



Biotech Daily

Wednesday May 3, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: MESOBLAST UP 8%; MICRO-X DOWN 13%**
- * **PHARMAUST 'OVER-SUBSCRIBED' PLACEMENT RAISES \$2.5m**
- * **LIVING CELL PLACES \$694k SHORTFALL; TOTAL \$2.5m**
- * **BCAL OPENS BLOOD SCREENING TOOL LABORATORY**
- * **PROTEOMICS PROMARKERD: DIABETES DRUG WORKS FOR DIABETES**
- * **IMUGENE ONCARLYTICS, ARTEMIS SYNERGY FOR TUMORS, IN-VIVO**
- * **NEUROTECH RECRUITS PHASE I/II MARIJUANA NTI164 TRIAL**
- * **ONCOSIL ENROLS 1st RADIATION-CHEMOTHERAPY PATIENT**
- * **UNIVERSAL BIOSENSORS LAUNCHES PETRACKR FOR CATS, DOGS**
- * **ALLEGRA SELLS ORTHOPAEDICS FOR \$4.3m TO RELATED ROBINWOOD**
- * **ARTRYA LODGES SALIX FDA Q-SUBMISSION**
- * **BLUECHIIP REQUESTS 'CAPITAL RAISING' TRADING HALT**
- * **DIMERIX TAKES 'CAPITAL RAISE' HALT TO SUSPENSION**
- * **HEALTH HOUSE 96% VOTE FOR CRESO TAKEOVER**
- * **G TO THE FOURTH TAKES 6.6% OF MESOBLAST**

MARKET REPORT

The Australian stock market fell 0.96 percent on Wednesday May 3, 2023, with the ASX200 down 70.0 points to 7,194.4 points. Eight of the Biotech Daily Top 40 stocks were up, 24 fell, three traded unchanged and five were untraded.

Mesoblast was the best, up 7.5 cents or 8.4 percent to 96.5 cents, with 4.1 million shares traded. Patrys improved 7.7 percent; Nova Eye climbed six percent; Cynata and Proteomics were up more than three percent; Avita and Universal Biosensors rose more than two percent; with Antisense and Resmed up by more than one percent.

Yesterday's 21.05 percent best, Micro-X, led the falls, down 1.5 cents or 13.0 percent to 10 cents, with 686,416 shares traded. Oncosil lost 9.1 percent; Clinuvel, Next Science and Polynovo were down more than six percent; Genetic Signatures, Immunetep and Kazia shed five percent or more; Starpharma fell 4.2 percent; Actinogen, Alcidion, Medical Developments, Opthea, Orthocell and Paradigm were down more than three percent; Atomo, Prescient and Volpara shed two percent or more; Cyclopharm and Pro Medicus were down one percent or more; with Cochlear, CSL, Emvision, Nanosonics, Neuren and Telix down by less than one percent.

PHARMAUST

Pharmaust says it has “binding commitments” to raise \$2.4 million in an “over-subscribed” placement at eight cents a share, with a further \$104,000 from directors.

Pharmaust said the eight cent share price was a 20 percent discount to the 30-day volume weighted average price.

The company said that for every two shares bought there would be one attaching option, exercisable at 15 cents each by April 30, 2026.

Pharmaust said the funds would be used for trials, the manufacture of monepantel tablets and working capital.

The company said that directors had subscribed for \$104,000 in shares, subject to shareholder approval at a general meeting to be announced.

Pharmaust fell 1.2 cents or 12 percent to 8.8 cents.

LIVING CELL TECHNOLOGIES

Living Cell says it has placed its \$693,972 rights offer shortfall with Alignment Capital Pty Ltd, taking the total raised to \$2.5 million.

In March, Living Cell said it hoped to raise up-to \$2,512,500 in a \$750,000 placement and a \$1.2 million rights issue at 0.75 cents a share, with commitments for the placement “from professional and sophisticated investors of Alignment” (BD: Mar 1, 2023).

Last month, Living Cell said its one-for-eight entitlement offer to raise 1.2 million at 0.75 cents a share had closed with a shortfall of \$693,972 (BD: Apr 18, 2023).

According to the Alignment Capital website, Living Cell chair David Hainsworth and director Brad Dilkes are associate directors of Alignment Capital.

Living Cell was up 0.05 cents or 6.25 percent to 0.85 cents.

BCAL DIAGNOSTICS

Bcal says it has opened its development and clinical service laboratory in Sydney for its non-invasive blood screening tool to be used with breast cancer screening.

Bcal said the laboratory would use liquid chromatography mass spectrometry platforms to advance the findings of its clinical research and the progress made by its US commercialization partner Precion Inc.

The company said the laboratory would act as a testing site for the ongoing and planned clinical validation studies and establish the quality systems and protocols needed to be compliant with various regulatory accreditations.

Bcal said the results from continued studies of its blood screening product would be presented in a poster titled ‘Lipodomic signature from plasma to detect localized breast cancer’ at the American Society of Clinical Oncology meeting in Chicago in June 2023.

The company said that the opening was “an important milestone ... as it advances commercialization of its non-invasive blood screening that is initially intended to be used alongside breast cancer screening methods, with results to date demonstrating 91 percent sensitivity and 80 percent specificity.

Bcal executive chair Jayne Shaw said the laboratory brought the company “one step closer to accomplishing this goal”.

“We are very excited by the market access opportunities that this laboratory provides, not only for current and future tests that may be developed by Bcal, but also for those developed by other companies seeking entry to the Australian market,” Ms Shaw said.

Bcal fell 0.4 cents or 4.4 percent to 8.6 cents.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Promarker diagnostic shows “a significant reduction” in risk scores for type 2 diabetes patients taking the diabetes medicine canagliflozin.

Proteomics said the study, in collaboration with Johnson & Johnson’s Janssen Research and Development examined the association between approved diabetes therapy canagliflozin and changes in Promarker scores in type 2 diabetes patients.

The company said the study, titled ‘Canagliflozin Attenuates Promarker Diabetic Kidney Disease Risk Prediction Scores’ was published in the Journal of Clinical Medicine, with an abstract available at: <https://www.mdpi.com/2077-0383/12/9/3247>.

Proteomics said the study showed the average Promarker blood test risk scores for predicting kidney disease were lowered in patients taking the canagliflozin SGLT2-inhibitor treatment, while the average score of placebo patients increased.

Proteomics managing director Dr Richard Lipscombe said the study showed that the gliflozin class drugs could lower Promarker risk scores and had the potential to treat at-risk patients identified by the test.

“The findings illustrate the benefits of using Promarker testing,” Dr Lipscombe said.

“It’s an elegant example of using precision medicine to enable early intervention and slow or stop the onset of disease,” Dr Lipscombe said.

Proteomics was up three cents or 3.6 percent to 87 cents.

IMUGENE

Imugene says its Oncarlytics technology with the Emeryville, California-based Eureka Therapeutics’ Artemis T cell platform showed “impressive in-vivo anti-tumor responses”.

In 2021, Imugene said it would work with Eureka to evaluate its CF33-CD19 oncolytic virus technology with Eureka’s Artemis T-cell therapy in solid tumors (BD: Nov 1, 2021).

The company said at that time that the partnership would aim to establish a “mark and kill” process in which its CD19 oncolytic virus technology would force tumors to express CD19, which could then be targeted by Eureka’s anti-CD19 Artemis T-Cell therapies.

Imugene said the study, titled ‘Effective combination immunotherapy using Oncarlytics and Artemis CD19 T cells against hepatocellular carcinoma’ would be presented at the American Society of Gene Cell Therapy meeting in Los Angeles from May 16 to 20, 2023.

Imugene said the abstract showed in vivo-anti tumor responses in a human xenograft model and the combination could be applied to otherwise targetless tumors such as hepatocellular carcinoma and other solid cancers as an immunotherapy approach.

Imugene was unchanged at 12.5 cents with 24.7 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has recruited all 15 patients in its phase I/II trial of the marijuana-based NTI164 for children with autoimmune neuropsychiatric disorders.

In February, Neurotech said it had treated the first patient in its trial of NTI164 for children with neuro-psychiatric disorders at Sydney’s Children’s Hospital at Westmead and Melbourne’s Monash Medical Centre (BD: Feb, 16, 2023).

The company said it expected results from the trial of NTI164 for paediatric autoimmune neuropsychiatric disorders associated with streptococcal infections and paediatric acute-onset neuropsychiatric syndrome by October 2023.

Neurotech executive director Dr Thomas Duthy said the rapid recruitment process was a “testament to the clinical interest in NTI164” for paediatric neurological disorders.

Neurotech was up 0.6 cents or 12 percent to 5.6 cents.

ONCOSIL MEDICAL

Oncosil says it has enrolled the first of 80 patients in its open-label, randomized trial of its phosphorous-32 radiation with chemotherapy for pancreatic cancer.

Oncosil said the study compared targeted intra-tumoral placement of phosphorous-32 in combination with Folfirinox (folinic acid, fluorouracil, irinotecan and oxaliplatin) chemotherapy with Folfirinox chemotherapy alone in patients with unresectable locally advanced pancreatic cancer.

The company said the study aimed to evaluate the safety and efficacy of its treatment and expand the Conformité Européenne (CE) mark use of the device in the UK and the EU for patients being treated with gemcitabine based or Folfirinox chemotherapies.

Oncosil said primary endpoints included safety, tolerability and local disease control at 16 weeks, with secondary endpoints overall survival, quality of life and resection rates.

Oncosil said the study would be at 15 hospitals in the UK and EU, with four sites in Belgium and Spain initiated and the first patient had been enrolled at the Pamplona-based Clinica Universidad de Navarra.

Oncosil fell 0.1 cents or 9.1 percent to one cent with three million shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has launched its Petrackr blood glucose monitor for cats and dogs with diabetes and has three US and Canada distribution partnerships.

Universal Biosensors said it had initial purchase orders of \$280,000 from the distributors and expected first year sales to be more than \$2 million with increased sales to follow.

The company said 10,000 Petrackr analyzers and 375,000 diabetes test strips were delivered and in transit to its warehouses in the US and Europe, with the remainder of the stock to be delivered by May 31, 2023.

In 2009, Universal Biosensors said it had signed a blood glucose diagnostic product agreement with partner Johnson and Johnson subsidiary Lifescan Inc amending the original October 2007 master services and supply agreement (BD: May 15, 2009).

Universal Biosensors was up half a cent or two percent to 25 cents.

ALLEGRA ORTHOPAEDICS

(FORMERLY ADVANCED SURGICAL DESIGN AND MANUFACTURE)

Allegra says it will sell its orthopaedics division for \$1 million cash and more than \$3.3 million for the cost value of inventory to shareholder Robinwood Investments Pty Ltd.

Allegra said the sale would allow it "to advance the business activities of the innovations division, particularly the spinal cage technology".

The company said the agreement also included no less than a \$1.2 million underwritten commitment from Robinwood Investments for any future capital raise, with the funds from the agreement to be used to pay down debt as interest rates continue to increase.

Allegra said that Robinwood was associated with director Dr Nicholas Hartnell and according to his most recent substantial shareholder notice Dr Hartnell held 39,499,038 shares or 37.81 percent of the company.

The company said that future capital raisings would be used to support the commercialization of its spinal cage device.

Allegra said its orthopaedics division continued to underperform following the Covid-19 pandemic, with revenues negatively impacted resulting in trading losses from the division for the 12 months to June 30, 2022 and the six months to December 31, 2022.

Allegra was untraded at 7.1 cents.

ARTRYA

Artrya says it has lodged a “Q-submission” to the US Food and Drug Administration for its Salix coronary anatomy system for coronary plaque identification.

The FDA website did not explain what the “Q” represented but said a ‘Q-Submission’ or ‘Q-Sub’ “refers to the system used to track the collection of interactions” and were opportunities for submitters to share information with the FDA and receive input beyond the submission of an application.

Artrya said the submission was a “key enabling step” in the US regulatory process and it expected a meeting with the FDA to present its approach to the Salix product’s development and clinical reader study within nine to 12 weeks.

The company said the meeting would provide feedback on its regulatory strategy, product definition, indications for use and product testing and clinical validation requirements.

Artrya chief executive officer Matthew Regan said “the feedback can save critical time and money during the FDA regulatory process”, with a final 510(k) application expected to be submitted by November 2023.

Artrya was up two cents or eight percent to 27 cents.

BLUECHIIP

Bluechiip says it has requested a trading halt “pending an announcement to the market in connection with a capital raising program”.

Trading will resume May 5, 2023, or on an earlier announcement.

Bluechiip last traded at 2.9 cents.

DIMERIX

Dimerix says it has requested a suspension to follow a trading halt “for the purposes of considering, planning and executing a capital raising” (BD: May 1, 2023).

Trading will resume May 4, 2023, or on an earlier announcement.

Dimerix last traded at 9.7 cents.

HEALTH HOUSE INTERNATIONAL, CRESO PHARMA

Health House says that shareholders have overwhelmingly voted in favor of Creso Pharma acquiring the company in a scheme of arrangement.

Last year, Creso said it had a non-binding agreement to acquire the Perth-based medical marijuana distributor Health House International for up to \$4,630,388 in shares and options (BD: Aug 1, 2022).

Today, Health Hose said that 36,433,931 votes (95.96%) supported the scheme of arrangement, with 1,534,751 votes (4.04%) opposed.

In its most recent filing Health House said it had 178,224,621 shares on issue.

Health House said the acquisition remained subject to the approval of the Supreme Court of Western Australia, with a second court hearing scheduled for May 4, an acquisition effective date of May 5, and an implementation date of May 16, 2023.

Creso was unchanged at one cent with 2.8 million shares traded.

Health House was up 0.1 cents or 25 percent to 0.5 cents.

MESOBLAST

The Tampa, Florida-based G to the Fourth Investments LLC says it has become substantial in Mesoblast with 53,920,195 shares or 6.62 percent.

G to the Fourth said on May 1, 2023 it bought 18,013,293 shares for \$US10,300,000 (\$A15,440,320), or 57 US cents (85 Australian cents) a share.

G to the Fourth Investments said that the share-holders were Gregory George, Grant George and James George.

Last week, Mesoblast said it raised about \$US40 million (\$A60.5 million) at 85 cents a share in a placement to existing US, UK and Australian shareholders (BD: Apr 26, 2023).

Mesoblast was up 7.5 cents or 8.4 percent to 96.5 cents with 4.1 million shares traded.