Biotech Daily

Thursday December 7, 2023

Daily news on ASX-listed biotechnology companies

*** ASX EVEN, BIOTECH UP: COMPUMEDICS UP 9%; RESONANCE DOWN 11%**

*** QUEENSLAND UNI IMAGING 'PREDICTS CHILD BRAIN INJURY RECOVERY'**

*** TELIX: 'TLX250-CDX TARGETS CAIX EXPRESSION IN BREAST CANCER'**

*** MICROBA MAP315 PHASE I TRIAL: 'BOTH DOSES SAFE, WELL-TOLERATED'**

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*** CARDIEX RECEIVES $6.3m CLINICHAIN SETTLEMENT**

*** 4D MEDICAL REQUESTS 'CAPITAL RAISING, ACQUISITION' TRADING HALT**

*** ANATARA RIGHTS RAISE $956k OF $1.1m; $100k SHORTFALL**

*** ADHERIUM COMPLETES 15-to-1 CONSOLIDATION**

*** IMMUTEP RECEIVES $2.6m FRENCH R&D TAX INCENTIVE**

*** ANTEOTECH: 1st COMMERCIAL ANTEO-X EV HIGH SILICON ANODE**

*** PERENNIAL TAKES 15% OF LUMOS**

*** CHAIR PAUL RENNIE INCREASES, DILUTED TO 6% OF PARADIGM**

*** REGAL FUNDS INCREASES, DILUTED TO 8% OF VECTUS**

*** CORRECTION: PARADIGM, HELEN FISHER**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Thursday December 7, 2023, with the ASX200 down 5.1 points to 7,173.3 points. Nineteen Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Compumedics was the best, up two cents or 8.7 percent to 25 cents, with 20,000 shares traded. Amplia and Starpharma climbed more than seven percent; Avita, Genetic Signatures and Micro-X improved four percent or more; Clarity, Clinuvel, Curvebeam, Immutep and SDI were up more than three percent; Atomo, Imugene and Polynovo rose two percent or more; Alcidion, Antisense, Emvision and Volpara were up one percent or more; with Nanosonics up by 0.5 percent.

Resonance led the falls, down 0.7 cents or 10.8 percent to 5.8 cents, with 70,862 shares traded. Nova Eye lost eight percent; Dimerix and Universal Biosensors shed more than six percent; Actinogen fell 4.2 percent; Orthocell was down 3.7 percent; Medical Developments, Paradigm, Proteomics and Telix shed more than two percent; Mesoblast, Neuren and Opthea were down one percent or more; with Cochlear, CSL, Pro Medicus and Resmed down by less than one percent.

TELIX PHARMACEUTICALS

Telix says a French investigator-led 12-patient pilot prospective trial of TLX250-CDx shows effective targeting of carbonic-anhydrase IX for triple negative breast cancer.

In an email announcement not released in the ASX, Telix said that TLX250-CDx (89-zirconium-TLX250-girentuximab) expressed and targeted carbonic-anhydrase IX (CAIX) in lesions in the breast, skin, adrenal gland and brain, at a rate of 100 percent.

The company said that expression in nodes and bone was 88.0 percent and 91.9 percent, respectively, and TLX250-CDxx was “safe and well-tolerated”.

Telix said the trial was conducted by Dr Caroline Rousseau at the St Herblain, France-based Institut de Cancérologie de l'Ouest.

The company said that the primary objective was to evaluate how carbonic anhydrase IX-targeting imaging with positron emission tomography could be used for the diagnosis and staging of triple negative breast cancer and to develop a “deeper understanding of [carbonic anhydrase IX] as a potential therapeutic target”.

The company said the results showed “the ability of TLX250-CDx to detect lesions that may resist chemotherapy and have a more aggressive profile resulting from hypoxia”.

Telix said the results supported expanding its CAIX program to indications beyond kidney cancer, including future applications for lutetium-177 and actinium-225 based therapies.

The company said the study titled, ‘Imaging Performance Assessment of 89-Ziconium-labelled Girentuximab (89Zr-TLX250) PET-CT in Metastatic Triple Negative Breast Cancer Patients (OPALESCENCE)’ was presented at the San Antonio Breast Cancer Symposium, held from December 5-to-9, 2023.

Telix chief executive officer Dr Christian Behrenbruch said “identifying new targets and treatment strategies for [triple negative breast cancer] is a severe unmet need where only 20 percent of diagnosed patients are currently eligible for [programmed death-ligand 1 (PD-L1)]-targeted therapies, the standard-of-care, with the remainder reliant on toxic chemotherapeutic regimens”.

“This top-line imaging data may demonstrate proof of concept for future therapeutic applications of radio-labelled girentuximab,” Dr Behrenbruch said.

Telix fell 24 cents or 2.4 percent to $9.62 with 856,317 shares traded.

THE UNIVERSITY OF QUEENSLAND

The University of Queensland says its technology can predict the recovery from mild traumatic brain injury in children with an 87 percent success rate.

The University said that the Neurite Orientation Dispersion and Density Imaging (Noddi) technology provided more detailed information on structural damage in the brain than traditional magnetic resonance imaging measurements.

The University said the research, titled ‘Evidence of Ongoing Cerebral Microstructural Reorganization in Children With Persisting Symptoms Following Mild Traumatic Brain Injury: A NODDI DTI Analysis’ was published in the Journal of Neurotrauma and the full article was available at: https://www.liebertpub.com/doi/10.1089/neu.2023.0196.

Co-author Athena Stein said that one month post injury, it could predict recovery “two to three months later, giving doctors more information to guide treatment and management”.

“The children with ongoing symptoms following mild [traumatic brain injury] had significantly lower structural integrity and more microstructural damage in their brain networks compared to the healthy controls,” Ms Stein said.

Ms Stein said the findings advanced clinical management of mild traumatic brain injury by predicting recovery and evidence of structural brain changes “supports delaying a child’s return to sport”.

MICROBA LIFE SCIENCES

Microba says a phase I trial of MAP315 in 32 healthy volunteers shows the live biotherapeutic was “safe and well-tolerated at both low and high doses”.
Earlier this year, Microba said it had dosed the first volunteer in its randomized, double-blind, placebo-controlled phase I study of MAP315 (BD: Jun 28, 2023).
Today, the company said that MAP315 was being developed for ulcerative colitis, or inflammatory bowel disease.
Microba said the trial enrolled two cohorts of 16 participants each, randomized to receive MAP315 or placebo for 14 consecutive days.
Microba said cohort one received a low dose of one MAP315 capsule, or placebo, per day while cohort two received a high dose of eight capsules per day.
The company said there was no evidence of translocation of MAP315 into the bloodstream and no impact on inflammatory biomarkers, with all participants completing the study and dosing.
Microba said “all reported adverse events were mild, with a higher proportion reported in the placebo group and there were no adverse events that lead to study discontinuation or drug withdrawal”.
The company said ongoing ‘metagenomic analysis’ of ‘faecal kinetics’ detected MAP315 14-days after dosing completion, which showed the study had successfully delivered live MAP315 into the gastro-intestinal tract.
Microba said this was an “important clinical development milestone for MAP315 as a potential new treatment option … for ulcerative colitis”.
Microba head of therapeutics Prof Trent Munro said the company was “very pleased with the results from this clinical study which provide the foundation for further clinical development of MAP315 in patients with ulcerative colitis”.
“Microbiome-based live biotherapeutics have the potential to be a revolutionary new therapeutic modality and this is exemplified by the observed safety profile in this study,” Prof Munro said.
Microba was unchanged at 22 cents.

RHINOMED

Rhinomed has requested a trading halt pending an announcement “in relation to an application to be removed from the official list of ASX”.
Rhinomed chair Ron Dewhurst told the November 17, 2023 annual general meeting that apart from the progress made by the company with its Rhinoswabs and Mute nasal dilators, the company faced “challenges”.
Mr Dewhurst said that markets had been “difficult for smaller companies … [and] shareholders in the smaller end of the market have endured challenging times”.
“There is often a disconnect between the size of the opportunity for our products, and how the stock market is prepared to acknowledge and reward those prospects in different market conditions,” Mr Dewhurst said.
Mr Dewhurst did not mention delisting from the ASX at the meeting but said: “the board will continue to examine any and all options to maximize Rhinomed’s potential”.
Mr Dewhurst said the business was based in Melbourne “but the bulk of our revenue is generated in North America and … we are increasingly devoting more time to ensure we structure ourselves to support and grow our manpower and allocate capital where needed”.
Trading will resume on December 11, 2023 or on an earlier announcement.
Rhinomed last traded at four cents.

CYNATA THERAPEUTICS

Cynata says it has approval to begin its up-to 60-patient, phase II trial of CYP-001 for high-risk acute graft versus host disease at sites in Türkiye (Turkey).
Earlier this year, Cynata said it had opened its first US trial site and had begun recruiting the randomized, controlled trial of CYP-001 mesenchymal stem cells at Sydney's Westmead Hospital (BD: Aug 10, Nov 2, 2023).
Today, the company said it hoped to open multiple clinical centres in Turkey, with the first Turkish site initiation visits expected by March 2023.
Cynata chief medical officer Dr Jolanta Airey said the company was "delighted to receive approval to commence this trial in Turkey, which is a country that we expect will make a substantial contribution to this trial".
"Start-up activities for this trial continue to progress well, and we remain focussed on our goals of completing patient recruitment by the end of 2024, with primary results expected in the second half of 2025," Dr Airey said.
Cynata was unchanged at 12.5 cents.

CHIMERIC THERAPEUTICS

Chimeric says its entitlement offer at 2.8 cents a share has raised $4.5 million of a hoped-for $10 million, leaving a $5.5 million non-underwritten shortfall.
In October, Chimeric said it hoped to raise $10 million through a two-for-three, non-renounceable, non-underwritten rights offer at 2.8 cents a share (BD: Oct 25, 2023).
Today, the company did not state whether it would place the shortfall.
Chimeric chief executive officer Jenn Chow said "we are pleased with the strong support shown by shareholders in our recent rights issue."
"This additional funding provides us with further runway to continue our programs and is additional to the focus on strict cost controls and cash management we have put in place during 2023," Ms Chow said.
Chimeric was unchanged at three cents with 3.5 million shares traded.

CARDIEX

Cardiex says it has received $US4.12 million ($A6.26 million) through the "full settlement of all contractual payments in relation to its Clinichain clinical trial".
In October, Cardiex said it would attempt to recoup $6,408,000 in trial payments from the Almere, Netherlands-based Clinichain BV, after Clinichain ordered its Atcor Xcel devices for an arterial health trial and then delayed the trial due to the "changing requirements of the underlying customer" (BD: Oct 4, 2023).
At that time, the company said that under its contract with Clinichain, its services were non-cancellable and it was enforcing its contractual rights through settlement discussions to recoup all outstanding contractual payments, worth about $6,408,000.
Cardiex was in a suspension and last traded at 13.5 cents.

4D MEDICAL

4D Medical has requested a trading halt pending an announcement "regarding a proposed capital raising and an acquisition".
Trading will resume on December 11, 2023, or on an earlier announcement.
4D Medical last traded at 95.5 cents.

ANATARA LIFESCIENCES

Anatara says its entitlement offer raised about $657,914 of a hoped-for $1,055,334, with the $397,422 shortfall partially underwritten to $297,723.
In November, Anatara said it hoped to raise about $1.055 million in a two-for-five, non-renounceable entitlement offer at 2.2 cents a share (BD: Nov 3, 2023).
Today, the company said the shortfall was partially underwritten by Taylor Collison and other sophisticated investors, and that it expected the remaining $99,699 shortfall to be "placed in the near future".
Anatara said the funds would be used for stage two of its irritable bowel syndrome trial.
Anatara was untraded at 2.7 cents.

ADHERIUM

Adherium says it has completed its 15-to-one stock consolidation and it has 333,439,981 post-consolidation shares on issue.
Last week, Adherium said that 96.73 percent of its annual general meeting voted for the 15-to-one stock consolidation (BD: Dec 1, 2023).
Adherium was up 0.2 cents or eight percent to 2.7 cents.

IMMUTEP

Immutep says it has received EUR1,595,475 ($A2,620,918) from the French Government under the Crédit d'Impôt Recherche scheme.
Immutep said the Research Tax credit scheme was a French incentive that reimbursed up-to 30 percent of eligible research and development expenditure in Europe.
The company said it qualified through its subsidiary Immutep SAS for research and development conducted at its laboratory in France, in 2022.
Immutep said the funds would support its clinical development of eftilagimod alpha and the preclinical development of IMP761.
Immutep was up one cent or 3.2 percent to 32 cents with 1.1 million shares traded.

ANTEOTECH

Anteotech says it has produced the first commercial high silicon anode containing its Anteo-X battery additive for electric vehicle (EV) lithium-ion battery manufacturing.
Anteotech said it optimized the anode design of an undisclosed European electric vehicle manufacturing company using Anteo X "achieving both cost and performance improvements when compared to their baseline design".
The company said the production confirmed the ability of anode manufacturers to produce the anode mix containing Anteo X at a larger scale and was "a key validation point in the development and commercial adoption" of Anteo X.
Anteotech was unchanged at 3.4 cents with 6.15 million shares traded.

LUMOS DIAGNOSTICS

Sydney's Perennial Value Management says it has increased its substantial shareholding in Lumos from 61,859,749 shares (13.95%) to 72,194,867 shares (15.00%).
Perennial said between September 20 and December 6, 2023 it bought and sold shares, with the single largest purchase 7,785,714 shares for $599,500, or 7.7 cents a share.
Lumos was unchanged at 6.4 cents with 7.8 million shares traded.

PARADIGM BIOPHARMACEUTICALS

Paradigm chair Paul Rennie says he has increased his holding in the company and been diluted from 20,391,234 shares (7.15%) to 20,678,805 shares (5.88%).
The Adelaide-based Mr Rennie said that between December 20, 2022 and November 30, 2023 he bought shares on-market, with his largest purchase through Kzee Pty Ltd of 466,000 shares for $200,380 or 43 cents a share in the recent capital raising, in which he was diluted.
Last month, Paradigm said its capital raising at 43 cents a share raised about $23.9 million (BD: Nov 23, 2023).
Paradigm fell one cent or 2.5 percent to 38.5 cents.

VECTUS BIOSYSTEMS

Regal Funds Management says it has increased its holding in Vectus and been diluted from 4,457,782 shares (9.43%) to 4,483,896 shares (8.43%).
The Sydney-based Regal Funds said it bought and sold shares between December 28, 2022 and May 15, 2023, with the single largest purchase 4,103,328 shares for $2,051,664, or 50 cents a share on May 15, with the same number of shares sold at the same price on the same day.
Regal Funds said it was diluted in Vectus “due to the issue of 19,482 shares on December 4, 2023”.
According to its most recent notification, Vectus had 53,209,361 shares on issue on the ASX.
Last year, Vectus said it raised $3,653,070 in a $3.5 million placement at 80 cents a share, and had a share plan for a further $1 million (BD: Dec 2, 2023).
In a cleansing notice on December 28, 2022, the company said it had issued 1,371,875 shares after the retail share purchase plan raised $697,500.
Vectus was up half a cent or 1.6 percent to 32 cents.

CORRECTION: PARADIGM BIOPHARMACEUTICALS

The first sentence of the November 20, 2023 edition incorrectly said that director Helen Fisher has resigned.
The headline and the rest of the copy was correct that Ms Fisher would resign when a replacement was found.
The error was made by the November Monday sub-editor who has been terminated without pay.