Biotech Daily

Thursday March 27, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PERCHERON UP 10%; GENETIC SIGS DOWN 11.5%**

*** MESOBLAST RYONCIL AVAILABLE IN US**

*** AMPLIA: '13 PARTIAL PANCREATIC CANCER RESPONSES TO AMP945'**

*** NEUREN STARTS NNZ-2591 FOR HYPOXIC-ISCHEMIC ENCEPHALOPATHY**

*** ALTERITY PHASE II ATH434 MSA LAST PATIENT VISIT**

*** EMVISION OPENS AUSTRALIA, US EMU VALIDATION TRIAL**

*** ACTINOGEN MEETS FDA ON XANAMEM FOR DEPRESSION**

*** AUSTCO PAYS $799k TEKNOCORP EARN-OUT, 4m ESCROW SHARES**

*** CLINUVEL 1.5m SHARE BUY-BACK**

*** ARCHER PROMOTES CTO DR SIMON RUFFELL TO CEO ON $330k PA**

*** AUSTRALIAN ETHICAL TAKES 17.5% OF NOVA EYE**

*** RACE M-D DR DANIEL TILLETT DILUTED TO 7% OF ISLAND**

*** FIL (FIDELITY) DILUTED TO 8.5% OF TRIVARX**

MARKET REPORT

The Australian stock market fell 0.38 percent on Thursday March 27, 2025, with the ASX200 down 30.0 points to 7,969.0 points. Twelve of the Biotech Daily Top 40 companies were up, 20 fell, six traded unchanged and two were untraded.

Percheron was the best, up 0.1 cents or 10 percent to 1.1 cents, with 1.8 million shares traded. Actinogen climbed 8.8 percent; Aroa was up 6.8 percent; Syntara rose 5.4 percent; Curvebeam was up 4.35 percent; Emvision improved 3.8 percent; Amplia, Compumedics and Universal Biosensors were up more than one percent; with Medical Developments, Nanosonics, Neuren and Resmed up by less than one percent.

Yesterday's best, Genetic Signatures, led the falls, down 6.5 cents or 11.5 percent to 50 cents, with 21,630 shares traded. EBR, Pro Medicus and Resonance lost more than seven percent; Paradigm was down 6.5 percent; Immutep, Orthocell and Telix were down five percent or more; Cyclopharm fell 4.6 percent; Avita, Clarity, Dimerix and Micro-X were down more than three percent; Clinuvel, Mesoblast and Proteomics shed two percent or more; 4D Medical, Cynata, SDI and Starpharma were down more than one percent; with Cochlear, CSL and Polynovo down by less than one percent.

MESOBLAST

Mesoblast says Ryoncil is available for purchase in the US for children two months and older with steroid-refractory, acute graft versus host disease (GvHD).
Last year, Mesoblast said the US Food and Drug Administration approved Ryoncil, or remestemcel-L, for GvHD in children aged two months and older (BD: Dec 19, 2024).
Last month, the company said Ryoncil was the first therapy for pediatric patients two months and older in GvHD and would cost $US194,000 ($A308,087) wholesale per intravenous infusion, with US availability in the “coming weeks” (BD: Feb 27, 2025).
Today, Mesoblast said it had opened the ‘My Mesoblast’ on-line patient hub for ordering Ryoncil.
The company said that to date nine commercial payers had published favorable medical policies, representing about 37 million US patients and it had been “engaging with commercial and government insurers to expedite patient access to therapy”.
Mesoblast said it would “enter into the National Drug Rebate Agreement with Medicaid and expects to be enrolled in the program in short order”.
Mesoblast managing-director Prof Silviu Itescu said the commercial availability of Ryoncil was “a significant milestone in our mission to bring innovative cellular medicines to patients in need”.
“We have made Ryoncil available three months after receiving FDA approval, a significant commercial achievement and a reflection of our team and partners who are driven by the overwhelming desire to help children and their families faced with this devasting disease,” Prof Itescu said.
Mesoblast fell five cents or 2.3 percent to $2.15 with 7.1 million shares traded.

AMPLIA THERAPEUTICS

Amplia says interim data from its 55-patient, phase IIa trial of narmafotinib for pancreatic cancer shows 13 patients had more than 30 percent tumor size reduction.
Last year, Amplia said six of 26 enrolled patients in its 50-patient, phase IIa, trial of AMP945 for pancreatic cancer showed reduced tumor size with no new lesions, allowing it to begin recruitment of the remaining 24 patients (BD: Sep 23, 2024).
Later, the company said it had nine confirmed partial responses in the 26-patient, phase IIa trial of narmafotinib, formerly AMP945 (BD: Dec 11, 2024).
In January, Amplia said it had enrolled 53 pancreatic cancer patients in the phase Ib/IIa trial and reported an additional confirmed partial response; and last month, said the US Food and Drug Administration agreed that proposed changes to the trial protocol appeared “reasonable” (BD: Jan 31, Mar 3, 2025).
Today, the company said a partial response was defined as a more than 30 percent reduction in tumor size sustained for two months with no new lesions apparent.
Amplia said an outcome of 15 partial responses or more “would indicate the narmafotinib combination performs better than chemotherapy alone”.
The company said tumor shrinkage assessments for the “majority of patients enrolled since December” were yet to be undertaken and 29 patients remained on study.
Amplia said the drug continued to be well-tolerated, with adverse events similar to those reported for chemotherapy alone, and that it would present further data in a poster at the American Association of Cancer Research in Chicago on April 28, 2025.
Amplia managing-director Dr Chris Burns said the data continued “to be extremely positive, with promising efficacy and good tolerability observed to date, and with tumor responses still being measured for the patients remaining on study”.
Amplia was up 0.1 cents or 1.4 percent to 7.2 cents.

NEUREN PHARMACEUTICALS

Neuren says it will develop NNZ-2591 to treat hypoxic-ischemic encephalopathy, which occurred when a baby's brain did not receive enough oxygen or blood flow during birth.
Previously, Neuren said it began three separate 20-patient, phase II trials of NNZ-2591 in children with the early childhood neurological disorders Angelman syndrome, Pitt Hopkins syndrome and Phelan-McDermid syndrome (BD: Aug 8, Jul 12, 2022; Jun 30, 2023).
In 2023, the company said its North America partner Acadia had US Food and Drug Administration approval for Daybue, or trofenitide, for Rett syndrome (BD: Mar 13, 2023).
Later, Neuren said that the three separate trials had shown NNZ-2591 led to a "statistically significant improvement" for Pitt Hopkins and Phelan-McDermid syndrome and an improvement in Angelman syndrome (BD: Dec 18, 2023; May 27, Aug 9, 2024).
Today, the company said hypoxic-ischemic encephalopathy (HIE) occurred before or shortly after birth and could lead to symptoms in surviving children such as developmental delays, cognitive impairment, cerebral palsy and seizures, with some children developing long-term complications that impacted them "well into adulthood".
Neuren said the only approved treatment was temporary hypothermia, or the cooling of the head or body to lower the baby's metabolic rate to allow time for recovery.
The company said hypothermia gave a "modest decrease in mortality and severe neuro-development disability, however even with hypothermia, 40-to-45 percent of children who survive HIE have significant neuro-developmental impairment at two years of age".
Neuren said that based on its therapeutic properties and the pre-clinical data, it believed NNZ-2591 could "provide a highly differentiated form of treatment continuing beyond acute treatment in the neonatal intensive care unit to target both the acute effects and chronic impairments resulting from HIE".
The company said it expected NNZ-2591 for HIE could qualify for US Food and Drug Administration orphan drug and rare pediatric disease designations.
Neuren said it expected to hold a pre-investigational new drug application meeting with the FDA by January 2026 before beginning a clinical trial.
Neuren chief scientific officer Larry Glass said the company was "very excited to announce HIE as a new indication for NNZ-2591".
"Neuren has a long heritage in brain injury, dating back to our inception at the University of Auckland and scientists at the University also played a major role in the development of hypothermia as the current standard-of-care for HIE," Mr Glass said.
Neuren was up eight cents or 0.7 percent to $12.01 with 709,596 shares traded.

ALTERITY THERAPEUTICS

Alterity says it has completed the last participant visit in its 10-patient, open-label, phase II biomarker study of ATH434 for multiple system atrophy (MSA).
In January, Alterity rose 137.5 percent on its 77-patient, phase II ATH434 trial showing a "statistically significant improvement" on MSA function and daily living (BD: Jan 30, 2025).
Today, the company said the phase II biomarker trial dosed 10 advanced MSA patients with a 75mg dose of ATH434 for 12 months and that the study would assess the impact of year-long treatment on brain value in a more advanced patient population than was studied in its 77-patient, phase II trial, with results expected to "in mid-year 2025".
Alterity chief executive officer Dr David Stamler said the study gave the company "the opportunity to evaluate the effects of ATH434 treatment in a population that faces severe challenges due to the stage of their illness".
Alterity was up 0.1 cents or 11.1 percent to one cent with 8.3 million shares traded.

EMVISION MEDICAL DEVICES

Emvision says it has begun a 300-patient, validation trial for its 'Emu' brain scanner for stroke diagnosis at the Royal Melbourne Hospital and Houston's University of Texas.
Last year, Emvision said it had "positive engagement" from the US Food and Drug Administration for the validation trial of its brain scanner; and last month, the company said it had US ethics approval to begin the trial (BD: Oct 29, 2024; Feb 12, 2025).
Today, the company said the trial would enrol patients for six-to-12 months at four sites in the US and two sites in Australia, with a primary objective of showing "haemorrhage detection sensitivity and specificity" of more than 80 percent.
Emvision said it had Australian ethics approval and had shipped a device to the US, with a site visit at the University of Texas Health Science Center "planned for the coming weeks".
The company said further trial sites in the US and Australia would be "named and activated shortly", with data to support FDA de novo clearance for the device.
Emvision managing-director Scott Kirkland said the company was "delighted to announce the commencement of the pivotal validation trial for the Emu point-of-care brain scanner to support market entry".
"This important milestone marks the culmination of many years of hard work and dedication from our team and our clinical collaborators, in pursuit of the development and validation of world-first neurodiagnostic technology that has the potential to significantly reduce the global burden of stroke," Mr Kirkland said.
Emvision was up 7.5 cents or 3.8 percent to $2.05.

ACTINOGEN MEDICAL

Actinogen says with the US Food and Drug Administration it has "reached a common understanding" on the studies required for approval of Xanamem for depression.
Actinogen said it had agreed with the FDA at a 'type C' meeting on the "additional clinical trials, ancillary clinical pharmacology trials and non-clinical studies required to apply for marketing approval of Xanamem for [major depressive disorder] in the future".
The company said the agreements were a major accomplishment and would be "important in future discussions with potential partners and granting bodies".
Actinogen said a similar meeting would be held with the FDA for Xanamem as a treatment for Alzheimer's disease "later in 2025".
Actinogen managing-director Dr Steven Gourlay said the company was "pleased with the clear guidance from this important 'type C' meeting with the FDA regarding our major depressive disorder program".
Actinogen was up 0.3 cents or 8.8 percent to 3.7 cents with 6.2 million shares traded.

AUSTCO HEALTHCARE

Austco says it has paid the final earn-out payment of $799,092 as part of its Teknocorp acquisition, with 3,888,889 shares from the acquisition to be released from escrow.
In 2023, Austco said it purchased Melbourne's Teknocorp for $1,900,000 cash and the issuance of 3,888,889 shares at 18.0 cents a share, or $700,000 (BD: Nov 28, 2023).
At that time, the company said it would pay Teknocorp a $1,250,000 earn-out.
Today, Austco said that the shares issued to Teknocorp as part of the acquisition would be released from voluntary escrow on March 31, 2025.
The company said Teknocorp had delivered "strong financial results contributing to our strong revenue and profit growth reported in our recently reported half year results".
Austco was up one cent or 3.6 percent to 29 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says it will begin another 12-month, on-market buy-back of up-to 1,500,000 shares, amounting to about 3.0 percent of its outstanding shares.
Last year, Clinuvel said it began a 12-month, on-market buy-back of up-to 1,500,000 shares (BD: Mar 14, 2024).
Today, the company said it had acquired 66,590 shares in the previous buy-back for $993,674, or an average $14.92 a share.
Clinuvel said the repurchase would “depend on market conditions and other factors”.
Clinuvel chair Prof Jeffrey Rosenfeld said that “in an uncertain macro-economic environment, prudent cash management remains a priority”.
“There may, however, be opportune moments to use capital to support our shareholders through an on-market share buy-back,” Prof Rosenfeld said.
“The board has closely monitored the buy-back program to date and decided that maintaining this option is in the best interests of the company and shareholders,” Prof Rosenfeld said.
Clinuvel fell 29 cents or 2.4 percent to $11.75 with 150,369 shares traded.

ARCHER MATERIALS

Archer says it has promoted chief technology officer Dr Simon Ruffell to chief executive officer, to be paid $330,000 a year, effective immediately.
Last year, Archer said it appointed Dr Ruffell chief technology officer and that Dr Choucair, the co-inventor of its quantum and biosensor technologies, had resigned for personal reasons (BD: Jul 15, Oct 14, 2024).
Today, the company said Dr Ruffell was appointed engineering manager in February 2024, had been principal hardware engineering manager at Microsoft, worked for Applied Materials and been semiconductor and quantum engagement manager at the University of Sydney.
Archer said Dr Ruffell held a Master of Electronic and Electrical Engineering from the England’s University of Surrey and a Doctor of Philosophy from Canada’s University of Western Ontario.
The company said Dr Ruffell would be eligible to receive an annual short-term incentive of up-to $49,500, equal to 15 percent of his salary, and may be eligible for any long-term incentive arrangements “operated or introduced by the company”.
Archer chair Greg English said Dr Ruffell had “already made remarkable progress in leading the development of the biochip and quantum technologies since he first joined the company 13 months ago, including launching a potential earlier revenue path through the [tunnel magneto-resistance] sensors”.
Archer was up one cent or 3.3 percent to 31 cents.

NOVA EYE MEDICAL

Australian Ethical says it has increased its substantial shareholding in Nova Eye from 40,113,310 shares (15.24%) to 49,738,310 shares (17.51%).
The Sydney-based Australian Ethical said that it bought 9,625,000 shares on March 25, 2025 for $1,155,000, or 12.0 cents a share.
Nova Eye was unchanged at 9.4 cents with 1.7 million shares traded.

ISLAND PHARMACEUTICALS

Sydney-based Race Oncology managing-director Dr Daniel Tillett says his substantial 14,127,577 share-holding in Island has been diluted from 7.82 percent to 6.72 percent.
Last week, the company said that it had raised $1,941,586 through the exercise of options issued in a March 2024 rights issue, in addition to a previous $779,413, for a total $2,720,999 (BD: Mar 19, 2024; Mar 19, 2025).
Island fell half a cent or 2.6 percent to 18.5 cents.

TRIVARX (FORMERLY MEDIBIO)

Hong Kong's FIL Limited (Fidelity Investment Management) says its 42,502,362 share-holding in Trivarx has been diluted from 9.30 percent to 7.47 percent.
Earlier this month, Trivarx said it had "firm commitments" to raise $2.25 million at 1.5 cents a share in an institutional placement with one attaching option for every two shares received (BD: Mar 17, 2025).
Trivarx was unchanged at 1.3 cents.