribution data" and it would dose the second cohort with 60mCi of RAD204, instead of 40mCi as "previously assumed in the protocol" with the second cohort expected to be enrolled by "mid-year 2025".

Radiopharm managing-director Riccardo Canevari said the company believed "that RAD204 has the potential to strongly improve clinical outcomes for patients with PD-L1 positive advanced cancers and we look forward to seeing data from the first two cohorts of patients later this year".

Radiopharm fell 0.05 cents or 2.3 percent to 2.1 cents with 4.1 million shares traded.

CLEO DIAGNOSTICS

Cleo says it has completed alpha testing of a prototype ovarian cancer pre-surgical triage assay kit, which showed “robust and reproducible performance”.

Last year, Cleo said it had recruited the first of “a minimum of 500 patients” in a US trial of its ovarian cancer blood test, with eight medical institutions in six US states recruiting patients, and the data to underpin a US Food and Drug Administration submission for the approval of its blood test in clinical use (BD: Sep 6, 2024)

Today, the company said testing was conducted on 120 blood samples at its laboratory and confirmed the performance of its assay kit in multiple metrics including “analytical precision, reproducibility and measurement range [and] ... confirmed differentiation of benign versus malignant ovarian disease”, consistent with previously published studies.

Cleo said it would conduct assay feasibility testing, optimization, verification and manufacturing scale-up for commercial production with US partner Research and Development Systems, a Minneapolis, Minnesota-based subsidiary of Bio-Techne Corp. In March, the company said it began transferring technology related to its ovarian cancer blood test to Bio-Techne Corporation for development (BD: Mar 18, 2025).

Cleo managing-director Dr Richard Allman said completing alpha-testing was “a pivotal achievement for Cleo”.

“This validation of technical performance now clears the path to proceed towards scaled-up manufacturing,” Dr Allman said.

Cleo fell 1.5 cents or 3.95 percent to 36.5 cents.

BOTANIX

Botanix has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.

The ASX said that the company’s share price dropped 17.2 percent from 46.5 cents a share at the close of trading on Friday May 9, 2025 to a low of 38.5 cents a share today, and noted a significant increase in the volume of shares traded.

Botanix said “an announcement apparently by [US] President [Donald] Trump on Telegram of a proposed executive order in relation to ‘Prescription Drug and Pharmaceutical Prices’” may explain the trading in its securities.

In a separate announcement, filed to the ASX at the same time as its price query letter response, Botanix said it was aware from the US announcement that “Mr Trump is proposing to issue an executive order that is focused on reducing costs of pharmaceuticals by instituting a ‘most favored nation’s policy’”.

The company said the policy meant that the US would “pay the same price as the nation that pays the lowest price for a drug, anywhere in the world”.

Botanix said its Sofdra, or sofipironium topical gel 12.45 percent for excessive underarm sweating, was only approved in the US and was not marketed in any other jurisdiction, its Ecclock (5%) gel was marketed in Japan and not the US and contained a different formulation and concentration of sofipironium bromide to Sofdra.

The company said that “based on the limited information currently available in relation to the US announcement and in light of the above, Botanix does not consider that it is likely that it will be subject to price reductions based on sales of Sofdra outside the US, as there are none”.

Botanix said it had “obviously not seen the executive order” and would review the proposed executive order when it became available.

Botanix closed down six cents or 12.9 percent to 40.5 cents with 60.8 million shares traded.

ATOMO DIAGNOSTICS

The Oakville, New South Wales-based GZ Family Holdings Pty Ltd says it has increased its holding in Atomo from 79,787,536 shares (12.48%) to 113,359,869 shares (16.52%). The GZ Family said it bought and sold shares between April 17 and May 8, 2025, with the single largest acquisition 27,027,027 shares on May 5 for \$500,000, or 1.85 cents a share. Last month, Atomo said that it had commitments to raise about \$2,113,000 in a placement at 1.85 cents a share, with a \$1.0 million, share plan to follow (BD: Apr 24, 2025). Atomo was up 0.1 cents or 6.25 percent to 1.7 cents.

IMEX HEALTH SERVICES

Melbourne's JM Financial Group Ltd and No Plan B Pty Ltd say they have increased and been diluted in Imex from 7,588,094 shares (16.54%) to 7,710,293 shares (15.28%). JM Financial said they bought shares between February 17 and March 17, 2025, with the single largest purchase 27,679 shares on February 17 for \$10,743, or 38.8 cents a share. Last month, Imex said it raised \$2.5 million at 35 cents a share in a placement, with a further \$1.0 million, non-underwritten share purchase plan to follow (BD: Apr 3, 2025). Imex fell half a cent or 1.45 percent to 34 cents

TRYPTAMINE THERAPEUTICS

Tryptamine says Herwig Janssen will replace chair Mark Davies, effective from May 12, 2025, with Chris Ntoumenopoulos promoted to executive director. Tryptamine said Mr Janssen had been a shareholder since listing and was previously head of licencing and acquisitions in emerging markets at Johnson & Johnson Innovative Medicine as well as US head of business development. The company said Mr Ntoumenopoulos had been a director since May 2025 and the transition was "in line with [his] ... intention to increase his operational and market engagement involvement" as it continued to develop TRP-8803 following phase I trials. Tryptamine said Mr Ntoumenopoulos had been managing-director of Twenty-1 Corporate, a director of Race and Resapp and was currently chair of Neuroscientific. According to his LinkedIn page, Mr Ntoumenopoulos is a director of Trivarx and Island and holds a Bachelor of Commerce from Perth's University of Western Australia. The company said Mr Ntoumenopoulos would be paid \$125,000 a year. Tryptamine was up 0.1 cents or 2.9 percent to 3.5 cents with 10.5 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has promoted clinical advisor Dr Jason Lickliter to chief medical officer, initially part-time while he continues as the chief medical officer of Nucleus Network. Amplia said Dr Lickliter had been a clinical advisor since 2021, chairing its safety committee and advising on the phase I trial of narmafotinib and its phase Ib/IIa 'Accent' trial of AMP945 in combination with nab-paclitaxel and gemcitabine for pancreatic cancer. According to his LinkedIn page, Dr Lickliter held a Bachelor of Medicine and Bachelor of Surgery from Brisbane's University of Queensland and a Doctor of Philosophy from the University of Melbourne. Amplia fell 0.1 cents or 1.85 percent to 5.3 cents.