Biotech Daily

Wednesday June 23, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: OPTISCAN UP 17%; ANTISENSE DOWN 8%**

*** CMRI, GYROSCOPE WORK ON CAPSIDS FOR GENE THERAPIES**

*** TELIX DOSES 1st TLX250-CDX BLADDER CANCER PATIENT**

*** ACTINOGEN: FDA OKAYS XANAFX PHASE II FRAGILE X STUDY PLAN**

*** ALTERITY: EMA BACKS ATH434 MSA TRIAL BIOMARKERS, DESIGN**

*** NEUROSCIENTIFIC APPOINTS LINEAR CLINICAL FOR EMTINB TRIAL**

*** EUROPE, CANADA PATENTS FOR MEDLAB NANOCELLE**

*** PALLA COMPLETES IRELAND, GERMANY CO-CODAMOL SUBMISSIONS**

*** ALTHEA SHIPS MARIJUANA TO SOUTH AFRICA**

*** RESPIRI: SIGMA TO SELL WHEEZO ASTHMA MONITORS**

*** INVEX TO RELEASE 21m ASX ESCROW SHARES**

*** REGAL FUNDS TAKES 17% OF OPTHEA**

*** RICHMOND HILL REDUCES TO 6% OF UNIVERSAL BIOSENSORS**

MARKET REPORT

The Australian stock market fell 0.6 percent on Wednesday June 23, 2021, with the ASX200 down 43.7 points to 7,298.5 points. Twelve of the Biotech Daily Top 40 stocks were up, 21 fell and seven traded unchanged.

Optiscan was the best, up 3.5 cents or 17.1 percent to 24 cents, with 853,459 shares traded. Prescient climbed 15.4 percent; Actinogen was up 6.9 percent; Alterity improved 5.45 percent; Neuren was up 4.15 percent; Compumedics was up 3.9 percent; Cyclopharm, Imugene and Resmed rose more than one percent; with Cochlear, Cynata, Nanosonics, Polynovo and Volpara up by less than one percent.

Antisense led the falls, down 1.5 cents or 7.7 percent to 18 cents, with 3.2 million shares traded. Osprey lost 6.7 percent; Pro Medicus was down 5.3 percent; Impedimed fell 4.8 percent; Mesoblast, Nova Eye, Oncosil and Proteomics were down more than three percent; Avita, CSL, Medical Developments, Paradigm, Patrys, Pharmaxis, Starpharma, Telix and Universal Biosensors shed two percent or more; Clinuvel, Genetic Signatures, Immutep and Opthea were down more than one percent; with Next Science down 0.3 percent.

CHILDREN'S MEDICAL RESEARCH INSTITUTE

The Children's Medical Research Institute says it will collaborate with London's Gyroscope Therapeutics to develop clinical capsids for gene therapies.
The CMRI said that it would work with Gyroscope to develop the "next generation" capsids - the protein shells of viral vectors used to deliver gene therapies.
The Institute said it would work with Gyroscope on the design and screening of capsid libraries to identify new capsids for enhanced delivery of ocular gene therapies.
The CMRI said that Gyroscope had an option to obtain an exclusive licence for ocular uses of capsids developed through the partnership.
The Institute said its team would led by Prof Leszek Lisowski, an "expert in viral vector-based gene therapy, vectorology and genotoxicity, with more than 15 years of experience in capsid generation and discovery".
"Gene therapies are being studied in many diseases of the eye and capsids play an important role in maximising the potential benefit of these therapies for patients," Dr Lisowski said.

TELIX PHARMACEUTICALS

Telix says it has dosed the first of 20-patients in its phase I study of TLX250-CDx for urothelial carcinoma, or bladder cancer, at Perth's Fiona Stanley Hospital.
Telix said the aim of the zirconium-girentuximab positron emission tomography in urothelial cancer patients (Zip-Up) study was to evaluate the feasibility of using TLX250-CDx positron emission tomography (PET) or TLX250-CDx computed tomography (CT) to detect localized and metastatic bladder cancer.
The company said the study was the first in a series of studies that would use TLX250-CDx or 89-zirconium-girentuximab to evaluate the expression of carbonic anhydrase IX (CA9) in cancers apart from renal cancer.
Telix said the study would recruit 20 patients over 12 months, 10 with known bladder cancer, and 10 patients that required primary staging of localized bladder cancer.
The company said the study would evaluate how CA9 imaging could be used for cancer diagnosis and staging, and the utility of CA9 as a therapeutic target.
Telix chief executive officer Dr Christian Behrenbruch said that TLX250-CDx had been granted breakthrough therapy designation by the US Food and Drug Administration for renal cancer imaging and it was "meaningful to test the potential of CA9 targeting in other cancers with the goal of rapid indication expansion beyond the initial kidney cancer application".
Telix fell 13 cents or 2.3 percent to $5.50 with 1.05 million shares traded.

ACTINOGEN MEDICAL

Actinogen says the US Food and Drug Administration "indicates" that its Fragile X data and phase II trial plan are sufficient for an investigational new drug application.
Actinogen said that subject to final review of supportive documentation, it planned to submit the application for the trial of about 40 patients by October 2021.
The company said the FDA agreed on its proposed adolescent patient population for the phase II Xanafx study which would be a randomized, placebo-controlled, double-blind, 12-week trial to investigate the safety and efficacy of Xanamem in male adolescents who suffer from Fragile X syndrome.
Actinogen said the Australian study was expected to begin this year.
Actinogen was up one cent or 6.9 percent to 15.5 cents with 18.9 million shares traded.

ALTERITY THERAPEUTICS

Alterity says the European Medicines Agency supports its intention to use biomarkers to diagnose early-stage multiple system atrophy patients for its ATH434 phase II trial.
Alterity said ATH434 was “a small molecule drug candidates designed to block the accumulation and aggregation of alpha-synuclein”, which, when aggregated in the brain, was a hallmark of Parkinsonian disorders such as multiple system atrophy (MSA).
The company said alpha-synuclein was a biologic target for neuro-degenerative diseases and ATH434 was thought to bind and redistribute excess iron in areas of pathology.
Alterity said the EMA “recognized the potential role of iron in the pathogenesis of MSA and accordingly supported the use of biomarker endpoints to assess iron content and alpha-synuclein pathogenesis”.
The company said there was no approved treatment for MSA and no regulatory precedence for defining the most suitable patient population or clinical endpoints in efficacy studies “thus requiring greater consideration in developing an optimal trial design”.
Alterity said it had sought input from clinical experts and regulatory authorities, and was conducting a natural history study, Biomuse, to identify biomarkers and clinical endpoints best suited to capture efficacy signals in the phase II study.
The company said that the Nashville, Tennessee Vanderbilt University Medical Center had enrolled more than half of the targeted patients in the Biomuse study.
Alterity said it expected to begin the trial this year.
Alterity chief executive officer Dr David Stamler said that with the EMA advice “we now have a clear path forward to finalize the study design”.
Alterity was up 0.15 cents or 5.45 percent to 2.9 cents with 79.7 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has appointed Perth’s Linear Clinical Research for an up-to 90-participant phase I trial of Emtinb.
Neuroscientific said it hoped to begin the trial by the end of the year with the primary endpoints of safety, tolerability and pharmaco-kinetics and the study would be used to support future phase II trials in Alzheimer’s disease and multiple sclerosis.
The company said that during the second half of this year, it would conduct a phase I trial of intra-vitreal Emtinb in glaucoma patients.
Neuroscientific managing director Matt Liddelow said that the appointment of Linear Clinical was “a significant milestone … and we are elated to be transitioning our [research and development] program into first-in-human trials”.
“The trial is also a significant milestone for the advancement of Emtinb as a potential disease-modifying drug for a range of neuro-degenerative conditions that currently lack such treatments, including Alzheimer’s disease and multiple sclerosis,” Mr Liddelow said.
Neuroscientific rose half a cent or 1.4 percent to 36.5 cents with 1.1 million shares traded.

MEDLAB CLINICAL

Medlab says that the European and Canadian Patent offices have granted patent protection for its Nanocelle delivery platform.
Medlab said that the patent, titled ‘Transmucosal and transdermal delivery systems’, would protect its intellectual property until 2036.
The company said patent protection for Nanocelle had been granted in Australia and New Zealand, with a grant request pending in Hong Kong.
Medlab was up one cent or 6.7 percent to 16 cents with 1.2 million shares traded.

PALLA PHARMA

Palla says it has completed regulatory submissions to the Ireland and Germany medicines regulators for its Co-Codamol products.
Earlier this week, Palla said it had appointed Alloga UK as its exclusive provider of pre-wholesale supply chain services for its 30mg codeine phosphate-500mg paracetamol tablet and caplet combination in the UK (BD: Jun 21, 2021).
Palla was up 2.5 cents or 6.7 percent to 40 cents.

ALTHEA GROUP HOLDINGS

Althea says it has completed its first shipment of medicinal cannabis products to Africann, its local partner and exclusive distributor in South Africa.
Althea said Africann was a licenced wholesaler that specialized in the import and distribution of medicinal cannabis products in South Africa.
Althea was up 1.5 cents or 4.7 percent to 33.5 cents with 1.1 million shares traded.

RESPIRI

Respiri says Sigma Healthcare has begun sales of its Wheezo asthma monitor at 570 pharmacies in Australia.
Respiri said that Melbourne's Sigma was a national wholesaler that owned pharmacy brands Amcal, Chemist King, Discount Drug Store, Guardian, Pharmasave and Wholelife.
Respiri was up half a cent or 7.1 percent to 7.5 cents with 5.1 million shares traded.

INVEX THERAPEUTICS

Invex says it will release 21,069,220 shares held in ASX escrow on July 7, 2021.
According to the company's most recent Appendix 2A application for quotation of securities, Invex had 54,084,628 shares on issue, meaning that following the release from escrow, the company would have 75,153,848 shares available for trading.
Invex was up 5.5 cents or 9.1 percent to 66 cents.

OPTHEA

Regal Funds Management says it has increased its holding in Opthea from equivalent to 51,235,825 shares (15.17%) to the equivalent of 59,294,620 shares (17.06%).
The Sydney-based Regal said that it bought and sold Australian shares between October 19, 2020 and June 18, 2021 with the single largest purchase 7,206,815 shares for $10,449,882 or $1.45 a share.
Regal said between October 21 and November 30, 2020 it bought and sold American depository shares (ADSs), with the single largest sale 31,000 ADSs representing 248,000 Australian shares, for $418,503 or $1.70 per share.
Opthea fell 2.5 cents or 1.9 percent to $1.28 with two million shares traded.

UNIVERSAL BIOSENSORS

Richmond Hill Capital says it has reduced its holding in Universal Biosensors from 12,559,109 Chess depository interests (CDIs) (7.07%) to 10,562,783 CDIs (5.95%).

The Melbourne-based Richmond Hill Capital said it sold 1,996,326 CDIs for $1,432,628 or 71.80 cents per CDI.

Universal Biosensors fell two cents or 2.5 percent to 78 cents.