Biotech Daily

Monday April 14, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NEUREN UP 21%; EBR DOWN 17%**

*** EBR: FDA APPROVES WISE LEADLESS CARDIAC PACER**

*** ADVANCELL WINS $18m FEDERAL MRFF GRANT**

*** ORTHOCELL Q3 RECEIPTS UP 111% TO RECORD $1.4m**

*** MEMPHASYS PLACEMENT RAISES $1.3m**

*** NEUREN: FDA OKAYS NNZ-2591 PHELAN-MCDERMID ENDPOINTS**

*** WOKE DOSES 24 PHASE IIb WP001 PSILOCYBIN PATIENTS**

*** RHYTHM RETAINS, EXTENDS ISO 13485:2016 CERTIFICATION**

*** EMYRIA OPENS 2nd PERTH EMPAX CENTRE**

*** BOTANIX REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NEUROSCIENTIFIC REQUESTS 'ACQUISITION, CAPITAL RAISING' HALT**

*** ADVANCE TAKES 14% OF OSTEOPORE**

*** POLYNOVO CFO JAN-MARCEL GIELEN REPLACES CO-SEC LIOR HAREL**

*** CYNATA APPOINTS ADVISORY BOARD**

MARKET REPORT

The Australian stock market was up 1.34 percent on Monday April 14, 2025, with the ASX200 up 102.1 points to 7,748.6 points. Twenty-three of the Biotech Daily Top 40 companies were up, 10 fell, six traded unchanged and one was untraded.

Neuren was the best, up $1.94 or 21.1 percent to $11.13, with two million shares traded. Atomo climbed 15.8 percent; Aroa was up 12.8 percent; Clarity and Imugene improved more than eight percent; Resonance was up 7.9 percent; Dimerix, Paradigm and Polynovo climbed more than six percent; Mesoblast and Pro Medicus rose more than five percent; Alcidion and Cochlear were up more than four percent; Emvision and Orthocell improved more than three percent; CSL, Cyclopharm, Genetic Signatures, Immutep and Impedimed rose more than two percent; Amplia, Clinuvel, Compumedics and Nanosonics were up more than one percent; with Avita and Telix up by less than one percent.

EBR led the falls, down 29 cents or 17.2 percent to $1.40, with six million shares traded. Nova Eye lost 9.1 percent; both Medical Developments and Syntara fell four percent; Actinogen was down 3.3 percent; 4D Medical, Cynata and Micro-X shed two percent or more; with Medadvisor, Resmed and Universal Biosensors down more than one percent.

EBR SYSTEMS

EBR says the US Food and Drug Administration has approved its leadless Wise cardiac resynchronization therapy (CRT) for left ventricular endocardial pacing.

EBR said CRT was “shown to improve clinical status and reduce heart failure hospitalizations and mortality”.

The company said “a material proportion of patients cannot be treated with a lead-based system” showing the need for an alternative for stimulating the left ventricle using CRT.

EBR said its Wise CRT system was designed for patients “left behind by conventional CRT … [and was] the only leadless [product] for left ventricular pacing, designed to work seamlessly with existing pacemakers, defibrillators and CRT devices that provide right ventricular pacing”.

In 2021, Brandon Capital said that the Sunnyvale, California-based EBR Systems Inc had raised $110 million at $1.08 a share to list on the ASX to develop its ‘Wise’ pacemaker, with the funds to be used for a pivotal if the device (BD: Nov 22, 2021).

At that time, Brandon said Wise was the “world’s first and only” wireless, inside-the-left-ventricle-of-the-heart pacing system for heart failure, targeting a US Food and Drug Administration FDA approval in 2023, with the device approved for use in Europe and having FDA breakthrough device designation.

In 2023, EBR said that its 183-patient, pivotal trial of Wise met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks, with a reduction of 16.4 percent using its Wise system compared to a performance goal of a reduction of 9.3 percent (p = 0.003) (BD: May 22, 2023).

Earlier this year, EBR said the FDA manufacturing inspection was completed, its Wise system had been accepted for expedited reimbursement and it had completed its 100-day meeting with the FDA (BD: Jan 19, 20, 2025).

Today, the company said the FDA had approved Wise for use in adult patients 22 years and older who were indicated for CRT, and had an existing implanted right ventricular pacing system.

EBR said Wise was indicated for patients who had unsuccessful or turned off coronary sinus lead implantations or patients with implemented pacemakers or implantable cardioverter-defibrillators for whom standard CRT upgrades were not advisable due to “high-risk upgrades”.

The company said it expected to qualify for two reimbursement schemes effective from October 1, 2025, including the “new technology add-on payment” and “transitional pass-through payment", which would provide payment to cover its selling price.

EBR said it was “expanding its team, strengthening training programs and working with hospitals to simplify implant workflows”, with a limited market release to begin in late 2025 and full commercial launch in early 2026.

EBR managing-director John McCutcheon said the company was “thrilled to announce this major milestone for EBR and to share this achievement with our dedicated team, shareholders, partners and stakeholders who have supported us on this journey”.

“Securing FDA approval for the Wise CRT system is a transformative moment, marking our transition from clinical development to commercialization,” Mr McCutcheon said.

“With FDA approval in hand, EBR is well-positioned to bring our innovative solution to market, delivering real impact to patients and servicing a significant unmet need,” Mr McCutcheon said.

“We look forward to executing our commercial strategy and achieving our first revenue in late 2025, paving the way for sustained growth and long-term success,” Mr McCutcheon said.

EBR fell 29 cents or 17.2 percent to $1.40 with six million shares traded.

ADVANCELL PTY LTD

Advancell says the Federal Government's Medical Research Future Fund (MRFF) Frontiers Initiative has awarded it $18 million for its prostate cancer research.

In February, the Sydney-based biotechnology incubator Proto Axiom said it contributed $US2 million ($A3.18 million) to Advancell's $US112 million ($A178 million) series C funding round for the development of cancer radio-therapies (BD: Feb 4, 2025).

Today, the company said it was developing a lead-212 alpha isotope-based targeted for therapeutic use in prostate cancer and would conduct a "first-in-field" clinical trial.

Advancell said it hoped to "transform the clinical management of prostate cancer by leveraging leading therapeutic radio-pharmaceutical technology paired [with] innovative clinical development and a deep understanding of tumor biology to improve the lives of patients with prostate cancer".

Advancell chief medical officer Dr Anna Karmann said that "targeted alpha therapies are among the most promising in oncology".

"We believe this MRFF-funded research can be practice changing and have a lasting positive impact on the lives of patients with prostate cancer," Dr Karmann said.

"We highly value the support and opportunity this funding provides to fast-track translation and accelerate the development of novel combination therapies in an industry-academic partnership," Dr Karmann said.

Advancell is a private company.

ORTHOCELL

Orthocell says receipts from customers for the three months to March 31, 2025 was up 110.7 percent to a record $1,359,000, compared to the previous corresponding period.

Orthocell said that record receipts for the nine months from sales of its Remplir for peripheral nerve reconstruction and Striate+ dental bone repair implant were up 56.3 percent to $3,811,000, compared to the prior corresponding period.

The company said that revenue was up 38 percent for the three months to March 31, 2025 compared to the three months to March 31, 2024 and did "not yet reflect any US Remplir sales".

Earlier this month, Orthocell said it had US Food and Drug Administration approval to commercialize its Remplir collagen wrap for nerve repair (BD: Apr 4, 2025).

Today, the company said it had a positive cash flow of $605,000 for the three months, with cash and cash equivalents of $31,719,000 at March 31, 2025 compared to $20,067,000 at March 31, 2024.

Orthocell was up 5.5 cents or 3.9 percent to $1.475 with 1.8 million shares traded.

MEMPHASYS

Memphasys says it has raised $1,275,000 at 0.6 cents a share in a placement, with one option issued for every share acquired.

Biotech Daily calculates that the 0.6 cents a share issue price is a 14.3 percent discount to the company's last closing price of 0.7 cents a share.

Memphasys said the options would be exercisable at 1.1 cents each by April 15, 2027.

The company said the funds would be used for "strategic discussions" for its Felix sperm separation system and Roxsta livestock reproductive device, including licensing, deals, distribution opportunities and studies, as well as working capital.

Memphasys fell 0.1 cents or 14.3 percent to 0.6 cents with 9.8 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says the US Food and Drug Administration has confirmed the primary endpoints for its phase III trial of NNZ-2591 for Phelan-McDermid syndrome.
Neuren said the primary endpoints for its 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).
The company said that 16 of 18 children showed VABS-3 improvement ($p = 0.0001$) in its phase II trial and an improvement from baseline on the PMSA-C scale ($p < 0.0001$).
Neuren said that 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 $1.94 or 21.1 percent to $11.13 with two million shares traded.

WOKE PHARMACEUTICALS, MACQUARIE UNIVERSITY

Woke says with Sydney’s Macquarie University it has dosed 24 patients in its up-to 240-patient, phase IIb trial of 1.0mg WP001 synthetic psilocybin for depression.
Last year, Woke said Macquarie University had begun enrolling its six-week, placebo-controlled, randomized, 266-patient, phase IIb trial of WP001 ‘low-dose’ synthetic psilocybin tablet for moderate depression (BD: Jun 21, 2024).
Today, the company said the drug candidate had been “extremely well-tolerated, with no notable acute adverse reactions reported”, following the screening of more than 300 patients and 250 dosing sessions of 24 people.
Woke said it had completed the “vanguard stage”, which included two visits from independent monitors, and that the trial had passed both audits.
Woke managing director Matthew Hayne said the Microdep Trial was “the largest psilocybin-based trial focusing on microdosing in the world”.
“The main stage of the trial will now test the efficacy of our drug candidate against placebo,” Mr Hayne said.
“Essentially, we will receive an early indication as to whether our unique drug candidate holds strong promise and merits a final phase III clinical trial, which is typically the last stage before a drug is reviewed for registration as an approved medicine,” Mr Hayne said.
Woke is a private company.

RHYTHM BIOSCIENCES

Rhythm says it has maintained and extended its International Organization of Standardization certification for its Colostat system and other devices.
Rhythm said its ISO 13485:2016 certification had been extended to include “design, manufacturing, distribution installation and servicing of in-vitro devices including immunoassay technology and algorithm software”.
The company said the certification, conducted by the British Standards Institution, was the “internationally recognized quality management standard for in-vitro diagnostics (IVD) and medical devices” and was the seventh consecutive year it had successfully achieved and maintained compliance with the standard.
Rhythm managing-director Dr David Atkins said the company continued “to maintain a quality management system in line with ISO 13485:2016, supporting both the international launch of Colostat and the company’s ability to supply high-quality raw materials for in-house [in-vitro device] applications”.
Rhythm was up 0.1 cents or 1.3 percent to 7.9 cents.

EMYRIA

Emyria says it has opened a second Empax Centre in Perth, which will begin treating two patients for depression and post-traumatic stress disorder (PTSD) today.

Last year, Emyria said it had opened an Empax Centre with Perth's Pax Centre for the delivery and evaluation of 3,4 methylene-dioxy-meth-amphetamine (MDMA)-assisted therapy (BD: Apr 10, 2024).

Later, the company said the New York-based Transcend Therapeutics would use its Empax Centre to evaluate the safety and efficacy of methylone for post-traumatic stress disorder (BD: Jun 20, 2024).

Today, Emyria said the opening of its second facility would increase its treatment capacity by 50 percent and was "designed to comply with the requirements of major healthcare funders seeking to cover evidence-based mental health therapies within licensed healthcare environments".

The company said it was discussing with "multiple East Coast hospital partners and clinicians and is aiming to announce further site openings in 2025".

Emyria was up 0.2 cents or 6.9 percent to 3.1 cents.

BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt "pending release of an announcement regarding a capital raising".

Trading will resume on April 16, 2025, or on an earlier announcement.

Botanix last traded at 35.5 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt "pending an announcement in relation to an acquisition and capital raising".

Trading will resume on April 16, 2025, or on an earlier announcement.

Neuroscientific last traded at 3.5 cents.

OSTEOPORE

The Cayman Islands-based Advance Opportunities Fund says it has become a substantial shareholder in Osteopore with 19,480,519 shares, or 13.88 percent.

In an initial substantial shareholder notice dated April 9, 2025, Advance Opportunities said it bought 19,480,519 shares for $300,000, or 1.5 cents a share.

In a second notice, Advance Opportunities said it increased its Osteopore holding from 19,480,519 shares to 19,980,519 shares without disclosing its voting power with the purchase of 500,000 shares on April 10, 2025 for $16,000, or 3.2 cents a share.

In a third notice, the company said it had reduced its holding from 19,980,519 shares (14.2%) to 19,480,519 shares (13.88%) with the sale of 500,000 shares on April 11, 2025 for $15,950, or 3.2 cents a share.

Last year, Osteopore said it expected to raise $20 million from Advance Opportunities for a redeemable convertible note at four percent a year, issuing in four equal tranches of 20 equal sub-tranches of $250,000 each (BD: Sep 27, 2024).

In February, the company said Advance had subscribed for $2.0 million worth of the $20 million redeemable convertible note; and last week, said Advance subscribed for a further $1.0 million (BD: Feb 17, Apr 8, 2025).

Osteopore fell 0.2 cents or 7.7 percent to 2.4 cents with 4.9 million shares traded.

POLYNOVO

Polynovo says chief financial officer Jan-Marcel Gielen has been appointed interim company secretary following the resignation of Lior Harel, effective from April 15, 2025.
Polynovo said Mr Harel had resigned as general counsel and company secretary and “had been a valuable member of the company's senior leadership team and has led the company’s legal, company secretarial and regulatory affairs functions over the last year”.
The company said Mr Gielen would remain its company secretary until the appointment of a replacement.
Polynovo was up 6.5 cents or 6.25 percent to $1.105 with 2.6 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has appointed Prof John Rasko, Prof Igor Slukvin and Dr Derek Hei as members of its scientific advisory board.
Cynata said Prof Rasko founded and directed the department of cell and molecular therapies at Sydney’s Royal Prince Alfred Hospital and the University of Sydney’s gene and stem cell therapy program and had been the president of the International Society for Cell and Gene Therapy from 2018 to 2020.
The company said the Madison-based University of Wisconsin’s Prof Slukvin was a co-founder of Cynata and a co-inventor of the stem cell technology used in its Cymerus manufacturing platform.
Cynata said Dr Hei had worked at Genentech and Cerus Corp and was currently leading the University of Wisconsin’s Waisman Biomanufacturing, a contract development and manufacturing organization for cell and gene therapies.
The company said Dr Hei was “instrumental in the establishment of Cynata’s Cymerus process at Waisman’.
The company said the advisory board would “provide strategic scientific guidance, support and oversight of the company’s research and development activities”.
Cynata fell half a cent or 2.6 percent to 18.5 cents.