Biotech Daily

Thursday November 4, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AVITA UP 16%; PRESCIENT DOWN 7%**

*** VALE PETER TURVEY (10.10.1951 - 27.10.2021)**

*** KAZIA RECRUITS 1st EVT801 SOLID TUMOR PATIENT**

*** AVITA: MEDICARE EXPANDS RECELL REIMBURSEMENT**

*** TRAJAN $1.3m FOR FORTH FEMALE HORMONE MAPPING**

*** IMPEDIMED: ASTRAZENECA EXTENDS SOZO CONTRACT 3 MONTHS**

*** INVEX PREPARES FOR PHASE III PRESENDIN FOR IIH TRIAL**

*** NOXOPHARM RECRUITS 1st DAART-2 PATIENT**

*** ALTERITY: STUDIES BACK ATH434 FOR PARKINSON'S, IN-VITRO, IN MICE**

*** AMPLIA: CRUK EXTENDS AMP886 MILESTONE DEADLINE**

*** US PATENT FOR MEDLAB NANOCELLE**

*** BIOXYNE DROPS PROPOSED ACQUISITION**

*** L1 CAPITAL TAKES 7.2% OF ANTERIS**

*** CRESO: WA LEGALISE CANNABIS MLC DR BRIAN WALKER ADVISOR**

MARKET REPORT

The Australian stock market was up 0.48 percent on Thursday November 4, 2021, with the ASX200 up 35.3 points to 7,428.0 points. Seventeen of Biotech Daily Top 40 stocks were up, 14 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Avita was the best, up 70 cents or 15.8 percent to $5.13, with 1.2 million shares traded. Osprey climbed 11.6 percent; Alterity was up 10.7 percent; Antisense and Immutep improved more than nine percent; Actinogen was up 6.45 percent; LBT rose five percent; Opthea improved 4.8 percent; Pro Medicus was up 3.3 percent; Clinuvel, Imugene, Next Science and Universal Biosensors rose two percent or more; Cochlear, Genetic Signatures, Mesoblast and Starpharma were up more than one percent; with CSL, Resmed and Volpara up by less than one percent.

Prescient led the falls, down two cents or 6.8 percent to 27.5 cents with 4.9 million shares traded. Paradigm lost 5.9 percent; Oncosil and Optiscan fell more than four percent; Dimerix and Impedimed shed two percent or more; Neuren, Nova Eye and Polynovo were down more than one percent; with Cyclopharm, Cynata, Medical Developments, Nanosonics and Telix down by more than one percent.

VALE PETER TURVEY

Biotechnology director and executive Peter Turvey has died, aged 70.
In July, Mr Turvey resigned his nine-year directorship of Starpharma, where he had been deputy chair, citing ill health (BD: July 30, 2021).
At that time, Starpharma chair Rob Thomas thanked Mr Turvey “for his exceptional contribution to the company during a period of significant growth”.
Former Ausbiotech chief executive officer Dr Anna Lavelle said that “it was a privilege to have Peter Turvey as part of the board”.
“He was many things, including, smart, funny, thoughtful, pragmatic, caring and a polished professional,” Dr Lavelle said.
Ausbiotech said that Mr Turvey was formerly CSL’s company secretary and intellectual property manager, before joining Foursight Associates as a principal.
The industry organization said that Mr Turvey was “heavily involved in CSL’s acquisitions and divestments”, including the acquisition of ZLB and Aventis Behring, and the sale of CSL’s animal health business to Pfizer.
CSL head of strategy Dr Sergio Scrofani said Mr Turvey “made a significant contribution to our company including through CSL’s transformation from a government owned enterprise to a public company in 1994”.
“He was instrumental to CSL’s formative years as a global company, and he leaves behind a valuable legacy as colleague, friend and mentor to many within the Australian biotech sector," Dr Scrofani said. "Peter is fondly remembered and respected by those who had the privilege of working with him during his long tenure at CSL.”
Mr Turvey was as a director of Viralytics and the then Allied Healthcare Group (later Admedus and now Anteris) and the privately-owned Immvirx and Cell Therapies Pty Ltd.
According to his Linkedin page, Mr Turvey completed a Bachelor of Laws and Bachelor of Arts at the Australian National University in Canberra in 1975.

KAZIA THERAPEUTICS

Kazia says it has enrolled the first of up to 60 patients in its first in-human, phase I trial of its oral, small-molecule drug EVT801 for advanced solid tumors.
Kazia said the trial’s principal site was Toulouse, France’s Institut Universitaire du Cancer de Toulouse Oncopole with principal investigator Dr Carlos Gomez-Roca.
In April, Kazia said it would pay the Hamburg, Germany-based Evotec SE up to $477.9 million to licence EVT801, originally invented by Sanofi (BD: April 20, 2021).
Today, the company said Evotec, in collaboration with the team at Oncopole, developed a tissue and blood biomarkers analyses program to better understand the effects of the drug, identify the most responsive patients and provide early predictors of clinical efficacy.
Kazia said the phase I, open label, single-arm trial would determine the safety, efficacy and pharmacokinetics of EVT801 and would be conducted in two stages.
Kazia said the first stage would recruit up to 48 patients in a multiple ascending dose study to determine the maximum tolerated dose and recommended phase II dose.
The company said the second study would recruit up-to 12 patients, of whom six would have been diagnosed with renal cell carcinoma and six with soft-tissue sarcoma.
Kazia said the 12 patients would receive EVT801 based on dose determined in the first stage to “better understand the biochemical activity of the drug”.
Kazia said it was collaborating with Belgium’s Radiomics to apply artificial intelligence-based analyses to the computed tomography and magnetic resonance imaging scans collected during the study.
Kazia was unchanged at $1.57.

AVITA MEDICAL

Avita says the US Centres for Medicare & Medicaid Services has approved reimbursement for Recell system in outpatient hospital and ambulatory surgical centres.
Avita said the approval for a "transitional pass-through payment device category code" would be effective from January 1, 2022 and would provide separate payment for its Recell spray-on skin system in outpatient and ambulatory surgical centres.
In 2018, Avita said the US Food and Drug Administration approved Recell for severe thermal burns in patients 18 years and older (BD: Sep 21, 2018).
In June, Avita said the US Food and Drug Administration has expanded the use of its Recell spray-on skin system to children and extensive burns (BD: June 11, 2021)
Today, Avita chief executive officer Dr Mike Perry said the approval "would expand access to the Recell System as a critical treatment option for Medicare burn patients treated in the hospital outpatient and ambulatory surgical settings".
"In addition to expanding burn treatment to a new care setting with existing customers, this device code lays the reimbursement foundation for the soft tissue repair indication we are working towards … [worth] $450 million," Dr Perry said.
Avita was up 70 cents or 15.8 percent to $5.13 with 1.2 million shares traded.

TRAJAN GROUP

Trajan says it has invested GBP705,002 ($A1,292,286) in the Chepstow, Wales-based Humankind Ventures, trading as Forth and will appoint and director to the company.
Trajan said its investment gave it 9.85 percent voting power in Humankind Ventures and its UK head of separation science Kayte Parlevliet would be appointed to the Humankind Ventures director, providing "an opportunity to explore future collaboration with Forth".
Forth co-founder and chief executive officer Sarah Bolt said the investment would "enable us to launch female hormone mapping and also develop more unique and insightful products to help people engage proactively with their health."
Trajan fell eight cents or 2.4 percent to $3.24.

IMPEDIMED

Impedimed says Astrazeneca has extended by three months its phase IIb heart failure and chronic kidney disease trial using the Sozo bioimpedance fluid volume system.
Impedimed said the 18-month trial was extended to 21 months and was scheduled to be completed in July 2022, with the number of Sozo devices leased to Astrazeneca increased from 175 to 211, generating $5.0 million in revenue from the trials.
The company said it recognized $1.8 million in revenue in 2020-'21, with the remainder to be recognized in 2021-'22 and 2022-'23.
The company said Sozo provided "a precise snapshot of fluid status and tissue composition in less than 30 seconds" providing an objective measure of fluid overload.
Impedimed said the study was using Sozo to monitor body fluid volumes to evaluate the efficacy, safety and tolerability of a combination of two Astrazeneca drugs in heart failure patients with chronic kidney disease.
Impedimed managing-director Richard Carreon said the trial was "providing a significant number of cardiologists and nephrologists … first-hand experience with Sozo".
"Heart failure and chronic kidney disease are two of our three strategic focus areas, and this contract addition provides continued validation of the applicability of our technology in both patient populations," Mr Carreon said.
Impedimed fell half a cent or 2.7 percent to 18 cents with 4.6 million shares traded.

INVEX THERAPEUTICS

Invex says it will apply for a 240-patient, phase III trial of Presendin for idiopathic intracranial hypertension (IIH) in Australia and Europe by the end of the year.
Invex said the randomized, placebo-controlled trial at 37 centres in the European Union, the UK and Australia.
The company said that the primary endpoint would be the mean difference in intracranial pressure from baseline at 24 weeks between patients on Presendin versus a placebo.
Invex said the secondary endpoints would assess the relative difference in vision, measured by perimetric mean deviation and papilloedema, and monthly headache days over 24 weeks.
Invex said the trial results would facilitate discussions with the US Food and Drug Administration.
Invex said the trial was fully funded from its existing cash reserves of $32 million at September 30, 2021.
Invex was up 8.5 cents or 13.0 percent to 74 cents.

NOXOPHARM

Noxopharm says it has recruited the first of up-to 100 patients in its Daart-2 phase II trial of Veyonda for cancer in the US.
Earlier this year, Noxopharm said the trial would treat patients with progressive, metastatic prostate, breast or lung cancers who had failed standard treatment and were eligible for low-dose, palliative radiotherapy to a single lesion (BD: Jun 10, 2021).
In July, the company said the US Food and Drug Administration approved the phase II, study combining Veyonda, or NOX66, with radiotherapy to an isolated tumor to trigger an abscopal, or whole-of-body, anti-cancer response (BD: July 1, 2021).
Today, Noxopharm said Veyonda treatment and interim data was expected in 2022.
Noxopharm fell one cent or two percent to 49 cents.

ALTERITY THERAPEUTICS

Alterity says it has published two pre-clinical studies on the potential of ATH434 to treat Parkinson's disease, in mice and in-vitro.
Alterity said the first article, titled 'ATH434 Reverses Colorectal Dysfunction in the A53T Mouse Model of Parkinson's Disease' was published in the Journal of Parkinson's Diseases and was available at: https://bit.ly/3wmPKXy.
The company said common gastro-intestinal complications associated with Parkinson's disease included swallowing difficulty, delayed stomach emptying, slower nutrient absorption from the gut, and chronic constipation.
Alterity said the study showed that ATH434 could reduce the aggregation of alpha-synuclein by binding and redistributing excess iron in areas of pathology.
The company said a second publication, titled 'The iron chelator, PBT434, modulates transcellular iron trafficking in brain microvascular endothelial cells' was published by the US Public Library of Science and was at: https://doi.org/10.1371/journal.pone.0254794.
Alterity said the study showed that ATH434 could bind and redistribute iron, thus limiting the downstream oxidative stress involved in cytotoxic protein aggregation.
The company said the in-vitro study concluded that the novel mechanism of action of ATH434 provided "a compelling case for its continued development as a therapeutic agent in neurodegenerative diseases associated with iron accumulation".
Alterity was up 0.3 cents or 10.7 percent to 3.1 cents with 35.4 million shares traded.

AMPLIA THERAPEUTICS

Amplia says Cancer Research UK has extended the deadline for AMP886 milestones from March 2021 to December 31, 2023, and has requested a capital raising trading halt.
Amplia chief executive officer Dr John Lambert told Biotech Daily that in March this year Cancer Research UK (CRUK) agreed to extend the deadline for negotiations on the licence agreement for focal adhesion kinase AMP886 for cancer until the end of this year.
In a media release to the ASX, the company said the licence agreement required it to file an investigational new drug application or begin a phase I trial of AMP886, and the deadline had been extended to December 31, 2023.
Amplia said the initial agreement with Cancer Research UK was signed in March 2018, with Amplia agreeing to either file an IND application or begin a phase I trial within three years.
Dr Lambert said the extension would "allow us to undertake further pre-clinical studies with this promising molecule which has a unique activity profile and identify therapeutic indications for which it is best suited before we initiate formal development".
Separately, Amplia requested a trading halt "to undertake a capital raising process".
Trading will resume on November 8, 2021, or on an earlier announcement.
Amplia last traded at 19.5 cents.

MEDLAB CLINICAL

Medlab says the US Patent and Trademark Office has granted a patent for its Nanocelle delivery platform.
Medlab said the patent, titled 'Transmucosal and transdermal delivery systems' would protect its intellectual property until 2036.
The company said patents for Nanocelle had been granted in Australia, the US, Canada and Europe with a grant requested in Hong Kong and under examination in Singapore.
Medlab was up two cents or 12.5 percent to 18 cents with 1.7 million shares traded.

BIOXYNE

Bioxyne says it "has determined not to proceed with the proposed acquisition at this time" and lifted its voluntary suspension.
Last week, Bioxyne requested a voluntary suspension to follow a trading halt "pending an announcement in relation to a potential acquisition" (BD: Oct 27, 29, 2021).
Bioxyne fell 0.1 cents or 3.3 percent to 2.9 cents.

ANTERIS TECHNOLOGIES

Melbourne's L1 Capital says it has become a substantial shareholder in Anteris with 625,000 shares of 7.16 percent.
Last week, Anteris said raised $5 million from Melbourne's L1 Capital Investors in a placement of 625,000 shares at $8.00 a share (BD: Oct 27, 2021).
Anteris fell 13 cents or 1.5 percent to $8.60.

CRESO PHARMA

Creso says it has appointed Western Australia Legalise Cannabis MLC Dr Brian Walker as a consultant and chair of its Scientific Advisory Committee.

Creso said Dr Walker was a medical practitioner, elected to the Western Australian Legislative Council for the East Metropolitan Region in March 2021, with his term beginning on May 24, 2021.

The company said Dr Walker would oversee and provide input into its medical marijuana, hemp and psychedelic products.

Creso said that as part of his remuneration package, it would issue Dr Walker 200,000 options, exercisable at 20 cents each by November 3, 2024.

Creso fell one cent or 6.9 percent to 13.5 cents with 10.1 million shares traded.