Biotech Daily

Tuesday April 15, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: 4D MEDICAL UP 20%; ATOMO DOWN 14%**

*** EBR: US CMS RECOMMENDS WISE CRT REIMBURSEMENT**

*** BOTANIX 'COMMITMENTS' FOR $40m PLACEMENT**

*** 4D MEDICAL, INTEGRAL DIAGNOSTICS CT LVAS DEAL**

*** TOUCH STARTS CHLAMYDIA, GONORRHOEA TEST SALES**

*** PRO MEDICUS, SAN FRANCISCO UNI VISAGE A.I. RESEARCH**

*** ATMO: RMIT TRANSFERS GAS CAPSULE I.P. FOR EQUITY**

*** CLARITY DOSES 1st PHASE II CU-67 SAR-BIS-PSMA PROSTATE PATIENT**

*** NOXOPHARM SOF-SKN PASSES IN-VIVO SAFETY TESTS**

*** ARGENT, AUSCANN DATA DEAL**

*** DIRECTOR MERILL GRAY REPLACES ANTEO M-D DAVID RADFORD**

*** PROF ANDREW WAY REPLACES ALCIDION DIRECTOR VICTORIA WEEKES**

MARKET REPORT

The Australian stock market was up 0.17 percent on Tuesday April 15, 2025, with the ASX200 up 13.1 points to 7,761.7 points. Seventeen of the Biotech Daily Top 40 companies were up, 17 fell, four traded unchanged and two were untraded.

4D Medical was the best, up five cents or 20 percent to 30 cents, with 2.6 million shares traded. Genetic Signatures was up 14.3 percent; Curvebeam climbed 10 percent; Imugene improved 7.7 percent; Universal Biosensors was up 6.45 percent; Cynata and Nova Eye were up five percent or more; Clarity was up 4.9 percent; Paradigm climbed 3.2 percent; CSL, Medadvisor, Mesoblast, Nanosonics and Syntara rose more than two percent; both Medical Developments and Starpharma were up one percent; with Clinuvel, Cochlear, EBR and Resmed up by less than one percent.

Atomo led the falls, down 0.3 cents or 13.6 percent to 1.9 cents, with 2.9 million shares traded. Percheron lost 9.1 percent; Actinogen and Immutep were down more than six percent; Aroa was down 5.7 percent; Proteomics fell 4.3 percent; Amplia was down 3.8 percent; Cyclopharm, Emvision, Resonance and SDI shed more than two percent; Alcidion, Dimerix, Neuren, Orthocell and Pro Medicus were down more than one percent; with Polynovo and Telix down by less than one percent.

EBR SYSTEMS

EBR says the US Centers for Medicare and Medicaid Services (CMS) recommends its leadless Wise CRT system receive the “new technology add-on payment”.
EBR said the CMS recommended its Wise cardiac resynchronization therapy (CRT) system receive the maximum add-on payment of 65 percent of its cost, in addition to the normal Medicare severity diagnosis-related group (MS-DRG) payment, effective from October 1, 2025.
Yesterday, the company said the US Food and Drug Administration had approved its Wise CRT for left ventricular endocardial pacing (BD: Apr 14, 2025).
Today, EBR said the new technology add-on payment was “designed to bridge the financial gap between the costs of innovative technologies and the standard MS-DRG payment structure in place, while encouraging early adoption of breakthrough medical advancements in the in-patient setting for Medicare patients”.
The company said eligible technologies had to be “new … sufficiently priced” and show “substantial clinical improvement over existing services or technologies”.
EBR said “the newness and substantial clinical improvement criteria are automatically met for devices like Wise CRT that have breakthrough device designation in place”.
The company said that the proposed ruling established that Wise CRT met all reimbursement criteria and was eligible for the add-on payment, which once formalized would remain in effect for three years once approved.
EBR said the approval represented a “significant milestone” in its commercialization strategy, bringing it closer to gaining US reimbursement for Medicare in-patients.
The company said that it would file an application for transitional pass-through reimbursement for out-patients “shortly”.
EBR managing-director John McCutcheon said the company expected reimbursement to be finalized by October “which would further our US commercialization strategy to accelerate market adoption and enable widespread access in the US”.
EBR was up one cent or 0.7 percent to $1.41 with 3.7 million shares traded.

BOTANIX

Botanix says it has “firm commitments” to raise $40 million at 33.0 cents a share, a 7.0 percent discount to its last traded price, in a non-underwritten institutional placement.
Botanix said the funds would be used for the US commercialization of Sofdra, expanding its sales force and infrastructure and digital platform as well as marketing and conference activities, inventory and logistics, platform expansion and additions, operating costs, and general and administrative expenses.
Last year, the company said the US Food and Drug Administration approved Sofdra, or sofpironium bromide topical gel, for excessive underarm sweating in adults and children aged nine years and older (BD: Jun 20, 2024).
Today, Botanix said that in the first nine weeks since Sofdra’s launch patient arrivals were “trending to more than 500 a week, at a run rate of more than 2,000 per month”.
The company said individual prescriber numbers exceeded 400 a week and more than 1,500 prescribers had written Sofdra prescriptions since sales launch, with revenue from Sofdra more than doubling from February to March 2025.
Botanix said Euroz Hartleys and E&P Capital were joint managers for the placement.
Botanix chair Vince Ippolito said the funds would allow the company “to accelerate the commercialization of Sofdra, which is particularly exciting given the sales performance of Sofdra in only the first nine weeks of launch”.
Botanix was up two cents or 5.6 percent to 37.5 cents with 21.9 million shares traded.

4D MEDICAL

4D Medical says it has a commercial contract for its lung imaging technology with Integral Diagnostics, the second largest diagnostic imaging provider in Australia.

In 2023, 4D Medical said Melbourne's Integral Diagnostics would distribute its fluoroscopy-enabled XV lung ventilation analysis software (Lvas) and computed tomography (CT) Lvas in Australia and New Zealand (BD: Oct 30, 2023).

Today, the company said the contract was an expansion of the 2023 pilot program with Melbourne's Lake Imaging, which later merged with companies including Capitol Health to form the Melbourne-based Integral Diagnostics.

The company said under the contract Integral Diagnostics would provide its lung ventilation imaging technology for routine clinical use at Lake Imaging locations in Ballarat, Albury, North Melbourne, Geelong, Warrnambool "and other locations as agreed between the parties from time to time".

4D Medical said practitioners, respiratory specialists, cardiologists and patients would have "greater access to the rich lung-function data provided by CT Lvas across Victoria".

The company said the increased services allow "healthcare providers to offer enhanced diagnostic capabilities for respiratory illnesses to their patients, ensuring timely and accurate diagnoses that improve patient outcomes".

4D Medical did not disclose commercial terms of the deal.

4D Medical managing-director Prof Andreas Fouras said the contract was a result of "interest from doctors to use our products in clinical practice and continues 4D Medical's record of converting 100 percent of pilot programs into full commercial contracts".

"This is another important step in 4D Medical's mission to revolutionize lung health and further strengthens our commercial presence in Australia," Mr Fouras said.

4D Medical was up five cents or 20 percent to 30 cents with 2.6 million shares traded.

TOUCH BIOTECHNOLOGY PTY LTD

Sydney's Touch Biotechnology says its "rapid", single-swab, self-test kit for chlamydia and gonorrhoea in women is available for sale in Australia.

Touch said its test was "Australia's first [Therapeutic Goods Administration]-approved rapid self-test for chlamydia and gonorrhoea for women".

A spokesperson for the company told Biotech Daily that the test received TGA approval in November 2024.

The company said the test produced a positive or negative result for both infections in 15 minutes, compared to previous laboratory or polymerase chain reaction (PCR) tests, which were an invasive process that could be costly and take one to three days for results.

According to its website, Touch sold its dual chlamydia and gonorrhoea swab for $24.00 a test, which was available for purchase online as well as at pharmacies.

The company said that over the last 10 years Australian chlamydia and gonorrhoea rates had increased by 26 percent and 157 percent, respectively, with more than 110,000 cases of chlamydia reported in 2023.

In 2022, Touch said the TGA approved its 'Combo' severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), influenza A and B rapid antigen test (BD: Nov 30, 2022).

In 2023, the company said the TGA approved the addition of respiratory syncytial virus (RSV) to its rapid antigen, single-swab nasal self-test, which had an accuracy rate of more than 98 percent for all four viruses and undisclosed sensitivity and specificity rates and allowed users to obtain results within 15 minutes (BD: May 15, 2023).

Touch Biotechnology is a private company.

PRO MEDICUS

Pro Medicus says with the University of California San Francisco it will conduct artificial intelligence (A.I.) research and development using its Visage A.I. Accelerator platform.
Pro Medicus said the “multi-year research collaboration agreement” was signed by its US subsidiary Visage Imaging Inc, and built on a previous deal with the University of California San Francisco for its Visage 7 Viewer technology.
The company said the agreement would “serve as the framework for collaboration between the two parties to facilitate development and commercialization leveraging the Visage A.I. Accelerator platform”.
Pro Medicus did not disclose commercial terms of the deal.
Visage Imaging chief technology officer Dr Malte Westerhoff said the “A.I. Accelerator program was designed to closely align Visage’s engineering and product development capability with clinical research partners”.
“It provides a unique set of tools for data de-identification, collection, curation, analysis and ‘path-to-production’ in research projects bringing the efficiency and speed of Visage technology to research, resulting in a unified link between the two domains,” Dr Westerhoff said.
“We have optimized our Visage 7 platform for A.I. enabling both our own, as well as third-party algorithms to be seamlessly integrated into the clinician’s desktop,” he said.
“We see this research collaboration agreement with [University of California San Francisco] as another significant piece of our A.I. strategy, one that has the potential to develop innovative A.I. solutions that meet well defined clinical goals and ultimately lead to better patient outcomes,” Dr Westerhoff said.
Pro Medicus fell $3.40 or 1.6 percent to $209.52 with 222,517 shares traded.

ATMO BIOSCIENCES, ROYAL MELBOURNE INSTITUTE OF TECHNOLOGY

Atmo says RMIT has transferred all patents and associated intellectual property related to its gas capsule “in exchange for an equity stake in the company”.
The Melbourne and Sydney-based Atmo said the intellectual property for the ingestible gas-sensing capsule was previously subject to an exclusive, royalty-based licence agreement between Atmo and RMIT.
The company said the deal was a “significant step in Atmo’s commercialization journey as it seeks regulatory clearance with the US Food and Drug Administration following the successful completion of a pivotal clinical study in a first indication last year”.
Last year, Atmo said a more than 200-patient study of its gas-sensing capsule for suspected gastro-intestinal motility disorders met its primary endpoint (BD: Apr 9, 2024).
Last month, the company said the study validated its ingestible gas-sensing capsule for assessing gastro-intestinal transit times to assist with diagnosis (BD: Mar 5, 2025).
At that time, Atmo said the data would support an FDA regulatory submission for an initial indication to evaluate whole and regional gut transit to assess common gastro-intestinal motility disorders.
Atomo chief executive officer Mal Hebblewhite told Biotech Daily that Atmo had re-filed a 510(k) application to the FDA about two weeks ago and was seeking to Conformité Européenne mark certification for its gas sensing capsule in Europe.
Mr Hebblewhite said RMIT’s equity stake in the company was commercial in confidence.
“Full ownership of our core [intellectual property] further strengthens Atmo’s position as we advance toward regulatory clearance and commercialization, ensuring long-term value for our company and bringing benefit to the patients we aim to serve,” Mr Hebblewhite said.
Atmo is a public-unlisted company.

CLARITY PHARMACEUTICALS

Clarity says it has treated the first of 24 patients in the expansion cohort of its phase II trial of 8.0GBq (giga-becquerels) of copper-67 Sar-Bis-PSMA for prostate cancer.
In 2022, Clarity said it had treated the first patient in its 44-patient, 'Secure' phase I/IIa trial of Cu-67 Sar-bis-prostate specific membrane antigen (PSMA) for metastatic non-resectable prostate cancer; and in 2023, said it had treated the first cohort in the trial and would increase the dose to 8.0GBq in cohort two (BD: Oct 7, 2022; May 24, 2023).
In 2024, the company said the first patient treated with two doses of 8.0GBq of Cu-67 Sar-Bis-PSMA had a complete response; and later, said that data from three patients in cohort four of the trial showed Cu-67 Sar-Bis-PSMA was safe and potentially reduced prostate-specific antigen (BD: Apr 30, Sep 12, 2024).
Today, Clarity said the safety review committee had recommended the trial progress to the cohort expansion phase and it had increased the total number of cycles to be administered from up-to four cycles to up-to six cycles.
The company said the 24 patients would receive a combination of an 8.0GBq dose of Cu-67 Sar-Bis-PSMA and enzalutamide, an androgen receptor pathway inhibitor.
Clarity said it would use an "improved Cu-67 Sar-Bis-PSMA product formulation … [which] offers room temperature stability, supply and scalability, which are essential for late-stage clinical trials and streamlined commercial-scale manufacture".
Clarity was up 8.5 cents or 4.9 percent to $1.83 with 3.2 million shares traded.

NOXOPHARM

Noxopharm says its SOF-SKN lupus medication has passed final in-vivo, pre-clinical safety studies ahead of regulatory submission for a phase Ia trial.
Last year, Noxopharm said it hoped to start a trial of its Sofra drug candidate SOF-SKN for cutaneous lupus erythematosus-related skin disease by 2025 (BD: Aug 19, 2024).
Today, the company said the in-vivo study examined "numerous safety and toxicity criteria to check there were no clinically relevant adverse effects, and that the drug would be considered safe to give to trial participants".
Noxopharm said there were "no clinically relevant safety issues identified" and that it would apply for human research ethics committee approval for a clinical trial.
Noxopharm was up 0.6 cents or 8.7 percent to 7.5 cents.

ARGENT BIOPHARMA

Argent says it has a deal with Auscann to share "proprietary datasets and regulatory expertise to streamline regulatory submissions and enhance market readiness".
Argent said Auscann would licence its marijuana-based Cannepil for non-epilepsy-related pharmaceutical programs in exchange for access to Auscann's self-emulsifying, hard-shell capsule formulation Neuvis, including pharmaco-kinetic and pharmaco-dynamic data.
The company said it would form a joint steering committee to oversee research and development, data optimization and streamline regulatory pathways.
Argent said the deal had a "deferred licencing fee structure, with royalties on pharmaceutical products developed using jointly leveraged data, research and development, or assets" and that the deal aimed to reduce development costs, accelerate timelines, and increase access to pre-clinical and clinical data.
Last year, the ASX said it had removed Auscann Group Holdings from the Official List under Listing Rule 17.15, for not paying its annual listing fees (BD: Aug 29, 2024).
Argent fell half a cent or 2.8 percent to 17.5 cents.

ANTEOTECH

Anteotech says it has appointed director Merrill Gray as interim chief executive officer and managing-director, with David Radford stepping down, effective from today.

In 2022, Anteotech said it appointed Mr Radford as managing-director and chief executive officer, on a base salary of $450,000 (BD: Jul 19, 2022).

Earlier this year, the company said it appointed the Europe-based Ms Gray as a non-executive director (BD: Jan 19, 2025).

Today, Anteotech said Mr Radford had “led the company through an important transition from a [research and development] focus to initial product sales with globval companies and the building of a sales pipeline with multiple potential customers and business partners”.

The company said Mr Radford would continue to serve as a strategic advisor for four weeks, working with Ms Gray to continue to advance the company’s energy and life science products.

Anteotech said Ms Gray’s appointment was effective on April 16, 2025 and that she was an experienced ASX-listed managing-director and chief executive officer in mineral processing and energy transitioning including critical minerals and battery materials supply chains.

According to her Linkedin profile, Ms Gray held a Bachelor of Engineering and a Bachelor of Science from Dunedin, New Zealand’s University of Otago, a Master of Business Administration from the University of Melbourne and a Doctor of Business Administration from Perth’s Curtin University.

Anteotech was up 0.1 cents or 10 percent to 1.1 cents with 3.3 million shares traded.

ALCIDION GROUP

Alcidion says it has appointed Prof Andrew Way as a non-executive director, to replace director Victoria Weekes who “will be stepping down mid-year”, effective from today.

Alcidion said Prof Way had been chief executive officer of Alfred Health, held senior positions in the UK National Health Service, was a professor at Monash University and held non-executive and advisory roles including chair of the Department of Health’s Heal Services Victoria.

According to his Linkedin page, Prof Way held a Bachelor of Science from England’s City Saint George’s University of London and a Master of Business Administration from the Staffordshire, England’s Keele University.

Alcidion fell 0.1 cents or 1.3 percent to 7.4 cents with one million shares traded.