



# Biotech Daily

Tuesday October 13, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: USCOM UP 5%; GENETIC SIGNATURES DOWN 6%**
- \* **MESOBLAST PHASE III REMESTEMCEL-L COVID-19 TRIAL HALF-WAY**
- \* **IMMURON RESTARTS IMM-124E PHASE III DIARRHOEA PROGRAM**
- \* **BIONOMICS RECEIVES \$2.9m FEDERAL R&D TAX INCENTIVE**
- \* **ACTINOGEN REQUESTS 'CAPITAL RAISING' TRADING HALT**
- \* **INVEX 800k DIRECTOR DR THOMAS DUTHY OPTIONS AGM**
- \* **CRESO CANCELS L1, LIND, CHIFLEY CONVERTIBLE NOTES**
- \* **W WHITNEY GEORGE REDUCES TO 40% OF RHINOMED**
- \* **L1 REDUCES TO 10.5% OF CRESO**
- \* **PARADIGM APPOINTS THREE EXECUTIVES**

## MARKET REPORT

The Australian stock market was up 1.04 percent on Tuesday October 13, 2020, with the ASX200 up 63.7 points to 6,195.7 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and two were untraded. All three Big Caps were up.

Uscom was the best, up one cent or 5.4 percent to 19.5 cents, with 128,877 shares traded. Amplia, Opthea, Osprey and Resonance climbed more than three percent; Compumedics was up 2.35 percent; Orthocell, Pharmaxis, Polynovo and Volpara were up more than one percent; with Cochlear, CSL, Kazia, Next Science, Pro Medicus and Resmed up by less than one percent.

Genetic Signatures led the falls, down 13 cents or 6.25 percent to \$1.95, with 150,091 shares traded. Cynata and Patrys Amplia lost five percent or more; Optiscan fell 4.35 percent; Dimerix was down 3.4 percent; Immutep, Mesoblast and Neuren shed two percent or more; Avita, Imugene, Medical Developments, Paradigm, Prescient, Proteomics and Universal Biosensors were down more than one percent; with Clinuvel, Nanosonics and Starpharma down by less than one percent.

## MESOBLAST

Mesoblast says it has enrolled half of the 300-patients in its phase III trial of Remestemcel-L for acute respiratory distress syndrome (Ards) due to Covid-19.

In April, Mesoblast said that 10 of 12 ventilator-dependent Covid-19 patients treated with its allogeneic mesenchymal stem cell product had survived a trial at New York's Mt Sinai Hospital, with nine no longer requiring ventilator support and the following week, began enrolling the 300-patient, phase II/III trial (BD: Apr 24, 30, 2020).

Last month, the company said the independent data safety monitoring board had reviewed the first 30 percent of patients in the study and had recommended that the trial continue (BD: Sep 4, 2020).

Today, Mesoblast said further interim analyses would be performed in early November when 45 percent of patients had completed the 30-day follow-up.

The company said the randomized, double-blind, controlled trial's primary endpoint was to reduce mortality in ventilator-dependent patients over 30 days relative to maximal care to confirm findings from the Mt Sinai pilot study.

Mesoblast said Remestemcel-L was being developed for severe diseases associated with excessive cytokine storm, including Ards and acute graft versus host disease.

Earlier this month, the company said the US Food and Drug Administration had knocked back Remestemcel-L for graft versus host disease pending a further randomized, controlled trial to provide further evidence (BD: Oct 2, 2020).

Mesoblast has said that discussions with the FDA were continuing, including the possibility of using the data from the Ards trial as supporting evidence for the graft-versus-host application.

In today's announcement, Mesoblast chief medical officer Dr Fred Grossman said, there was "an urgent need for targeted treatments to reduce the continued high mortality in Covid-19 ARDS patients who are dependent on mechanical ventilators".

"We expect to complete the enrolment target in this important trial by the end of the year as the enrolment rate continues to increase in line with the surge in new infections across the United States," Dr Grossman said.

Mesoblast fell seven cents or 2.1 percent to \$3.27 with 8.9 million shares traded.

## IMMURON

Immuron says it has restarted its IMM-124E program for travellers' diarrhoea, including a planned phase III trial and US investigational new drug application.

Immuron said the Bethesda, Maryland-based Uniformed Services University had informed the company that it had recommenced a randomized, double-blind, placebo-controlled, multi-centre trial to evaluate the efficacy of three commercially available non-antibiotic over-the-counter products, including IMM-124E, the active ingredient of Immuron's over-the-counter Travelan for travellers' diarrhoea.

The company said the trial would administer either the pre-biotic Bimuno, pro-biotic Florastor, IMM-124E, or a placebo to 1,336 study participants, with 334 in each study arm. Immuron said the trial would be conducted by the University's Infectious Diseases Clinical Research Program, the UK Ministry of Defence and the New York City Travel Clinic and it would receive a purchase order to provide IMM-124E for the trial.

The company said it also had a consultancy agreement with infectious disease epidemiologist and the Detroit, Michigan-based Wayne State University's Prof Teena Chopra.

Immuron fell four cents or 12.3 percent to 28.5 cents with 5.5 million shares traded.

### BIONOMICS

Bionomics says it has received \$2,919,541 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Bionomics said the rebate related to research and development expenditure for the year to June 30, 2020.

Bionomics fell half a cent or 3.85 percent to 12.5 cents with 1.3 million shares traded.

### ACTINOGEN MEDICAL

Actinogen has requested a trading halt pending an announcement regarding “a potential capital raise”.

Trading will resume on October 15, 2020 or on an earlier announcement.

Actinogen last traded at 2.8 cents.

### INVEX THERAPEUTICS

Invex says its annual general meeting will vote to issue executive director Dr Thomas Duthy 800,000 options exercisable at \$1.30 per option within three years.

Invex said the options, valued at \$312,000, would be an “incentive”, vesting in two equal tranches after 12 months and 24 months with the company.

The company said the meeting would vote to adopt its remuneration report and elect Dr Duthy and David McAuliffe as directors.

The virtual meeting will be held on November 18, 2020 at 3:30pm (AWST) via:

[https://us02web.zoom.us/webinar/register/WN\\_2z0RDi\\_nRxqf2lirQPF4Fg](https://us02web.zoom.us/webinar/register/WN_2z0RDi_nRxqf2lirQPF4Fg).

Invex fell 2.5 cents or 2.5 percent to 97 cents.

### CRESO PHARMA

Creso says it has made cash payments to L1 Capital Global Opportunities Master Fund, Lind Global Macro Fund and Chifley Portfolios to cancel their convertible notes.

Last week, Creso said it expected to raise \$8,992,531 through a placement to repay debt and amounts owed to L1 Capital, Lind and Chifley for outstanding convertible notes, including \$1,802,653 and 29,169,010 collateral shares for L1 Capital, \$222,927 and 21,000,000 collateral shares for Lind and \$325,000 and 2,555,555 collateral shares for Chifley (BD: Oct 7, 2020).

Today, the company said it had been released from its ongoing obligations related to the convertible notes.

Creso said that following the cancellation, it would have 1,666,667 convertible notes on issue held by Suburban Holdings, and it would seek shareholder approval for early redemption of these notes.

Creso fell 0.3 cents or 8.8 percent to 3.1 cents with 57.2 million shares traded.

### RHINOMED

W Whitney George says he has reduced his substantial shareholding in Rhinomed from 105,277,880 shares (41.48%) to 101,777,880 shares (40.10%).

The Darien, Connecticut-based Mr George said that between September 22 and 30, 2020 he sold 3,500,000 shares for \$US364,190 (\$A506,907) or 14.5 cents a share.

Rhinomed was up half a cent or 2.9 percent to 18 cents with 1.7 million shares traded.

## CRESO PHARMA

L1 Capital Global Opportunities Master Fund says it has reduced its holding in Creso from 49,412,496 shares (11.99%) to 43,062,496 shares (10.45%).

In July, the Cayman Islands-based L1 said it had ceased to be substantial in Creso and last week, said it had become substantial again with 49,412,496 shares or 11.99 percent of the company (BD: Jul 15, Oct 7, 2020).

Today, L1 said that it disposed of 6,350,000 shares on October 9, 2020.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says it has appointed Beverley Huttman, Justin Cahill and Dr Catherine Stapledon as executives.

Paradigm said that Ms Huttman would be the head of commercialization, Mr Cahill the chief financial officer and Dr Stapledon the research and development translational scientist.

The company said Ms Huttman had more than 25 years' experience with pharmaceutical companies including CSL and Glaxosmithkline and had previously held senior commercial roles.

Paradigm said Mr Cahill had more than 20 years' experience in strategic finance, including nine years at CSL and five years as CSL Plasma's US divisional chief financial officer.

The company said Dr Stapledon held a Doctor of Philosophy from the University of Adelaide's Centre for Orthopaedic and Trauma Research.

Paradigm fell five cents or 1.7 percent to \$2.95 with 861,181 shares traded.