Biotech Daily

Thursday April 10, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: NOVA EYE UP 26%; MEDADVISOR DOWN 2%**

*** OPTHEA CUTS COSTS, 65% OF STAFF**

*** IMMURON RECORD YTD TRAVELAN SALES UP 46% TO $5m**

*** RECCE PLACEMENT RAISES $5m; $11m RIGHTS OFFER TO GO**

*** 4D MEDICAL SIGNS 2 CONTRACTS; NAMED IN US CONGRESS HEARING**

*** CYCLOPHARM 1st US DEFENSE HOSPITAL TECHNEGAS INSTALLATION**

*** ORTHOCELL FILES HONG KONG REMPLIR SUBMISSION**

*** PYC DOSES 1st PHASE Ia PYC-003 KIDNEY DISEASE VOLUNTEER**

*** ENA, MARYLAND UNI START PHASE II INNA-051 TRIAL**

*** TRYPTAMINE, SWINBURNE UNI PSILOCYBIN TRP-8803 BINGE-EATING TRIAL**

*** RENERVE, NETCENTRIX TO LAUNCH NERVALIGN IN INDIA**

*** ASX LONG-TERM SUSPENSION LIST INCLUDES 4 BIOTECHS**

*** MEMPHASYS REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** CARDIEX 22.5m M-D, CHAIR, STAFF RIGHTS EGM**

*** JENCAY CAPITAL TAKES 7% OF MEDADVISOR**

*** MARK AZZI TAKES 5% OF NYRADA**

*** PRESCIENT APPOINTS MELANIE FARRIS DIRECTOR**

MARKET REPORT

The Australian stock market recovered 4.54 percent on Thursday April 10, 2025, with the ASX200 up 334.6 points to 7,709.6 points. Thirty of the Biotech Daily Top 40 stocks were up, three fell, six traded unchanged and one was untraded. All four Big Caps were up.

Nova Eye was the best, up 2.3 cents or 26.4 percent to 11 cents, with 2.5 million shares traded. EBR improved 21.2 percent; Orthocell was up 19.5 percent; Clarity climbed 13.4 percent; Avita was up 12 percent; Alcidion rose 11.6 percent; Percheron and Polynovo were up 10 percent or more; Neuren was up 9.75 percent; Mesoblast, Pro Medicus and Telix were up more than eight percent; Clinuvel and Dimerix were up more than seven percent; Syntara was up 6.1 percent; Amplia, Compumedics, Impedimed, Paradigm and Prescient were up more than five percent; 4D, Medical Developments and Nanosonics climbed four percent or more; Actinogen and CSL were up more than three percent; Cochlear, Cynata, Emvision, Immutep, Proteomics, Resonance and Starpharma rose more than two percent; with Genetic Signatures and Resmed up more than one percent.

Medadvisor led the three falls, down 0.2 cents or 2.2 percent to nine cents, with 1.4 million shares traded. Universal Biosensors lost 1.7 percent; with Cyclopharm down 0.9 percent.

OPTHEA

Opthea says that “in light of the negative trial results” it will decrease costs, including reducing its workforce by about 65 percent, effective from May 1, 2025.

Last month, Opthea said its 993-patient, phase III Coast trial of OPT-302 with aflibercept for wet AMD “failed to meet [its] primary endpoint” and it might be required to pay its Development Funding Agreement (DFA) investors amounts that would have a material adverse impact on its solvency (BD: Mar 24, 2025).

Later, the company said it would discontinue its wet age-related macular degeneration (AMD) trials after its ‘Shore’ phase III trial of OPT-302 with ranibizumab missed its primary endpoint of mean change in best corrected visual acuity (BD: Mar 31, 2025).

Today, Opthea said a limited number of employees would remain in place to ensure the compliant termination of clinical trial activities and oversee administration operations.

The company said the staff reductions would cost about $US4.5 million ($A7.3 million) and save about $US1 million ($A1.63 million) monthly.

Opthea said it had cash and cash equivalents about $US100 million at March 31, 2025.

Today, the company said it remained “in active negotiations with its [development funding agreement] DFA investors … to explore possible options to deliver the best outcome for the company and its shareholders”.

Opthea said there remained “material uncertainty as to Opthea's ability to continue as a going concern … [and it could] not be certain as to the outcome of [its DFA] … discussions or when that outcome may become known”.

Opthea chief executive officer Dr Frederic Guerard said following the trial results and in consultation with the DFA investors the board “concluded that it is in the best interest of our investors to conserve cash”.

“We are grateful for the numerous contributions of our colleagues leaving Opthea and wish them the best for their future endeavors,” Dr Guerard said.

Opthea was in a suspension and last traded at 60 cents.

IMMURON

Immuron says its Travelan for traveler’s diarrhoea sales for the nine months to March 31, 2025 were up 46 percent to a record $5.3 million.

Last year, Immuron said revenue from sales of its products including Travelan for the year to June 30, 2024 rose 171.7 percent to $4,902,865 (BD: Aug 30, 2024).

Today, the company said sales for the three months to March 31, 2025 were up two percent to $1.3 million, compared to the prior corresponding period.

Immuron said Australian Travelan sales for the nine months were up 34 percent to $3,700,000 compared to the previous 12 months, with sales for the three months to March 31, 2025 down eight percent to $800,000.

The company said North American sales for the nine months were up 86 percent on the prior year to $1,600,000, with three-month sales up 28 percent to $500,000.

Immuron chief commercial officer Flavio Palumbo said it was the first time the company “exceeded $5 million in sales, our highest fiscal year sales … with a quarter to come”.

“This is a fantastic result, with [a] record sales quarter in December for Australia on the back of our travel activation program and importantly our North American business continues to produce record results ahead of the key spring summer travel period”.

“The December quarter was a record with Australian pharmacy wholesalers stocking up on the back of Immuron’s expanded pharmacy banner group agreements and ahead of the peak Christmas, New Year holiday period,” Mr Palumbo said.

Immuron was up 0.7 cents or 11.7 percent to 6.7 cents.

RECCE PHARMACEUTICALS

Recce says it has raised $5.0 million at 28.0 cents a share in a placement, with a one-for-six, pro-rata, non-underwritten rights offer for up-to $10.8 million to follow.
Recce said the placement was to an unnamed “Australian-based private investor” and that the offer price was a 19.8 percent to the five-day volume weighted average price.
The company said the funds would be used for its phase III trials, clinical activities, and its investigational new drug application to the US Food and Drug Administration.
Recce said its directors intended to take-up their entitlements in part or in full.
The company said the rights offer had a record date of April 16, would open on April 22 and close on May 5, 2025.
Recce fell 2.5 cents or 7.7 percent to 30 cents with 1.1 million shares traded.

4D MEDICAL

4D Medical says lung ventilation imaging software will be used in two clinical trials and that its technology was “referenced” by Philips in a us congressional testimony.
4D Medical said it would provide its computed tomography ventilation-perfusion (CT VQ) software for an initial $US40,000 ($A65,000), for a trial of stem cells for chronic obstructive pulmonary embolism by San Diego’s SMS Biotech, using CT VQ to assess baseline lung health before therapy and tracking changes in lung function and structure.
The company said it would provide its imaging and functional analysis tools for use in a trial with an unnamed medical device developer, whose identity was “not material and that the announcement contained all material information relevant to the contract”.
4D Medical said that Philips North America chief executive officer Jeff DiLullo told the US House of Representatives Committee on Veterans’ Affairs that “Philips, in concert with … 4D Medical, innovated a [US Food and Drug Administration]-cleared cardio-pulmonary software that can transform standard CT imaging into a detailed four-dimensional image … [which] allows [the Department of Veterans Affairs] clinicians to better assess pulmonary function and leads to faster diagnoses and less invasive procedures”.
Mr DiLullo said the 4D Medical lung screening meant the Department of Veterans Affairs could “improve outcomes for veterans and reduce dependency on taxpayer resources”.
4D Medical was up one cent or four percent to 26 cents with 2.7 million shares traded.

CYCLOPHARM

Cyclopharm says it has installed Technegas for lung ventilation imaging at its first Department of Defense hospital at the Houston, Texas’ Brooke Army Medical Center.
Last year, Cyclopharm said it had an interim agreement to supply 120 US Government Veterans Health Administration hospitals with Technegas for computed tomography-based lung ventilation imaging (BD: Oct 3, 2024).
Today, Cyclopharm said the Brooke Center was the largest military medical facility in the US and the only level one trauma centre within the Department of Defense system.
The company did not disclose the commercial terms of the installation.
Cyclopharm managing-director James McBrayer said the Brooke Center was “more than a hospital, it plays a critical role in the [Department of Defense] healthcare system as a premier medical facility and a cornerstone of military medicine and education”.
“This milestone serves as a strategic step in expanding the deployment of Technegas to other veteran administration and [Department of Defense] hospitals covered under our five-year commercial contract with the US Federal Government,” Mr McBrayer said.
Cyclopharm fell one cent or 0.9 percent to $1.12.

ORTHOCELL

Orthocell says it has submitted a regulatory application for Remplir to the Hong Kong Department of Health's medical device division, with sales expected by 2026.
Last week, Orthocell said it had US Food and Drug Administration 510(k) approval to begin commercial sales of its Remplir collagen-based wrap for use in peripheral nerve repair in the US (BD: Dec 19, 2024; Apr 4, 2025).
Earlier this year, the company said it had submitted a regulatory application for its Remplir collagen-based wrap to the Thai Food and Drug Administration, and expected to submit Remplir for approval in Canada, Thailand, the UK, the European Union and Brazil this year (BD: Jan 22, Feb 21, 2025).
Today, Orthocell managing-director Paul Anderson said the company saw "an excellent opportunity for Remplir throughout Asian markets".
Orthocell was up 24.5 cents or 19.5 percent to $1.50 with 4.1 million shares traded.

PYC THERAPEUTICS

PYC says it has dosed the first participant in its up-to 24-volunteer, phase Ia trial of PYC-003 for polycystic kidney disease.
In February, PYC said it had approval to begin human trials of PYC-003 for polycystic kidney disease in a single ascending dose study, with a primary endpoint of safety, with data expected by 2026 (BD: Feb 10, 2025).
At the time, the company said it would study 0.4mg/kg, 1.2mg/kg and 2.4mg/kg in three cohorts of eight patients, with an optional fourth cohort to receive 4.0mg/kg, if required.
Today, PYC said the first patient received a 0.4mg/kg dose of PYC-003 intravenously, with seven more healthy volunteers to receive either the drug candidate at that dose or a placebo control in the "coming weeks".
The company said the safety review committee would review four-week follow-up data from all subjects in the first cohort before proceeding to dose the second cohort.
PYC was up two cents or two percent to $1.015 with 1.2 million shares traded.

ENA RESPIRATORY

ENA says it will conduct a phase II trial with College Park's University of Maryland to study the safety, tolerability and efficacy of INNA-051 for viral respiratory infections.
ENA said the randomized, double-blind, placebo-controlled trial would study its once-a-week, nasal dry powder INNA-051 in generally healthy adult participants at increased risk of viral respiratory infections during the North American autumn and winter.
The company said it intended INNA-051 to be used "to reduce the impact of viral respiratory infections and prevent severe complications in at-risk populations, including the elderly, those with underlying medical conditions and individuals with occupational risk such [as] first responders, military or essential services personnel".
ENA said top line data was expected by October 2026, with former scientific advisor Prof Justin Ortiz appointed principal investigator.
ENA chief executive officer Dr Christophe Demaison told Biotech Daily that the company had "yet to finalize the study protocol so it's too early to disclose" the number of patients expected to be enrolled in the trial.
Dr Demaison said the University of Maryland partnership and having Prof Ortiz as one of the principal investigators for the trial was "a significant step" for the company.
ENA is a private company.

TRYPTAMINE THERAPEUTICS (FORMERLY EXOPHARM)

Tryptamine says it will conduct a 12-patient, open-label trial of TRP-8803 psilocybin for binge eating disorder with Melbourne's Swinburne University of Technology.
Last year, Tryptamine said an 11-healthy volunteer, phase Ib trial showed TRP-8803 was "generally safe and well-tolerated"; and later confirmed the required dose for a phase II trial, but did not state the dose (BD: Oct 18, Nov 19, 2024).
Previously, the company said that psilocin was the active psychedelic metabolite of psilocybin found in 'magic mushrooms' (BD: Jul 1, 2024).
Today, Tryptamine said the trial would study TRP-8803 with psychotherapy in two, six-person cohorts of adult patients with binge eating disorder, administered with either a two mid-range or two high-range doses two weeks apart.
The company said it expected to enrol patients by July 2025.
Tryptamine said that a separate phase IIa trial by Gainesville's University of Florida had previously showed an oral psilocybin-based TRP-8802 treatment reduced binge eating disorder by more than 80 percent.
The company said its trial's secondary and exploratory objectives included the ability of "inducing the psychedelic state with TRP-8803" and determining clinical activity and the effects of TRP-8803 on the frequency of binge-eating episodes and other weight-related indicators in binge eating patients, four weeks after second dosing.
The company said it expected Swinburne University results by 2026.
Tryptamine said plans for additional trials on larger cohorts of patients in "multiple neuropsychiatry indications are well advanced and expected to commence" by 2026.
Tryptamine chief executive officer Jason Carroll said the agreement with Swinburne University was "important step forward in Tryptamine's clinical development pathway and builds off the strong results from our phase Ib trials … where TRP-8803 met key safety parameters for a diverse subject population".
Tryptamine fell 0.2 cents or 6.45 percent to 2.9 cents with 1.8 million shares traded.

RENERVE

Renerve says with Chennai, Tamil Nadu's Netcentrix Ventures it will commercialize its Nervalign nerve cuff for peripheral nerve repair in India.
Renerve said that through its Indian government partnerships Netcentrix specialized in assisting Australian companies with product testing, validation and approvals to "enable their products to be launched, sold and distributed" in India.
The company did not disclose commercial terms of the deal.
Renerve managing-director Dr Julian Chick said that Netcentrix provided "specialized local expertise and established distribution networks that are essential for a successful entry into an incredibly significant market".
"This agreement complements our existing partnerships in Taiwan, Hong Kong, the Middle East and Mexico," Dr Chick said.
Renerve was up half a cent or 4.55 percent to 11.5 cents.

ASX, BLUECHIIP, EPSILON, GENETIC TECHNOLOGIES, HEXIMA

The ASX has released its list of 79 long-term suspended entities and their deadlines, which includes Bluechiip, Epsilon, Genetic Technologies and Hexima.
The ASX said the companies had been suspended for more than three months for failing to lodge their periodic financial reports, and that if they did not meet the one-year or two-year deadlines they would be removed from the official list.

MEMPHASYS

Memphasys has requested a trading halt pending an announcement “regarding a proposed capital raising”.
Trading will resume on April 14, 2025, or on an earlier announcement.
Memphasys was unchanged at 0.7 cents with 4.3 million shares traded.

CARDIEX

Cardiex says investors will vote to issue 22,500,000 performance rights to managing-director Craig Cooper, chair Niall Cairns and chief strategy officer Catherine Liao.
Cardiex said it would vote to issue Mr Cooper Mr Cairns and Ms Liao 7,500,000 performance rights, each, as long-term incentives, which would vest in three equal tranches when its share priced reached 20 cents, 25 cents and 30 cents.
The company said the performance rights would expire on May 9, 2030 and were in addition to Mr Cooper’s $US420,000 ($A685,875) and Mr Cairns’ $300,000 salaries.
Cardiex said Ms Liao was “not a related party of the company, member of the company’s key management personnel, substantial holder of the company, adviser of the company or an associate of any of these parties”.
According to the company’s website, Ms Liao was its chief strategy officer.
Cardiex said shareholders would vote to ratify the prior issue of placement shares and options as well as the participation of Charlie Taylor in the placement.
The meeting will be held at 24-26 Kent Street, Sydney on May 9, 2025 at 9.30am (AEST).
Cardiex was unchanged at 6.2 cents.

MEDADVISOR

Jencay Capital Pty Ltd says it has increased its substantial shareholding in Medadvisor from 34,263,689 shares (6.21%) to 43,247,079 shares (7.24%).
The Sydney-based Jencay said that it bought 8,983,390 shares on market and in a placement between March 10 and April 8, 2025 for $911,157, or an average of 10.1 cents a share.
Last week, Medadvisor said it raised $5 million at 10 cents a share, with a $2 million share plan to follow, its revenue might fall and it had cut jobs (BD: Apr 1, 2025).
Medadvisor fell 0.2 cents or 2.2 percent to nine cents with 1.4 million shares traded.

NYRADA

Nyrada says Mark Azzie has become a substantial shareholder of the company with 10,814,420 Chess depositary interests (CDIs), or 5.14 percent.
Nyrada said that Mr Azzi became a substantial shareholder on April 7, 2025 following its “deed poll dated January 6, 2020 issued by the company in favour of ASX Limited in respect of the initial public offering of its Chess depository interests”.
In 2020, Noxopharm spin-out Nyrada opened 52.5 percent above its 20-cent initial public offer at 30.5 cents, having raised $8.5 million for cholesterol and pain drug development (BD: Jan 19, 2020).
Nyrada was up half a cent or 4.8 percent to 11 cents.

PRESCIENT THERAPEUTICS

Prescient says it has appointed former Invion director Melanie Farris as an independent, non-executive director.

Prescient said Ms Farris had been non-executive director and company secretary at Factor Therapeutics, non-executive director, chief financial officer and company secretary at Invion, chair of Synapse Australia as well as head of governance risk and compliance, chief governance and risk officer and company secretary at Telix.

According to Linkedin page, Ms Farris held a Bachelor of Communication from the Gold Coast, Queensland's Griffith University.

Prescient was up 0.2 cents or 5.1 percent to 4.1 cents with 2.15 million shares traded.