Biotech Daily

Tuesday December 5, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: NEXT SCIENCE UP 4.55%; MESOBLAST DOWN 22%**

*** CYCLOPHARM SIGNS 1st COMMERCIAL US TECHNEGAS CONTRACT**

*** MESOBLAST PLACEMENT, INSTO RIGHTS RAISE $55m; $42m TO GO**

*** NEUREN ENROLS PHASE II NNZ-2591 PITT HOPKINS TRIAL**

*** TELIX IMAGES 1st TLX250-CDX EARLY ACCESS KIDNEY CANCER PATIENT**

*** MELBOURNE UNI $480k FOR CARBON CYBERNETICS FOR EPILEPSY**

*** IMMURON ENROLS 1st US NAVY CAMPETEC DIARRHOEA VOLUNTEER**

*** TGA: VITURA, CDA CLINICS QLD 'UNLAWFUL ADVERTISING' LEGAL ACTION**

*** ALLEGRA TO SUBMIT FDA SPINAL CAGE RESPONSE**

*** SYNTARA RECEIVES $5.2m FEDERAL R&D TAX INCENTIVE**

*** NUHEARA RECEIVES $1.4m FEDERAL R&D TAX INCENTIVE**

*** HARBOUR, JARDEN REDUCE TO 14% IN PACIFIC EDGE**

*** NEUROSCIENTIFIC: RENNIE, QUANTRILL OUT; NTOUMENOPOULOS, KEATING IN**

*** BIO-MELBOURNE LOSES CEO JEFF MALONE; NEW CEO WANTED**

MARKET REPORT

The Australian stock market fell 0.89 percent on Tuesday December 5, 2023, with the ASX200 down 63.1 points to 7,061.6 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, seven traded unchanged and one was untraded.

Next Science was the best, up one cent or 4.55 percent to 23 cents, with 33,484 shares traded. Avita climbed 4.1 percent; Opthea and Orthocell were up more than three percent; Nanosonics rose 2.2 percent; Alcidion, Cochlear, Pro Medicus, Resmed and Volpara were up more than one percent; with Clarity and Telix up by less than one percent.

Mesoblast led the falls, down nine cents or 22.2 percent to 31.5 cents, with 20.1 million shares traded. Prescient lost 13.3 percent; Compumedics and Universal Biosensors fell eight percent or more; Syntara/Pharmaxis shed 6.7 percent; SDI was down 5.6 percent; Actinogen, Clinuvel and Micro-X fell four percent or more; Curvebeam, Dimerix, Emvision, Genetic Signatures, Impedimed, Imugene, Medical Developments, Polynovo and Proteomics were down more than three percent; Cyclopharm, Neuren and Paradigm shed more than two percent; Amplia was down 1.3 percent; with CSL down 0.4 percent.

CYCLOPHARM

Cyclopharm says it has signed its first US commercial contract with the Durham, North Carolina's Duke University Hospital for its Technegas lung imaging system.
In October, Cyclopharm said that the US Food and Drug Administration had approved the Technegas system for pulmonary embolism imaging (BD: Oct 2, 2023).
Today, Cyclopharm managing-director James McBrayer told Biotech Daily that the company would receive $US7,000 ($A10,585) for the installation of the Technegas generator, a licence fee of $US7,000 a year and a per patient payment of $US225.
Mr McBrayer he was "unable to disclose the number of patients likely to be treated at Duke University Hospital".
The company said the agreement was "a major milestone" and that Duke University Hospital was a teaching hospital part of the larger Duke University Health System and was one of 10 US locations that took part in its Technegas clinical trial.
"The implementation of Technegas at Duke will be on full commercial terms as previously communicated to the market and will be leveraging off Technegas' wide indication for use approved by the US FDA," Mr McBrayer said.
Cyclopharm fell 4.5 cents or 2.25 percent to $1.955.

MESOBLAST

Mesoblast says it has raised about $36 million in an "over-subscribed" placement and $19 million in the institutional component of its rights offer, at 30 cents a share.
Yesterday, Mesoblast said it hoped to raise up-to $36 million in an institutional placement and $61 million in a one-for-four retail and institutional entitlement offer, at 30 cents a share (BD: Dec 4, 2023).
Today, the company said the retail offer would open on December 8, 2023, and would raise a maximum of about $42 million.
Mesoblast said chief executive Prof Silviu Itescu had committed to taking up a majority of his entitlement in the offer.
Mesoblast fell nine cents or 22.2 percent to 31.5 cents with 20.1 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has completed enrolment in its up-to 20-child patient, phase II trial of NNZ-2591 for Pitt Hopkins syndrome, with top-line results expected by July 2024.
Last year, Neuren said it had begun the phase II trial of NNZ-2591 for Pitt Hopkins syndrome (BD: Aug 8, 2022).
Today, the company said the trial was in children aged three-to-17 years of age at five US hospitals and was examining safety, tolerability, pharmacokinetics and efficacy during 13 weeks of twice daily oral liquid doses of NNZ-2591.
Neuren said Pitt Hopkins was a neuro-developmental condition caused by the loss of one copy or a mutation of the TCF4 gene on chromosome 18 that led to developmental delays with moderate-to-severe intellectual disability and behavioral differences.
The company said it was conducting three other phase II clinical trials of NNZ-2591 in children with Phelan McDermid syndrome, Angelman syndrome and Prader-Willi syndrome, with all four programs having orphan drug designation by the US Food and Drug Administration and being developed under investigational new drug applications.
Neuren fell 45 cents or 2.8 percent to $15.66 with 528,613 shares traded.

TELIX PHARMACEUTICALS

Telix says it has imaged the first renal cell carcinoma patient in its Netherlands early access program with its positron emission tomography imaging agent TLX250-CDx.
In an email not released to the ASX, Telix said the first clear cell renal cell carcinoma patient was dosed at the Nijmegen, Netherlands' Radboud University Medical Centre.
The company said clear cell renal cell carcinoma was "the most common and aggressive form of kidney cancer".
Telix said the program allowed physicians to seek individual access to TLX250-CDx, or 89-zirconium- des-ferri-oxamine-girentuximab (89Zr-DFO- girentuximab), for use in positron emission tomography (PET) scans characterizing renal masses as clear cell renal cell carcinomas.
The company said that in the Netherlands the use of medicinal products in an individual patient prior to marketing authorization and outside the context of a clinical trial was permitted in exceptional circumstances.
Telix said it was progressing towards a biologics licence application submission for TLX250-CDx with the US Food and Drug Administration and other equivalent applications with regulatory agencies in other jurisdictions.
Radboud University Medical Centre's Prof Dr Peter Mulders said "continued access to this investigational imaging agent is critically important".
"The detection of [clear cell renal cell carcinoma] in the early stages of disease can often be challenging, and reliant on invasive biopsy and nephrectomy, [or] kidney removal", Prof Mulders said. "It is therefore extremely good news that TLX250-CDx, which offers a non-invasive option, or 'molecular biopsy', is now available in the Netherlands on a named patient basis."
Telix was up two cents or 0.2 percent to $9.75 with 739,311 shares traded.

CARBON CYBERNETICS, THE UNIVERSITY OF MELBOURNE

Carbon Cybernetics says it has $480,000 for epilepsy and other neurological conditions treatments and appointed Justin Spangaro as its chief executive officer.
Melbourne's Carbon Cybernetics said that the University of Melbourne has invested the funds as a pre-seed investment for its "neural implant technology".
The company said it came from the University's School of Physics to develop "a brain-machine interface" for epilepsy and other neurological conditions.
Carbon Cybernetics said that the device delivered "a stream of high-resolution data that provides the ability to record individual neurons within the brain, enabling more effective therapies including providing precision neurostimulation".
The company said that the University of Melbourne investment would support commercial development and pre-clinical activities in preparation for a feasibility in-human study.
The University of Melbourne, research innovation and commercialization managing-director Ken Jefferd said Carbon Cybernetics was "a great example of successful technology transfer out of the academic sector".
"As an early investor, the University is proud to see Carbon Cybernetics take these important next steps towards translating their exciting technology in a new device with the potential to improve lives and deliver impact at scale," Mr Jefferd said.
Carbon Cybernetics said that Mr Spagaro was an entrepreneur and was previously Wave Computing's Australian managing-director and worked for Volant Trading.
The company said that founding chief executive officer David Garrett would continue as its chief technology officer.
Carbon Cybernetics is a public unlisted company.

IMMURON

Immuron says it has enrolled the first of up to 30 healthy volunteers in its phase I trial with the US Naval Medical Research Command of Campetec for travelers' diarrhoea.
Immuron said Campetec was a prophylactic designed to protect against campylobacter and entero-toxigenic Escherichia coli (Etec) infections, which were two of the major causes of travelers' diarrhoea.
The company said with the US Navy the study would "evaluate the efficacy of the product to prevent infectious diarrhoea caused by Campylobacter".
Immuron said the study was designed to evaluate the safety and efficacy of the product compared to a placebo in a controlled human infection model and that the primary efficacy outcome was prevention and, or reduction of moderate to severe diarrhoea.
The company said the dosing, challenge and in-patient stage of the study was expected to be completed by the end of 2023, with results expected by the end of 2024.
Immuron was up half a cent or 6.2 percent to 8.6 cents.

THERAPEUTIC GOODS ADMINISTRATION, VITURA HEALTH

The Therapeutic Goods Administration says it has begun proceedings against Vitura's CDA Clinics Qld Pty Ltd for the alleged unlawful advertising of cannabidiol (CBD).
Yesterday, Vitura Health said the Department of Health and Aged Care filed proceedings against wholly-owned subsidiary CDA Clinics Qld Pty Ltd, relating to "historic advertisements of products" (BD: Dec 4, 2023).
The company said the matter predated its Cannabis Doctors Australia (CDA) merger and it was in the process of deregistering CDA Clinics Qld when the proceedings were filed.
Vitura said that CDA Clinics Qld had "no assets, no debts and no operations".
Today, in a media release, the TGA said it was alleged that CDA Clinics Qld's website, CDA Express "enabled patients to purchase prescription-only medicines containing cannabidiol after completing a 'virtual consultation' process involving an online.
The TGA said it was alleged the CDA Express website and social media advertisements were unlawful due to medicinal cannabis products being prescription-only medicines that could not be advertised directly to consumers under the Therapeutic Goods Act 1989.
The TGA said the company allegedly promoted the use of cannabidiol (CBD) for the treatment of serious diseases, conditions and disorders, which were known as restricted representations or prohibited representations and were not allowed to be included in advertising for therapeutic goods unless it had given approval or permission to do so.
In the Federal Court notice of filing and hearing, the secretary of the Department of Health and Aged Care alleged that prohibited representations in CDA Express' advertisements regarded the treatment, cure or prevention of cancer, gonorrhoea, depression, anxiety, post-traumatic stress disorder and, or autism.
The filings alleged the CDA Express' advertisements included restricted representations referring to cannabidiol as a cure for fibromyalgia, epilepsy, autoimmune conditions, chronic pain, seizures, meningitis and, or autism.
The TGA said "despite being warned … about its alleged non-compliant advertising, the company continued to advertise the products for several months".
The TGA said the products that were allegedly advertised were also not entered on the Australian Register of Therapeutic Goods, which was unlawful unless specifically exempt.
The TGA said as a priority, it was "taking strong enforcement action to deter and disrupt unlawful advertising of medicinal cannabis".
The TGA named Dr Benjamin Jansen as a former director of CDA Clinics Qld.
Vitura was unchanged at 29 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra says it has complied with the US Food and Drug Administration further data request for its spinal cage 510(k) application and expects to file by February 4, 2024.
In March, Allegra said it submitted a 510(k) application to the FDA for its Sr-Ht-Gahnite spinal cage device for bone healing (BD: Mar 31, 2023).
In August, the company said the FDA requested “more information” regarding its spinal cage device application (BD: Aug 17, 2023).
Allegra was untraded at five cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has received $5,205,123 from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Syntara said the rebate related to expenditure for the year to June 30, 2023.
The company said it would use the funds to repay its $4.4 million loan from Paddington Street Finance and the remaining cash would increase its balance by about $700,000.
Syntara chief executive officer Gary Phillips said the company’s clinical development pipeline included “PXS-5505 in myelofibrosis where the next arm of a phase II trial in combination with standard-of-care is expected to shortly dose its first patients”.
Syntara fell 0.2 cents or 6.7 percent to 2.8 cents.

NUHEARA

Nuheara says it has received $1.4 million from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.
Nuheara was unchanged at 12.5 cents.

PACIFIC EDGE

Harbour Asset Management and Jarden Securities say they have reduced their Pacific Edge holding from 134,190,009 shares (16.559%) to 124,296,760 shares (15.332%)
The Wellington, New Zealand-based Harbour said with Jarden Securities it bought, sold and transferred shares between June 13 and December 4, 2023, with the total sale of 25,287,635 shares for $NZ3,006,572 ($A2,801,436), or 11.9 NZ cents (11.08 Australian cents) a share.
Pacific Edge fell 0.25 cents or 2.7 percent to nine cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says chair Paul Rennie and director Stephen Quantrill will be replaced by directors Chris Ntoumenopoulos and Dr Tony Keating, effective immediately.
Neuroscientific said Mr Rennie and Mr Quantrill had resigned from their positions “to focus on their other corporate commitments”.
The company said Dr Keating was appointed as a director, today, and had co-founded and led Resapp from start-up to its $180 million acquisition by Pfizer, and prior to that had been director of commercial engagement at Uniquest.
According to his Linkedin profile, Dr Keating held a Bachelor of Engineering, a Master of Engineering and a Doctor of Philosophy from the University of Queensland.
Neuroscientific said Mr Keating would be paid $50,000 a year in director fees.
Neuroscientific was up 0.2 cents or 4.2 percent to five cents.

BIO-MELBOURNE NETWORK

The Bio-Melbourne Network says chief executive officer Jeff Malone has resigned effective from March 1, 2024.

The Network said that Mr Malone had overseen the development of the Wilam life sciences industry community platform and the Bio-Resource Hub platform for education and insights.

Bio-Melbourne chair David Herd said that Mr Malone was “instrumental in achieving organizational change for success, and as such we are no longer just Australia’s first state based [health technology] industry-led membership body, playing an important role in confirming Victoria’s leadership position, as Australia’s biotechnology capital, but we also have successfully taken our brand and impact to international communities”.

The Network said it had begun a search for a new chief executive officer.