Biotech Daily

Wednesday September 14, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMPEDIMED UP 8%; COMPUMEDICS DOWN 7%**

*** IMRICOR RAISES $3m IN 'OVERSUBSCRIBED' US PLACEMENT**

*** BIOTRON STARTS BIT225 COVID-19 HIV SUB-STUDY**

*** CLARITY IMAGES 1st SAR-BOMBESIN PROSTATE CANCER PATIENTS**

*** VECTUS VB0004 PHASE Ia STUDY SAFE; PHASE Ib TO BEGIN**

*** VGI, INVICTUS RECRUITS 1st PHASE II IVB001 NAFLD, NASH PATIENT**

*** CRESO STARTS CANADA PSILOCYBIN PTSD TRIAL**

*** NOXOPHARM CRO-67 'PROMISING' FOR PANCREATIC CANCER, IN VITRO**

*** RADIOPHARM, MD ANDERSON RADIO-PHARMACEUTICAL J-V**

*** PRESCIENT TO UNVEIL CELLPRYME-A IN BOSTON**

*** ADHERIUM REQUESTS 'PLACEMENT' TRADING HALT**

*** NSW SUPREME COURT SCHEME OK; RESAPP GOES TOMORROW**

*** LIVING CELL BOARD SPILL CALL**

*** BILAL AHMAD TAKES 10.9% OF DORSAVI**

*** FIREBRICK APPOINTS SCIENTIFIC ADVISORY BOARD**

MARKET REPORT

The Australian stock market followed the US down 2.58 percent on Wednesday September 14, 2022, with the ASX200 down 181.1 points to 6,828.6 points. Fifteen of the Biotech Daily Top 40 were up, 18 fell, five traded unchanged and two were untraded.

Impedimed was the best, up 0.5 cents or 7.7 percent to seven cents, with 686,493 shares traded. Resonance rose 7.3 percent; Actinogen and Prescient improved more than five percent; Antisense, Mesoblast and Neuren were up more than three percent; Starpharma and Volpara rose more than two percent; Avita, Immutep and Oncosil were up one percent or more; with Emvision, Opthea, Polynovo and Resmed up less than one percent.

Compumedics led the falls, down two cents or 7.3 percent to 25.5 cents, with 98,523 shares traded. Clinuvel fell 6.9 percent; Cyclopharm lost 5.8 percent; Alcidion, Dimerix, Medical Developments, Micro-X and Nova Eye were down more than three percent; Imugene, Kazia, Nanosonics, Proteomics and Telix shed more than two percent; CSL, Cynata, Next Science, Orthocell, Pro Medicus and Universal Biosensors were down more than one percent; with Cochlear down 0.9 percent.

IMRICOR MEDICAL SYSTEMS

Imricor says an “oversubscribed” US placement raised $2.92 million at 38 cents a share, a 27 percent premium to its five-day volume-weighted average price to September 13, 2022.
Imricor said that the proceeds would be used for general working capital as it nears its trial of magnetic resonance imaging (MRI) cardiac ablation trials for ventricular tachycardia.
The company said that the US stock would be subject to a holding lock for 12 months, after which each share would be convertible to a Chess depositary interest (CDI) on a one-to-one basis.
Imricor chair Steve Wedan said the placement was “a good opportunity for our US investor base to purchase shares of Imricor common stock”.
“These investors recognize the value that the current CDI price reflects” but due to regulations prohibiting US citizens from buying the CDIs on the ASX “they have been unable to act on their desire to invest”.
“This raise also represents just one piece of a larger strategy to minimize dilution for our security holders and extend our runway as we grow our sales post-pandemic and as we progress toward [ventricular tachycardia] indications,” Mr Wedan said.
Imricor was up one cent or 3.5 percent to 29.5 cents.

BIOTRON

Biotron says it has begun a sub-study of BIT-225 in Covid-19 as part of its Thailand-based phase II trial of BIT225 for HIV-1.
Last year, Biotron said it had begun a 27-patient, Thailand-based phase II trial and a 20-patient, Sydney-based phase II trial of BIT225 for HIV-1, and later said that BIT225 had shown “substantial and clinically meaningful efficacy” against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) in mice (BD: Nov 1, 25, 2021).
Today, Biotron said that any of the 27 trial participants diagnosed with symptomatic Covid-19 would be enrolled in the Covid-19 sub-study, with the HIV study’s randomization and blind continuing throughout the sub-study.
Biotron said the changes in Sars-Cov-2 viral loads and Covid-related symptoms had been incorporated as exploratory objectives and the primary and secondary objectives of the trial remain unchanged from those announced last year.
Biotron managing-director Dr Michelle Miller said there were “minimal additional costs associated with the sub-study and no expected impact on timing of the results of the BIT225-010 trial as it is fully recruited”.
“The sub-study provides a speedy and cost-effective pathway to explore the potential benefit of BIT225 against Sars-Cov-2 in a high-risk patient population,” Dr Miller said.
The company said the trial was expected to conclude in February 2023 with results in mid-2023.
Biotron was up 0.05 cents or 0.9 percent to 5.7 cents with 5.8 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has imaged the first participants in its up-to 30 patient, phase II trial of 64-copper SAR-Bombesin for prostate cancer.
Clarity said the trial at Sydney’s St Vincent’s Hospital would recruit patients with suspected biochemical recurrence of their prostate cancer who were negative to prostate-specific membrane antigen (PSMA), and those with metastatic, castrate-resistant prostate cancer ineligible for PSMA therapy.
Clarity fell one cent or 1.6 percent to 63 cents.

VECTUS BIOSYSTEMS

Vectus says it has completed a phase I, dose-escalation, safety, tolerability and pharmacokinetics trial of VB0004, with 'no significant adverse side effects reported'.
Vectus said the most recent cohort of healthy volunteers were dosed with 100mg of VB0004 for 14 consecutive days with no significant adverse events reported.
The company said that it permission to start the phase Ib stage of the trial, in which patients with uncomplicated hypertension would be treated for 28 days at a dose of 30mg a day.
Vectus chair Dr Ronald Shnier said the end of the phase Ia study was "a significant milestone in proving the safety of our anti-fibrotic, anti-hypertensive drug".
"This is particularly pleasing as we move towards the next phase of testing of a compound that can have a significant and widespread global positive impact on disease, the pathology of which has many aetiologies," Mr Shnier said.
Vectus fell two cents or 2.6 percent to 75 cents.

VGI HEALTH TECHNOLOGY

VGI says subsidiary, Invictus Ops Pty Ltd, has begun its 80-patient, phase II trial of IVB001 for non-alcoholic fatty liver disease and non-alcoholic steato-hepatitis.
VGI said the randomized, double-blind, placebo-controlled trial would analyse the efficacy and safety of IVB001 for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steato-hepatitis (NASH).
The company said that IVB001 was based on the non-invasive and direct delivery of tocotrienols using Invictus' transmucosal delivery platform.
VGI said it had trial approvals from Perth's Fiona Stanley Hospital, the Concord Repatriation General Hospital and the John Hunter Hospital in New South Wales, the Gallipoli Medical Research Foundation in Queensland and the Royal Melbourne Hospital.
The company said the first patient had been and was expected to begin dosing on October 5, 2022
VGI and Invictus chief executive officer Dr Glenn Tong told Biotech Daily that Invictus "expects to demerge from VGI by the end of the year".
On the National Stock Exchange, VGI was untraded at three cents.

CRESO PHARMA

Creso says its Canadian subsidiary Halucenex has approval for a 20-patient, phase II trial of psilocybin for treatment-resistant post-traumatic stress disorder.
Creso said Health Canada had authorized Halucenex to trial its Lucenex synthetic psilocybin aqueous product in both 10mg and 25mg formats.
The company said patient recruitment was underway.
Halucenex chief executive officer Bill Flaming said the company's management and clinical trial staff had "mobilized quickly following the … approval and begun the patient recruitment process".
"We have received a significant amount of in-bound enquiries, which further highlights the importance of our planned trial," Mr Fleming said.
Creso fell 0.1 cents or 2.6 percent to 3.7 cents with 5.7 million shares traded.

NOXOPHARM

Noxopharm says pancreatic cancer tumor cells exposed to its CRO-67 decreased by 85 percent, with barrier cells decreasing 87 percent, in-vitro.
Noxopharm said six patient samples were treated at doses of 10 micrograms per millilitre (µg/ml), 20µg/ml and 50µg/ml and "a dose-response relationship was found, such that greater amounts of drug resulted in highly statistically significant effects".
Noxopharm said the highest dose levels resulted in an 85 percent decrease in tumor cells ($p < 0.0002$) and an 87 percent decrease in barrier cells ($p < 0.0001$), compared to untreated controls.
Noxopharm fell one cent or 3.3 percent to 29 cents with 1.6 million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it has a joint-venture with the Houston, Texas-based MD Anderson Cancer Centre to develop novel radio-pharmaceutical products for cancer.
Radiopharm said the joint venture would be named Radiopharm Ventures LLC and target development of at least four therapeutic products based on the MD Anderson Centre's intellectual property.
The company said the first potential therapeutic candidate would be a humanized immunoglobulin G antibody against the tumor-specific antigen B7-H3, also known as CD276, which was highly expressed in several common tumors but not in healthy cells.
Radiopharm chief executive officer Riccardo Canevari said that radio-pharmaceuticals "continue to be rapidly developed as a highly promising therapeutic frontier in oncology".
"We are pleased to have this opportunity to collaborate with MD Anderson and its tremendous scientists as we work to make significant in-roads into cancer therapy for the benefit of patients," Mr Canevari said.
Radiopharm fell one cent or 5.7 percent to 16.5 cents.

PRESCIENT THERAPEUTICS

Prescient says will unveil the second component of its Cellpryme cell therapy platform, as well as further information on Omnicar at Boston's CAR-TCR Summit.
Prescient said that head of scientific affairs Dr Rebecca Lim would discuss Cellpryme-A, in a session titled 'Enhancing Persistence & Efficacy of CAR-T Therapies', on September 21, 2022.
Last week, the company said it would work with the Houston, Texas-based MD Anderson Cancer Centre to combine its Omnicar with one of MD Anderson's blood cancer binders (BD: Sep 7, 2022).
Today, Prescient said its head of business development and alliances Dr Daniel Shelly, would present the advantages and capabilities of the Omnicar technology in a session titled 'Simultaneous & Sequential Multi-Antigen Targeting with a Novel Universal Immune Receptor' on September 22, 2022.
Prescient was up one cent or 5.6 percent to 19 cents with 1.85 million shares traded.

ADHERIUM

Adherium has requested a trading halt pending an announcement "in relation to a proposed placement to sophisticated and professional investors".
Trading will resume on September 16, 2022.
Adherium last traded at 0.8 cents.

RESAPP HEALTH

Resapp says the New South Wales Supreme Court has approved the Pfizer Australia scheme of arrangement to acquire its shares for $179 million or 20.8 cents a share.
Last week, Resapp said the two resolutions to accept the Pfizer $179 million offer were passed with more than 82 percent of votes (BD: Sep 8, 2022).
Today, the company said it expected its shares to be suspended from trading on the ASX from the close of trading on September 15, 2022.
Resapp said the implementation date for the scheme, at which point shareholders would receive 20.8 cents for each share held, was expected to be September 26, 2022.
Resapp was up 0.5 cents or 2.4 percent to 21 cents with 11.1 million shares traded.

LIVING CELL TECHNOLOGIES

Living Cell says it has received a section 249D board spill notice from shareholders controlling more than five percent of the company.
In 2017, Living Cell fell as much as 88.8 percent to 2.3 cents on news there was no statistical significance for the efficacy of its NTCell treatment for Parkinson's disease, although three of the four primary endpoints were met in its 18-patient, phase IIb trial, with no product or procedure adverse events and no evidence of xenogeneic infection in patients and their partners (BD: Nov 10, 2017).
In 2018, the company said that 12-month data showed a "statistically significant improvement" in patients who had 40 or 80 NTCell capsules implanted to the putamen on both sides of the brain, according to the Unified Parkinson's Disease Rating Scale, but patients implanted with 120 NTCell capsules did not appear to have a significant improvement change (BD: May 15, 2018).
In 2021, Living Cell said it had raised $361,264 of a hoped for $4 million in a rights issue for a third trial of NTCell for Parkinson's disease (BD: Mar 21, 2021).
According to Commsec data, in the past 12 months, Living Cell has traded between 0.4 cents and 1.3 cents and has been below two cents since January 2020.
Living Cell said that the board spill meeting had been requisitioned by EZR Systems Pty Ltd, Union Square Capital Pty Ltd and Ellaz Pty Ltd as trustee for the Ripper Family Trust.
The company said the resolutions called for the removal of executive chair Prof Bernie Tuch and directors Robert Willcocks and Dr Andrew Kelly, to be replaced by David Hainsworth and Bradley Dilkes.
Living Cell said it would consider the notice and if valid call an extraordinary general meeting within two months.
A separate substantial shareholder notice said that Melbourne's EZR and Julian Jarman, Cipater Pty Ltd and Bradley Dilkes, and the Perth, Western Australia-based Union Square and David Hainsworth and Ellaz and Francesco Scullino held 68,358,292 shares or 5.32 percent of the company.
Mr Jarman, Mr Dilkes and Mr Hainsworth are directors of Melbourne's Alignment Capital.
Living Cell was unchanged at 1.2 cents with 12.9 million shares traded.

DORSAVI

Bilal Ahmad says he has increased his substantial holding in Dorsavi from 39,067,233 shares (9.85%) to 47,397,833 shares (10.90%).
The Perth-based Mr Ahmad said that between the August 15 and September 9, 2022, he bought 8,330,600 shares for $90,751, or 1.1 cents a share.
Dorsavi was up 0.1 cents or 8.3 percent to 1.3 cents with 1.7 million shares traded.

FIREBRICK PHARMA

Firebrick says it has formed a scientific advisory board comprising Prof Richard Strugnell, Prof Ronald Turner, Prof Andrew Wilks and Dr Bobby Singh.

Firebrick said that executive chair Dr Peter Molloy, directors Dr Stephen Goodall, Prof Phyllis Gardner and Dr Richard Treagus, and chief scientific officer Dr Simon Tucker would participate in scientific advisory meetings.

The company said Prof Strugnell was an academic microbiologist, Prof Turner was a professor emeritus of paediatrics at the University of Virginia School of Medicine, Prof Wilks held an adjunct professorship in the Department of Medicine, Nursing and Health Sciences at Monash University, and Dr Singh was chief operating officer of Corsair Pharma.

Firebrick fell three cents or 9.7 percent to 28 cents.