Biotech Daily

Monday April 28, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: COMPUMEDICS UP 12.5%; RESONANCE DOWN 12.5%**

*** FDA APPROVES EPIMINDER EPILEPSY MONITOR IMPLANT**

*** TELIX: FDA REQUIRES MORE TLX101-CDx DATA**

*** PACIFIC EDGE LOSES CXBLADDER US MEDICARE REIMBURSEMENT**

*** BIOXYNE 9-MONTH RECEIPTS UP 202% TO $22m**

*** CLEVER CULTURE 9-MONTH RECEIPTS UP 335% TO $3.8m**

*** ATOMO 9-MONTH RECEIPTS UP 36% TO $3.7m**

*** CANN TAKES $836k RADIUM R&D TAX INCENTIVE LOAN**

*** ORTHOCELL REMPLIR APPROVED IN THAILAND**

*** PYC: 'VP-001 IMPROVES VISION FOR RP11'**

*** RADIOPHARM IMAGES 1st PHASE IIb RAD101 BRAIN CANCER PATIENT**

*** DIMERIX: FDA CONFIRMS DMX-200 FSGS ENDPOINT**

*** EMVISION OPENS 'EMU' STROKE TRIAL AT MAYO CLINIC**

*** RECCE, US ARMY R327 FOR BIO-DEFENCE PATHOGENS STUDY, IN-VITRO**

*** CLEO, UNIVERSITY COLLEGE LONDON OVARIAN CANCER STUDIES**

*** PERCHERON EGM DEFEATS 2nd BOARD SPILL CALL**

*** PLATINUM REDUCES TO 12% OF SYNTARA**

*** TRIVARX US VETERANS DEPRESSION TRIAL PROTOCOL APPROVED**

MARKET REPORT

The Australian stock market was up 0.36 percent on Monday April 28, 2025, with the ASX200 up 28.9 points to 7,997.1 points. Sixteen of the Biotech Daily Top 40 stocks were up, 18 fell, three traded unchanged and three were untraded. All four Big Caps were up.

Compumedics was the best, up 3.5 cents or 12.5 percent to 31.5 cents, with 193,751 shares traded. Percheron climbed 11.1 percent; Orthocell was up 8.5 percent; Aroa rose 7.7 percent; Amplia, Dimerix, Impedimed and Starpharma were up more than five percent; Immutep was up four percent; Curvebeam, Paradigm and Pro Medicus were up more than three percent; Medical Developments and Resmed rose more than two percent; 4D Medical, Cochlear, CSL and Micro-X were up one percent or more; with Avita and Emvision up less than one percent.

Resonance led the falls, down 0.5 cents or 12.5 percent to 3.5 cents, with 1.3 million shares traded. Syntara lost 9.3 percent; Clarity was down 8.3 percent; Genetic Signatures and Telix were down more than six percent; Atomo was down 5.3 percent; Prescient and Universal Biosensors fell more than four percent; Actinogen and Neuren were down more than three percent; Proteomics shed 2.6 percent; Alcidion, Clinuvel, EBR, Nova Eye and Polynovo were down one percent or more; with Cyclopharm and Nanosonics down by less than one percent.

EPIMINDER

Epiminder says it has US Food and Drug Administration de novo clearance for its Minder implantable electro-encephalogram for monitoring drug-resistant epilepsy.

The Melbourne-based Epiminder said that its electro-encephalogram (EEG) device was implanted under the scalp, sent brain activity data to a wearable device that received the recordings and wirelessly transmitted them into a smartphone application, allowing for the continuous monitoring of brain activity in epilepsy patients.

The company said it received FDA clearance on Easter Friday April 18, 2025 (AEDT) and that following the approval its Minder device was “the first and only implantable continuous EEG monitor approved in US”.

Epiminder said the de novo authorization was “significant as it creates a new classification of device which underscores both the innovation and the clinical validation behind Minder”.

According to its website, Epiminder was founded in 2018 with Cochlear, St Vincent’s Hospital, the University of Melbourne and the Bionics Institute to develop and commercialize the intellectual property of Prof Mark Cook and Prof Chris Williams.

The company said Prof Cook was its founder and chief medical officer and that Dr Rohan Hoare was its chief executive officer

Epiminder said the device was “developed to address the shortcomings in current electro-encephalogram technologies”.

The company said the device could “provide health care professionals and their patients with more accurate and timely diagnoses, enhanced therapeutic drug monitoring, and can better inform decisions on non-drug treatments like surgery”.

Epiminder said the software application was supported by data from a prospective, case-controlled, comparator, clinical trial held at Australian hospitals from 2019 to 2023.

Prof Cook said the study exceeded the company’s expectations and showed Minder “delivered actionable clinical insights for nearly 90 percent of study participants, highlighting the real-life benefits that Epiminder's best-in-class [implantable continuous electro-encephalogram monitor] can deliver relative to the current standard-of-care”.

Prof Cook said the study included “a groundbreaking five-year continuous recording in one participant”.

Epiminder said epilepsy was “one of the most common serious chronic neurological disorders, affecting approximately 52,000,000 people worldwide including 250,000 Australians and 3,400,000 Americans”.

The company said epilepsy was a neurological condition where a person experiences recurrent seizures caused by abnormal electrical activity in the brain, with seizures presenting in a variety of ways including motor symptoms, absence or focal impaired awareness or with subtle or no outward physical signs.

Epiminder said that the occurrence of seizures varied in frequency among patients, from less than one a year to several a day.

The company said it intended to begin US commercialization of Minder this year, with a roll-out in epilepsy centres as part of a program to show the clinical utility of the device.

Epiminder chief executive officer Dr Rohan Hoare said “by extending the monitoring window of an EEG from days using current technologies to months or even years with Minder, we can deliver unprecedented access to a high-fidelity stream of continuous [electro-encephalogram] data to health care professionals and their patients”.

“Looking ahead, Epiminder plans to develop a suite of integrated software solutions that will extend the clinical impact of the Minder device, for example by providing patients with advance notice of seizures through [artificial intelligence]-enabled forecasting,” Dr Hoare said.

Epiminder is a private company.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration requires “additional confirmatory clinical evidence” for its new drug application of TLX101-CDx for brain cancer imaging.

Last year, Telix said the FDA had granted fast-track designation for Pixclara, or TLX101-CDx, positron emission tomography (PET) for glioma imaging; later, filed a new drug application for the imaging agent with the FDA, which had granted ‘priority review’ for the submission (BD: Apr 16, Aug 28, Oct 24, 2024).

Today, Telix said that in “a complete response letter” the FDA ruled that the new drug application “cannot be approved in its current form” … [and] the FDA stated additional confirmatory clinical evidence is required to progress the application, despite a robust consultation process prior to submission and during review of the [new drug application]”.

Telix said the FDA had not raised any concerns about the safety for TLX101-CDx and that it would “be requesting a hearing with the FDA to review the basis for the decision and is assessing clinical strategies available to augment the package in the near term”.

The company said fluorine-18-based positron emission tomography, such as its TLX101-CDx was “recommended medical best practice in relevant international oncology practice guidelines and is used extensively in other parts of the world”.

Telix said the FDA response did not impact its 2024-’25 financial guidance “as guidance excludes revenue forecasts from unapproved products”.

Telix managing-director Dr Chris Behrenbruch said the company had “multiple go-forward pathways available to us, such as providing additional confirmatory data through several active clinical programs, including company-led studies”.

“Our immediate focus is understanding the FDA’s feedback and augmenting our submission with additional data to satisfy the agency as soon as possible,” he said.

Telix fell $1.88 or 6.6 percent to $26.68 with 3.8 million shares traded.

PACIFIC EDGE

Pacific Edge says local coverage determination changes halting US Medicare coverage of its Cxbladder urine test became effective on April 24, 2025.

In 2023, Pacific Edge said that US Medicare administrative contractor Novitas did not consider its Cxbladder urine tests for bladder cancer “medically reasonable and necessary” and would cease reimbursement (BD: Jul 28, 2023).

In January, the company said options included a legal challenge and last week said a Pennsylvania court did “not have jurisdiction” (BD: Jan 19, Apr 24, 2025).

Today, Pacific Edge said lobbying had “not yet yielded a change to the effective date or retirement of the local coverage determination”.

The company said it generated 60 percent of US revenue from Medicare and would “focus on the paths available” including reconsideration requests for its Cxbladder Triage and Cxbladder Monitor products, but would “not seek re-coverage of Cxbladder Detect as no new evidence has been published that can be submitted for reconsideration”.

The company said Novitas reconsideration requests were estimated to take six to nine months per product.

Pacific Edge said the loss of Medicare coverage was “expected to have a significant impact on testing volume” but it would “continue to bill and receive reimbursement from contracted commercial US payers without interruption … and from non-contracted private payers in line with historic reimbursement rates”.

Pacific Edge chief executive officer Dr Peter Meintjes said the company was “obviously disappointed we have been unable to maintain coverage of our tests in the short term”.

Pacific Edge fell 3.5 cents or 31.8 percent to 7.5 cents.

BIOXYNE

Bioxyne says receipts from customers for the nine months to March 31, 2025 were up 202.0 percent to $21,689,000, compared to the previous corresponding period.
Bioxyne said customer receipts from the manufacture and wholesale of its medical marijuana, 3,4 methylene-dioxy-methamphetamine (MDMA) and psilocybin products for the three months to March 31, 2025 were up 238.3 percent to $8,478,000, compared to the prior corresponding period.
The company said the increased revenue was “attributable to significant outperformance from [subsidiary Breathe Life Sciences] Australia and will be enhanced by increased manufacturing capacity”.
Bioxyne said it had a positive cash flow of $1,859,000 for the three months, with cash and equivalents of $6,478,000 at March 31, 2025 compared to $749,000 at March 31, 2024.
Bioxyne fell 0.1 cents or 4.2 percent to 2.3 cents with 9.4 million shares traded.

CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture says receipts from customers for the nine months to March 31, 2025 were up 334.9 percent to $3,762,000, compared to the prior corresponding period.
Clever Culture said customer receipts for the three months to March 31, 2025 from sales and contracts of its automated plate assessment system (Apas) Independence for microbiology culture plate analysis were up 706.4 percent to $2,145,000, compared to the previous corresponding period.
The company said it had a positive cash flow of $1,107,000 for the three months, its second consecutive positive cash flow period, with cash and cash equivalents of $2,215,000 at March 31, 2025 compared to $2,480,000 at March 31, 2024.
Clever Culture was unchanged at 1.6 cents.

ATOMO DIAGNOSTICS

Atomo says receipts from customers for the nine months to March 31, 2025 were up 36.2 percent to $3,715,000, compared to the previous corresponding period.
Atomo said receipts from sales of its HIV finger-prick blood self-test and Pascal original equipment manufacturer sales for the three months to March 31, 2025 were up 4.9 percent to $828,000, compared to the prior corresponding period.
The company said it had a cash burn of $901,000 for the three months, with cash and cash equivalents of $1,971,000 at March 31, 2025 compared to $5,208,000 at March 31, 2024.
Atomo fell 0.1 cents or 5.3 percent to 1.8 cents.

CANN GROUP

Cann says it has taken a $836,469 loan from Melbourne’s Radium Capital at 15.0 percent annual interest against its Federal Research and Development Tax Incentive.
Cann said the loan was against its expected Research and Development Tax Incentive for activities conducted up to the end of February 2025 and was repayable on the earlier of the receipt of the incentive or October 31, 2025.
Cann was unchanged at 1.6 cents with 15.8 million shares traded.

ORTHOCELL

Orthocell says it has Thai Food and Drug Administration approval to begin sales of its Remplir collagen-based wrap for use in nerve repair surgeries.
Earlier this 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).
Today, the company said it intended to appoint a “local on-the-ground specialist distributor to drive sales in the Thai market”.
Orthocell said it expected first sales in Thailand “in the second half of 2025”.
The company said it expected to file Remplir to the European Union and UK regulators “in the next six-to-12 months and approval is currently pending in Canada”.
Orthocell managing-director Paul Anderson said Thailand was “the second largest market for Remplir, after the US, that received approval for”.
Orthocell was up 11 cents or 8.5 percent to $1.40 with 3.1 million shares traded.

PYC THERAPEUTICS

PYC says its phase I/II trial of VP-001 for retinitis pigmentosa type-11 (RP11) shows “statistically significant improvements in vision”.
In 2023, PYC said it had dosed the first of nine patients in its phase I, single-ascending dose study of VP-001 for the blinding eye disease retinitis pigmentosa type-11; with a phase II, multi-dose study to follow; and last year said it had begun a six-patient, multiple-ascending dose study of VP-001 (BD: (BD: Jun 30, 2023; Jul 10, 2024).
Today, PYC said patients dosed with VP-001 showed “clinically-meaningful and statistically significant improvements in vision in the treated eye” compared to the untreated eye, but did not disclose the total number of patients referenced in the trial data.
PYC said the study showed a statistically significant increase in visual acuity as assessed by low luminance visual acuity when compared to the untreated eye and the history of RP11 disease progression ($0 < 0.002$ and $p < 0.0001$, respectively).
The company said patients treated with 30 micrograms or more of VP-001 had improved visual function as measured by microperimetry, “which compared favorably to other precision therapies for different forms of inherited retinal disease”.
PYC said the phase I/II study showed VP-001 had a favorable risk-benefit profile, was safe and well-tolerated with no treatment or procedure-related serious adverse events.
The company said it would meet the US Food and Drug Administration on June 6, 2025 to discuss a registrational study design for VP-001 in RP11.
PYC was up 8.5 cents or 7.6 percent to $1.20.

RADIOPHARM THERANOSTICS

Radiopharm says it has imaged the first of 30 patients in its phase IIb trial of fluorine-18 RAD101 for recurrent brain metastasis.
Last year, Radiopharm said it had investigational new drug approval from the US Food and Drug Administration for a phase IIb/III trial of fluorine-18 (18F)-pivalate, or RAD101, for imaging brain metastasis (BD: May 29, 2023, Jul 23, 2024)
Today, the company said the primary endpoint of the study was concordance between RAD101 positive lesions and those seen in conventional magnetic resonance imaging with gadolinium in participants with suspected recurrent brain metastases.
Radiopharm managing-director Riccardo Canevari said the company expected to report “topline data in the second half of 2025”.
Radiopharm was up 0.1 cents or 4.8 percent to 2.2 cents with 2.65 million shares traded.

DIMERIX

Dimerix says the US regulator has confirmed proteinuria as an appropriate endpoint for full marketing approval of DMX-200 for focal segmental glomerular sclerosis (FSGS).
Dimerix said that in a type C meeting with the US Food and Drug Administration the regulator "confirmed that suitable proteinuria primary endpoints could include either the proportion of patients achieving a defined proteinuria reduction compared to the placebo arm after two years of treatment, or the percentage change in proteinuria from baseline after two years of treatment".
The company said the percentage change in proteinuria from baseline primary endpoint proposed by the FDA aligned with existing preclinical and clinical data on DMX-200, including interim phase III trial data showing there was a reduction in proteinuria in the treatment arm compared to placebo at 35 weeks.
Last year, Dimerix said that it had dosed half, or 144 patients, in its up-to 286-patient, phase III trial of DMX-200 for FSGS (BD: Jan 19, 2025).
Today, the company said the trial had dosed 183 patients and that the FDA remained "open to discussion on endpoints that could support a potential accelerated approval application and verify clinical benefit".
Dimerix was up 2.5 cents or 5.5 percent to 48 cents with 8.6 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it will open its second site for its 300-patient, US validation trial of the 'Emu' brain scanner for stroke diagnosis at Jacksonville, Florida's Mayo Clinic.
Last year, Emvision said it had "positive engagement" from the US Food and Drug Administration for the validation trial of its brain scanner; and later, said it had US ethics approval to begin the trial (BD: Oct 29, 2024; Feb 12, 2025).
Last month, the company said it began the trial at the Royal Melbourne Hospital and Houston's University of Texas (BD: Mar 27, 2025).
Today, Emvision said it had shipped an 'Emu' brain scanner to the Mayo Clinic, with site initiation visit and training scheduled to begin in "early May".
The company said additional trial sites "in the US and Australia will be announced and activated shortly".
Emvision was up one cent or 0.5 percent to $1.96.

RECCE PHARMACEUTICALS

Recce says it will conduct in-vitro studies of R327 for pathogens of bio-defence concern with the US Army Medical Research Institute of Infectious diseases.
Recce said it had a cooperative research and development agreement with partnership and funding from the Defense Threat Reduction Agency, but did not disclose the commercial terms of the agreement.
The company said the collaboration was in addition to the $US2 million ($A2.95 million) US Department of Defense grant for its R327 gel for burn wound infections.
Recce said on successful testing with in-vitro infection models the partnership may progress to small animal model testing.
Recce managing-director James Graham said the program would "see the US Army test R327 against some of the world's deadliest pathogens and comes in addition to an ongoing [Department of Defense] burn wound program, further bolstering Recce's on-going US Government partnerships".
Recce fell half a cent or 1.7 percent to 28.5 cents.

CLEO DIAGNOSTICS

Cleo says with University College London it will conduct two studies of its ovarian cancer blood test using more than 2,000 samples from a previous study.
Cleo said that it had a collaboration agreement with University College London (UCL) to access more than 2,000 samples from the UK Collaborative Trial of Ovarian Cancer Screening, “the world’s largest ovarian cancer screening trial”.
The company said it would use the samples to study whether its test could “discriminate a benign from malignant adnexal mass in a prospectively collected cohort”.
Cleo said the samples would also be used to evaluate whether its test can “improve diagnostic lead time in an asymptomatic average risk population”.
The company said the data collected using its test would “be independently analysed in partnership with UCL, providing unbiased validation of Cleo’s ovarian cancer technology”.
Cleo fell four cents or 9.1 percent to 40 cents.

PERCHERON THERAPEUTICS (FORMERLY ANTISENSE THERAPEUTICS)

Percheron says its second extraordinary general meeting has voted up to 73.46 percent against the removal of its board and the appointment of replacements.
Last year, Percheron fell as much as 91.5 percent after its phase IIb trial of avicursen for Duchenne muscular dystrophy did not meet its primary endpoint (BD: Dec 18, 2024).
In January, the company said it had a call to replace chair Dr Charmaine Charmaine Gittleson and Dr James Garner with Gregory Peters and Gennadi Koutchin; and in February it had a separate notice from Powerhouse Ventures calling to replace its board with Doran Eldar, Dr Julian Chick and Richard Hamersley (BD: Jan 19, Feb 25, 2025).
Last month, the company said a first meeting voted up to 56.55 percent against the removal of Dr Gittleson and Dr Garner and the appointment of Mr Peters and Mr Koutchin (BD: Mar 4, 2025).
Today, Percheron said the removal of Dr Garner was lost with 435,335,046 votes (73.46%) against and 157,273,883 votes (26.54%) in favor, with similar opposition and support seen for Dr Gittleson and the removal of director Dr Ben Price blocked by 423, 975,066 votes (71.54%) against and supported by 168,633,863 votes (28.46%).
The company said the appointments of Mr Eldar, Dr Chick and Mr Hamersley were all defeated by 426,475,066 votes (72.48%) opposition, with 161,929,505 votes (27.52%) in support.
Percheron said more than 450 shareholders voted or directed a proxy in the meeting, with 419 shareholders voting against the board spill and between 39 and 42 shareholders voting in support.
According to its most recent filing, Percheron had 1,087,437,633 shares on offer, meaning that the largest vote in favor of the board spill, 168,633,863 votes, amounted to 15.5 percent of the company, sufficient to win a remuneration report strike or requisition extraordinary general meetings.
Percheron was up 0.1 cents or 11.1 percent to one cent with 1.15 million shares traded.

SYNTARA

Platinum Investment Management says it has reduced its substantial shareholding in Syntara from 207,683,591 shares (12.79%) to 190,988,001 shares (11.76%).
The Sydney-based Platinum said that it sold shares between April 1 and 23, 2025, with the single largest sale 5,638,693 shares on April 17 for $276,205, or 4.9 cents a share.
Syntara fell half a cent or 9.3 percent to 4.9 cents with 7.15 million shares traded.

TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has institutional review board approval for the protocol for its US Department of Veterans Affairs trial of its sleep analysis tool for depression.

Last month, Trivarx said that with the US Department of Veterans Affairs it would conduct a 60-patient, 12-week trial of its screening algorithm for current major depressive episodes (BD: Mar 13, 2025).

Today, the company said it had signed a cooperative research and development agreement with the Greater Los Angeles Veterans Research and Education Foundation and US Department of Veterans Affairs “to formalize the relationship”.

Trivarx said the approval allowed the trial to begin, with first patients expected to be enrolled “in the coming weeks”.

Trivarx chairman David Trimboli said the company was “now focused on finalizing site selection and patient recruitment initiatives”.

“Given the work undertaken to date, we expect first enrolments in the coming weeks with results to follow 12 weeks after,” Mr Trimboli said.

Trivarx was unchanged at 1.2 cents.