Biotech Daily

Monday May 5, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMMUTEP UP 13%; IMPEDIMED DOWN 13%**

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*** ENLITIC UP-TO $50m GE HEALTHCARE DEAL; $10m PLACEMENT**

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*** JAKE VAN DER HOEK REPLACES ARCHER CO-SEC DAMIEN CONNOR**

MARKET REPORT

The Australian stock market fell 0.97 percent on Monday May 5, 2025, with the ASX200 down 80.2 points to 8,157.8 points. Ten of the Biotech Daily Top 40 stocks were up, 26 fell, three traded unchanged and one was untraded.

Immutep was the best, up 3.5 cents or 13.0 percent to 30.5 cents, with 11.8 million shares traded. Genetic Signatures and Prescient climbed more than six percent; Amplia and Nova Eye were up more than four percent; Actinogen and Starpharma rose more than three percent; 4D Medical, Cyclopharm and Emvision were up more than one percent; with CSL up by 0.2 percent.

Impedimed led the falls, down 0.5 cents or 12.8 percent to 3.4 cents, with two million shares traded. Atomo lost 10.5 percent; Dimerix and Optiscan were down more than seven percent; Clarity was down 6.9 percent; Compumedics fell 5.1 percent; Alcidion was down 4.55 percent; Avita, Curvebeam, EBR, Medical Developments, Nanosonics, Paradigm, Syntara and Universal Biosensors were down three percent or more; Aroa, Clinuvel, Cochlear, Medadvisor, Mesoblast and Proteomics shed more than two percent; Botanix, Micro-X, Neuren, Polynovo and Pro Medicus were down more than one percent; with Orthocell, Resmed and Telix down by less than one percent.

IMMUTEP

Immutep says its phase IIb trial of eftilagimod alpha, or 'efti', with Keytruda for head and neck cancer shows median overall survival of 17.6 months in 31 patients.

Last year, Immutep said a 171-patient trial showed efti, previously IMP321, with anti-programmed cell death-1 therapy pembrolizumab, marketed as Keytruda, in patients with a combined positive score of more than one (CPS > 1), cohort A, led to "overall response rates that exceed Keytruda monotherapy" (BD: Jun 27, 2024).

At that time, the company said 58 of 118 evaluable patients in cohort A had a 32.8 percent overall response when treated with the combination, compared to a 26.7 percent overall response in the 60 patients treated with Keytruda alone.

In September, Immutep said that cohort A patients who were dosed with efti and Keytruda had a complete response rate of 6.9 percent, compared to 3.7 percent for Keytruda alone (BD: Sep 16, 2024).

In December, the company said in results from cohort B, 31 head and neck cancer patients with combined positive score of less than one (CPS < 1) showed "strong overall survival, progression-free survival, and durability" (BD: Dec 12, 2024).

Today, Immutep said the 17.6-month median overall survival in the 31 evaluable cohort B patients compared "favorably" to historical results from the two current standard-of-care treatments for first line head and neck squamous cell carcinoma patients with CPS < 1.

The company said the standard-of-care cetuximab and chemotherapy led to 10.7 months median overall survival, anti-programmed death-1 therapy and chemotherapy led to 11.3 months median overall survival and anti-programmed death-1(PD-1) monotherapy led to 7.9 months median overall survival.

Immutep said that up to 20 percent of head and neck cancer patients had a combined positive score of less than 1 (CPS < 1) and that anti-PD-1 therapy alone was only approved for patients who expressed PD-L1 (CPS < 1).

The company said efti in combination with pembrolizumab continued to be "well-tolerated with no new safety signals".

Immutep said it had requested a meeting with the US Food and Drug Administration to discuss next steps, including potential paths to approval of efti for first line head and neck cancer with PD-L1 CPS < 1.

The company said patient follow-up, data collection, cleaning and analysis continued, with plans to provide "a further update later this year".

Immutep managing-director Marc Voigt said the company was "excited to see this strong survival benefit for head and neck cancer patients with such cold tumors".

"Combining these two complementary immuno-therapies has led to a seven-fold increase in response rates and a more than doubling of median overall survival as compared to historical results from anti-PD-1 monotherapy," Mr Voigt said.

"Driving durable responses that translate into clinically meaningful survival holds tremendous promise for these patients in need of more tolerable and efficacious therapies," Mr Voigt said.

"There is a high unmet need in [first line head and neck squamous cell cancer] patients with cold tumors and PD-L1, CPS < 1, due to the lack of an approved immuno-therapy only treatment regimen and a lack of competitor trials with chemotherapy-free approaches targeting this patient population," Mr Voigt said.

"Given the strength of the efficacy and safety results generated to date with efti in combination with pembrolizumab, we will meet with regulators to discuss next steps and potential paths to approval," Mr Voigt said.

Immutep was up 3.5 cents or 13.0 percent to 30.5 cents with 11.8 million shares traded.

ENLITIC

Enlitic says it has an up-to $50 million “migration services” deal with GE Precision Healthcare and hopes to raise $10 million at 4.0 cents a share in a placement.

Enlitic said subsidiary Laitek had a 5-year deal with Chicago’s General Electric (GE) Healthcare to deliver between $5 million and $10 million of “annual migration capacity”, subject to raising a minimum $10 million “in funding from external sources”.

Earlier this year, Enlitic said GE Healthcare’s Genesis imaging program would include its artificial intelligence (A.I.)-based Ensight Suite program for medical imaging migrations and the transmission of imaging data (BD: Mar 5, 2025).

Today, the company said GE Healthcare agreed to repay $US2 million ($A3.1 million) for Laitek’s migration services and that the total revenue opportunity was between $25 million and $50 million, with the memorandum to remain in effect until December 31, 2025, by which time a definitive agreement was expected to be finalized.

Enlitic said it had “firm commitments” to raise $10 million in a non-underwritten, placement of Chess depositary interests (CDIs) at four cents each, a 21.2 percent discount to the 15-day volume weighted average price.

The company said that investors would receive one attaching option for every two CDIs issued, exercisable at 5.0 cents each within three years of issue.

Enlitic said the funds would be used for research and development, quality and regulatory activities, strategic development, sales, marketing and customer service.

The company said that managing-director Michael Sistenich would subscribe for 1,250,000 CDIs, subject to shareholder approval.

The company said Taylor Collison and MST Financial Services were co-managers of the placement and it still expected operational cashflow break-even by 2026.

Enlitic managing-director Michael Sistenich said the company’s “Ensight suite of data intelligence tools turn what was once a cumbersome challenge into a strategic opportunity, to improve data quality and accelerate the adoption of modern, A.I.-driven healthcare solutions delivering better outcomes for patients”.

Enlitic fell 0.95 cents or 20.0 percent to 3.8 cents with 2.1 million shares traded.

AUSBIOTECH

Ausbiotech says it “welcomes the re-election of the Albanese Government and calls for a renewed national focus on life sciences”.

Ausbiotech chief executive officer Rebekah Cassidy congratulated Prime Minister Anthony Albanese “on his decisive victory”.

“The Albanese Government’s re-election presents a renewed opportunity to strengthen Australia's life sciences sector and deepen our collaborative efforts,” Ms Cassidy said.

Ms Cassidy said the biotechnology sector had been held back by “long held and stubborn challenges” and said that a whole-of-government approach was “essential, starting with the establishment of a National Life Sciences Council as a strategic partnership between industry and government”.

Ausbiotech said the Australian Government should establish a “whole-of-government National Life Sciences Strategy to guide long-term policy, investment, and coordination” and an Australian Life Sciences Council “to shape a shared vision and address sector-wide challenges”.

The industry organization called for “recognition of life sciences as a priority industry for national growth, innovation and resilience … [and] greater investment in data and evidence-based policy to support smarter decision-making and drive measurable outcomes”.

CORRECTION: MICRO-X

Friday's edition reported that Peter Rowland was the founder of Micro-X.
EG Capital co-founder Alison Coutts says she co-founded Micro-X in 2011 with Ko Koike, and appointed Peter Rowland as CEO.
Peter Rowland told Biotech Daily that he founded the company.
Biotech Daily apologizes for the confusion.
Micro-X fell 0.1 cents or 1.7 percent to 5.8 cents.

4D MEDICAL

4D Medical says it will provide its pulmonary hypertension analysis artificial intelligence (A.I.)-based algorithm to the Salt Lake City, Utah-based Intermountain Health.
4D Medical said "the first year's payment by Intermountain Health to Nuance is fixed, at a price that represents only a small volume of scans … however, in future years the payments will build to the number of scans in use across the 33 hospitals in the system, thereby representing a significant opportunity".
The company did not disclose the value of the contract.
A 4D Medical spokesperson told Biotech Daily the pulmonary hypertension analysis algorithm received FDA 510(k) clearance on August 27, 2024 through subsidiary Imbio.
In 2023, the company said it acquired the Minneapolis, Minnesota-based imaging company Imbio for $US25 million ($A38.6 million) (BD: Dec 18, 2023).
Today, 4D Medical said Intermountain Health was a network with 33 hospitals, 400 clinics and nearly 4,000 physicians in Utah, Idaho, Nevada, Colorado and Montana.
The company said its algorithm was used in acute care settings to assess pulmonary hypertension secondary to pulmonary embolism by measuring right ventricle, main pulmonary artery diameters and clinically relevant ratios, which were indicators of pulmonary hypertension resulting from pulmonary embolism-related thrombus.
4D Medical said the contract was secured by the Microsoft-owned Nuance Communications as part of a distribution deal, and that Nuance provided A.I. clinical documentation and diagnostic imaging solutions to healthcare providers in the US.
4D Medical said the deal was the first major deployment of its algorithm in a "large, integrated health network".
4D Medical was up half a cent or 1.7 percent to 30 cents with 2.8 million shares traded.

ALTERITY THERAPEUTICS

Alterity says the US Food and Drug Administration has granted ATH434 fast track designation for the treatment of multiple system atrophy (MSA).
Alterity said the designation was intended to "facilitate and expedite the development and review of new drugs for serious conditions with unmet medical needs".
Alterity chief executive officer Dr David Stamler said receiving FDA fast track designation for ATH434, alongside the orphan drug designation already received, underscored "the promise of this novel agent to address the urgent need for a disease modifying therapy for individuals with MSA".
"This designation reinforces the potential of ATH434 as demonstrated by recent scientific findings related to its mechanism-of-action and the robust and clinically meaningful efficacy from our double-blind phase II clinical trial," Dr Stamler said. "Importantly, the fast-track designation provides us the opportunity to interact with the FDA more frequently on the advancement of ATH434, potentially accelerating its development path and approval."
Alterity was up 0.1 cents or 11.1 percent to one cent with 120.4 million shares traded.

EBR SYSTEMS

EBR says it has applied to the US Centers for Medicare and Medicaid Services (CMS) for transitional pass-through reimbursement for its Wise cardiac resynchronization therapy.
Last month, EBR said it had US Food and Drug Administration approval for its Wise cardiac resynchronization therapy CRT for left ventricular pacing and later said CMS recommended it receive the maximum “new technology add-on payment” of 65 percent of cost, in addition to normal reimbursement (BD: Apr 14, 15, 2025).
Today, EBR said the transitional pass-through reimbursement was designed to facilitate hospital adoption of breakthrough medical technologies that showed “substantial clinical improvement for patients, but whose costs are not yet fully incorporated into standard Medicare payment rates”.
EBR managing-director John McCutcheon said that transitional pass-through reimbursement would “provide a clear reimbursement pathway to hospitals”.
EBR fell 4.5 cents or 3.6 percent to $1.22.

AROVELLA THERAPEUTICS

Arovella says it has the option to licence two chimeric antigen receptors (CAR) targeting solid tumors, from the Houston, Texas-based Baylor University.
Arovella said it had the exclusive right to licence multiple patent families from Baylor to “broaden the utility” of its invariant natural killer T-cell (INKT) platform.
The company said one of the CAR platforms targeted GD2, found on the surface of solid tumors including neuroblastoma, melanoma, glioma, small-cell lung carcinoma and various breast cancers, and the other targeted GPC3, which was found on the surface of numerous cancers including hepatocellular carcinoma, or liver cancer.
Arovella said if it exercised its licencing option, it would develop the chimeric antigen receptors into allogeneic CAR-INKT products targeting GD2 and GPC3.
The company said there were no fees payable for the grant of the option, which had a six-month term, and that it would negotiate a licence agreement.
Arovella managing-director Dr Michael Baker said access to two additional solid tumor targets was “an excellent opportunity for Arovella to leverage the progress it has made in developing its proprietary manufacturing process”.
Arovella was unchanged at 8.8 cents with four million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it has dosed all 10 patients in its open-label, 12-month extension study of NUZ-001, formerly monepantel, for amyotrophic lateral sclerosis.
Last year, the then Pharmaust said it had dosed the first of up-to 12 patients in its open-label, phase I, 12-month extension study of the then monepantel for motor neuron disease, or amyotrophic lateral sclerosis (BD: Feb 14, 2024).
Today, the company said updated survival data of NUZ-001 compared to unmatched historical controls showed the drug “significantly increased survival ($p = 0.000717$)” and “significantly reduced the risk of death by 78.5 percent ($p = 0.0015$)”.
The company said that NUZ-001 “may provide substantial clinical benefits for this cohort of patients, potentially extending the median survival by approximately 11 months”.
Neurizon said seven of the original 12 patients were still alive, six patients continued to receive NUZ-001 under a compassionate use program and were 31 months into continuous treatment, with top-line results expected by October 2025.
Neurizon was unchanged at 14 cents.

NEUROTECH INTERNATIONAL

Neurotech says 28 days of repeat dosing with NTI164 oral marijuana for paediatric neurological disorders was shown to be well-tolerated in 116 rats and 42 dogs.
Neurotech said it dosed 116 rats and 42 dogs with twice-daily oral doses for 28-days, including low, mid and high-level doses, followed by a 14-day recovery period.
The company said the data was required for investigational new drug submission and supported regulatory filings with the US Food and Drug Administration, the Australian Therapeutic Goods Administration and the European Medicines Agency.
Neurotech managing-director Dr Anthony Filippis said the company was “extremely encouraged by these robust safety findings, which mark a crucial step in our regulatory and clinical development pathway”.
Neurotech was up 0.2 cents or 8.7 percent to 2.5 cents with 2.5 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has received $US175,122 ($A271,987) from the Canadian Government under its Scientific Research and Experimental Development Tax Incentive program.
Recce said the incentive covered 10 percent of its expenditure for research conducted in Canada and was in addition to the 43.5 percent Federal Research and Development Tax Incentive it expected from the Australia Government “later this calendar year”.
Recce was up half a cent or 1.7 percent to 29.5 cents.

NEXT SCIENCE

Next Science says Florida’s Duval County, Fourth Judicial Circuit Court has dismissed former employee Michael Morello’s derivative complaint for “lack of standing”.
In January, Next Science said former head of wound care sales Mr Morello had filed a lawsuit in a Florida court “alleging breaches of fiduciary duties and mismanagement against several employees” (BD: Jan 19, 2025).
At that time, the company said Mr Morello had filed in the Fourth Judicial Circuit Court in Florida and alleged its Xbio was not approved by the US Food and Drug Administration as a biofilm eradication process and that it “did not take adequate measures to address safety concerns about the use of … Xperience in breast implant procedures”.
Today, Next Science said its non-compete litigation against Mr Morello and “several other former employees for breach of post-employment restraints is ongoing”.
Next Science was up 0.4 cents or 4.4 percent to 9.5 cents.

MEDADVISOR

Medadvisor says it has been reinstated to the ASX following a voluntary suspension relating to the late lodgment of a cleansing notice.
Last month, Medadvisor requested a suspension following a trading halt in relation to a court order under section 1322 of the Corporations Act (2001) regarding a cleansing notice lodged to the ASX (BD: Apr 24, 29, 2025).
Today, the company said the Federal Court of Australia had heard its application “for the orders and granted the relief sought”.
Last month, the company said it raised $5 million at 10 cents a share and hoped for $2 million in a share plan (BD: Apr 1, 2025), and in a cleansing notice announced on April 23, 2025, said it had issued 45,750,000 placement shares.
Medadvisor fell 0.2 cents or 2.1 percent to 9.4 cents with two million shares traded.

RACE ONCOLOGY

Race says it has appointed Dr Jose Iglesias as its chief medical officer and Dr Simon Fisher as its head of clinical, effective immediately.

Race said Dr Iglesias had been head of clinical development and chief medical officer of Abraxis Bioscience, head of clinical development at Celgene and had worked for Amgen, Bionomics, Biothera Pharmaceuticals, Apobiologix and Eli Lilly.

According to his Linkedin page, Dr Iglesias held undisclosed degrees from Uruguay's University of Montevideo, Ontario's University of Toronto and Durham, North Carolina's Duke University.

The company said Dr Fisher had experience in clinical development, regulatory strategy and executive management, including at Novartis, Astrazeneca and Bristol-Myers Squibb, and was most recently the senior medical director of Johnson and Johnson in Australia and New Zealand.

According to his Linkedin profile, Dr Fisher held a Bachelor of Medicine, Bachelor of Surgery and a Master of Business Administration from Melbourne's Monash University.

Race fell eight cents or 6.6 percent to $1.13.

ARCHER MATERIALS

Archer says it has appointed Jake van der Hoek as its company secretary, replacing resigning company secretary and chief financial officer Damien Connor.

Archer said Mr van der Hoeck was a director of corporate secretarial and financial services firm HLB Mann Judd, had nearly 10 years' experience in the financial sector and was currently joint company secretary of Hillgrove Resources.

The company said Mr Connor had "agreed to assist as required to ensure a smooth transition through to June 30, 2025".

Archer was up one cent or 3.7 percent to 28 cents.