



# Biotech Daily

Tuesday July 21, 2020

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: IMMUTEP UP 17%; CYNATA DOWN 6%**
- \* **MESOBLAST: US FDA REMESTEMCEL-L PAEDIATRIC GvHD REVIEW**
- \* **TELIX RECEIVES \$11.4m R&D TAX INCENTIVE**
- \* **GENETIC TECHNOLOGIES RAISES \$7.3m**
- \* **BOD RECEIPTS UP 205.1% TO \$3.6m**
- \* **CLARITY, IMAGINAB WORK ON ANTIBODIES FOR CANCER**
- \* **HERAMED EXPANDS MAYO PREGNANCY PLATFORM DEAL**
- \* **G MEDICAL, HOMESTAY DEAL FOR REMOTE PATIENT MONITORING**
- \* **INVEX: EXANATIDE US PATENT FOR INTRACRANIAL PRESSURE**
- \* **IMMURON: 'IMM-124E ANTIVIRAL ACTIVITY AGAINST SARS-COV-2'; UP 250%**
- \* **PRESCIENT: DOHERTY TESTS 2 UNNAMED DRUGS FOR SARS-COV-2**
- \* **RESPIRI: ZIP CO WHEEZO PRICE \$336 OVER 6 MONTHS**
- \* **ZELIRA EGM: 22% DISSENT TO 150% DIRECTORS' FEES HIKE**
- \* **NEUROSCIENTIFIC TO RELEASE 19.3m ESCROW SHARES**
- \* **EVERBEST, CONSTELLATION TAKE LOSS, BELOW 5% IN ANTERIS (ADMEDUS)**

## MARKET REPORT

The Australian stock market was up 2.58 percent on Tuesday July 21, 2020, with the ASX200 up 154.7 points to 6,156.3 points. Twenty-seven of the Biotech Daily Top 40 stocks were up, eight fell and five traded unchanged. All three Big Caps were up.

Immutep was the best, up three cents or 16.7 percent to 21 cents, with 8.2 million shares traded. Prescient climbed 15.5 percent; Mesoblast was up 10.45 percent; Avita rose 8.25 percent; Patrys was up 7.7 percent; Orthocell, Polynovo and Starpharma were up more than six percent; Cochlear, Kazia, Paradigm and Pro Medicus improved more than five percent; Actinogen, Clinuvel, Next Science and Volpara were up four percent or more; CSL, Genetic Signatures and Resmed rose three percent or more; Alterity, Dimerix, Impedimed, Medical Developments, Nanosonics, Optiscan, Pharmaxis and Universal Biosensors climbed more than two percent; Neuren and Telix were up more than one percent; with Cyclopharm up 0.7 percent.

Cynata led the falls, down 4.5 cents or 6.1 percent to 69.5 cents, with 743,576 shares traded. Both Amplia and Proteomics lost 5.9 percent; both Antisense and Imugene fell 4.55 percent; with Nova (Ellex), Osprey and Uscom down more than two percent.

## MESOBLAST

Mesoblast says the US Food and Drug Administration has scheduled an August 13 meeting to review remestemcel-L data for graft-versus-host disease in children.

Mesoblast said the FDA would review the data for the biologics licence application for remestemcel-L, or Ryoncil, for steroid-refractory acute graft versus host disease in children, a potentially life-threatening complication of allogeneic bone marrow transplant for blood cancer.

The company said the Prescription Drug User Fee Act (Pdufa) action date was September 30, 2020.

Mesoblast said the FDA's Oncologic Drugs Advisory Committee review would include a morning session to discuss characterization and critical quality attributes and an afternoon session to discuss results from clinical trials.

The company said that although the FDA would consider the recommendation of the panel, the final decision regarding the approval of the product is made by the FDA solely, and the recommendations by the panel are non-binding.

Mesoblast was up 35 cents or 10.45 percent to \$3.70 with 8.8 million shares traded.

## TELIX PHARMACEUTICALS

Telix says it has received \$11.4 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Telix said the rebate related to research and development for the year to December 31, 2019.

Telix was up 1.5 cents or 1.1 percent to \$1.33.

## GENETIC TECHNOLOGIES

Genetic Technologies says it has raised \$US5.1 million (\$A7.3 million) in a placement of American depository shares (ADS) at \$US5.00 each (BD: Jul 17, 2020).

Genetic Technologies said each ADS represented 600 Australia shares at 1.2 cents each.

In April, the company said it had raised \$US3.22 million in two separate placements of ADSs at \$US2.00 and \$US1.75 each (BD: Apr 2, 6, 21, 2020)

In May, the company said it would raise \$US8 million (\$A12.05 million) through the issue of 4,000,000 ADSs at \$US2.00 each (BD: May 27, 2020).

Today, Genetic Technologies said it would use the funds for distribute products in the US, for general research and development, preparation for its Covid-19 severity risk test, potential acquisitions and working capital.

Genetic Technologies fell 0.2 cents or 16.7 percent to one cent with 50.9 million shares traded.

## BOD AUSTRALIA

Bod says receipts from customers for the year to June 30, 2020 were up 205.1 percent to \$3,634,000 compared to the previous corresponding period.

Bod said receipts for the three months to June 30, 2020 rose 1,166.8 percent to \$2,331,000, with the increase due to cannabidiol products sales in the UK, hemp based Swisse Wellness products in Australia and Medicabilis sales in Australia and the UK.

Bod said it had cash and cash equivalents of \$6,386,000 at June 30, 2020 compared to \$2,837,000 at June 30, 2019 and it had an estimated nine quarters of cash.

Bod was up one cent or 3.85 percent to 27 cents.

## CLARITY PHARMACEUTICALS

Clarity says it will work with the Ingelwood, California-based Imaginab Inc to develop targeted diagnostic and therapeutic products for cancers.

Clarity said the companies would combine Imaginab's expertise at designing antibodies called "minibodies" and "cys-diabodies" for its radio-pharmaceutical products, "to ensure rapid and highly specific targeting of tumors" using positron emission tomography (PET), and its copper chelator technology.

Clarity executive chairman Dr Alan Taylor said this would "allow us to fully exploit the perfect pairing of copper-64 for diagnosis and copper-67 for therapy".

Clarity is a public unlisted company.

## HERAMED

Heramed says it has expanded its Mayo Clinic collaboration agreement to develop its Heracare pregnancy management platform.

Last year, Heramed said it would partner with the Rochester, Minnesota-based Mayo Clinic for a platform to improve at-home pregnancy care, based on Mayo's OB Nest project (BD: Sep 17, 2019).

Today, the company said the Heracare platform would include its Herabeat smart pregnancy monitor for home use, additional medical connected devices for blood pressure and weight, Mayo's educational content and a smart, task-based application for pregnant mothers and care providers.

Heramed said Mayo would provide \$US100,000 (\$A142,430) for 1,581,538 shares within 30 days to fund the project.

The company said it would issue Mayo 1,186,153 shares to the value of \$107,940 within 30 days and 1,186,153 shares or \$107,940 on completion of the Heracare pilot and acceptance of proof-of-concept by Mayo.

Heramed said it would issue Mayo a further 1,581,538 performance options or \$143,920 upon US Food and Drug Administration clearance for Herabeat Plus for home care and 1,581,538 performance options or \$143,920 on the commercial launch of the Heracare platform and following first revenues.

The company said it would also pay Mayo a four percent royalty on net sales if the product was developed in collaboration with Mayo and a two percent royalty if the collaboration was based on Mayo's know-how or licenced content.

Heramed fell 0.1 cents or 1.1 percent to 8.8 cents with 1.5 million shares traded.

## G MEDICAL INNOVATIONS HOLDINGS

G Medical says it has expanded its Homestay Care Technology Group agreement to introduce 24-hour remote patient monitoring in Australia and New Zealand.

In April, G Medical said Perth's Homestay Care would distribute its Prizma vital signs smart phone application in Australia and New Zealand through its Uvue telehealth platform for nursing home patients (BD: Apr 22, 2020).

Today, the company said it would implement its independent diagnostic facilities testing (IDTF) type infrastructure and remote monitoring, which could be utilised by hospitals, health insurance companies and independent practice organisations for transitional care programs to allow patients to return home earlier.

G Medical said patients enrolled would be charged a subscription fee of between \$19 and \$35 a month, shared between the company, Homestay and third-party providers.

G Medical was up 0.6 cents or 11.3 percent to 5.9 cents with 3.3 million shares traded.

## INVEX THERAPEUTICS

Invex says a US patent has been allowed for glucagon-like peptide-1 (GLP-1) receptor agonists, including Exenatide, as a treatment for elevated intracranial pressure.

Invex said the patent, titled 'Elevated Intracranial Pressure Treatment', would protect its intellectual property until August 2035.

Invex was up 3.5 cents or 3.2 percent to \$1.14.

## IMMURON

Immuron jumped 250 percent on news that IMM-124E showed antiviral activity against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Immuron said that Melbourne's 360 Biolabs used a cytopathic effect inhibition assay to measure virus replication and in-vitro susceptibility of the virus to four production lots of IMM-124E compared to a high protein milk powder placebo.

The company said it used the Sars-Cov-2 virus obtained by Melbourne's Peter Doherty Institute for Infection and Immunity to target Sars-Cov-2 in the gastrointestinal tract.

Immuron said no toxicity was observed and all four production lots inhibited virus replication by 50 percent at concentrations of between 40.5 micrograms per millilitre ( $\mu$ /mL) and 91.9 $\mu$ /mL, and by 90 percent at between 48.7 $\mu$ /mL and 155.4 $\mu$ /mL.

The company said that in comparison, the placebo inhibited viral replication at more than 25,000 $\mu$ /mL, and did not inhibit viral replication at doses at which it was cytotoxic to cells.

Immuron said cell viability in the presence of IMM-124E was greatly enhanced by between 180 and 260 percent compared to the placebo.

The company said that the possibility of producing a hyper-immune bovine colostrum for Sars-Cov-2 was quite high, but the prevalence of digestive system involvement in Covid-19 patients remained largely unknown.

Immuron chief executive officer Dr Jerry Kanellos said that Sars-CoV-2 caused an influenza-like disease that was primarily thought to infect the lungs with transmission through the respiratory route ranging from mild respiratory symptoms to severe lung injury, multi-organ failure, and death.

"Respiratory symptoms have dominated the clinical focus, however gastrointestinal symptoms such as diarrhoea, vomiting and abdominal pain are also observed in a growing subset of patients often presenting with no respiratory symptoms," Dr Kanellos said.

He said the US Centers for Disease Control and Prevention recently updated the symptoms of coronavirus to include diarrhoea and there was evidence suggesting that the gastro-intestinal tract might be another viral target organ.

"The virus RNA has been detected in anal swabs of patients even after naso-pharyngeal testing has turned negative and cells in the inner-gut lining express high amounts of the angiotensin-converting enzyme 2 (ACE2) receptor that Sars-Cov-2 uses to gain entry to cells implying the potential for gastrointestinal infection and a faecal-oral transmission route," Dr Kanellos said.

"If faecal-oral transmission is a significant factor in the pandemic then the consequences for an oral therapeutic would be significant, however the research is still inconclusive," Dr Kanellos said.

"The preliminary data set we have generated potentially offers a new oral therapeutic approach to target and directly inhibit the virus in the gastro-intestinal tract and warrants further evaluation to identify the inhibitory substances in our products," Dr Kanellos said. Immuron said it had filed a provisional patent application.

Immuron was up 61 cents or 249.0 percent to 85.5 cents with 63.8 million shares traded.

## PRESCIENT THERAPEUTICS

Prescient says two unnamed drug candidates have been “selected” by the Peter Doherty Institute for severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Prescient said the candidates would be included in the Doherty Institute’s Sars-Cov-2 antiviral drugs program as “group 1 priority candidates” with the “highest or strong likelihood of anti-viral efficacy”.

The company said they were selected based on detailed review of available existing data and additional pre-clinical data.

A Prescient spokesperson said the drug candidates would remain unnamed “on the advice of patent attorneys to maximize the establishment of adequate patent protection”.

In May, Prescient said it licenced an immune receptor platform from the University of Pennsylvania and a related molecular binding system Oxford University to recognize and kill cancer cells hidden from the patient’s immune system and it has an ongoing phase Ib study of PTX-100 for cancer (BD: Apr 22, May 26, 2020).

Today, Prescient said it would pay \$70,000 for the testing of both candidates, including in-vitro testing and a potential in-vivo study in “small animals”, with results in September and October 2020.

Prescient was up 0.9 cents or 15.5 percent to 6.7 cents with 34.8 million shares traded.

## RESPIRI

Respiri says Zip Co customers will pay \$14 per week for six months or \$336 compared to \$347 for the \$299 upfront and \$8 monthly charge for its Wheezo asthma monitor.

Yesterday, Respiri said it had a merchant services agreement with Zip Co subsidiary and buy-now-pay-later provider Zip Money Payments Pty Ltd to provide financial flexibility to Wheezo asthmatic patients (BD: Jul 20, 2020).

Respiri was unchanged at 15 cents with 6.7 million shares traded.

## ZELIRA THERAPEUTICS

Zelira says all extraordinary general meeting resolutions were carried, but with 21.8 percent opposition to a 150 percent increase to its directors’ fees pool.

Zelira said there were 24,360,317 votes (78.2%) in favour of the increase or directors’ fees from \$300,000 to \$750,000 per year with 6,786,453 votes (21.8%) opposed.

The company said all other resolutions were carried more easily.

According to Zelira’s most recent Appendix 2A application for quotation of securities, the company had 972,528,406 shares on issue, meaning the 6,787,453 votes opposed to the director’s remuneration increase amounted to 0.7 percent of the company, not sufficient to requisition extraordinary general meetings.

Zelira was untraded at 5.3 cents.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it will release 19,349,506 shares, 36,000,000 options, expiring March 7, 2021, and 2,800,000 performance shares from ASX escrow on July 27, 2020.

Neuroscientific’s most recent Appendix 3B new issue announcement said that it had 59,035,078 shares on issue, meaning that following the release it would have 78,384,584 shares available for trading.

Neuroscientific fell one cent or 4.55 percent to 21 cents.

### [ANTERIS TECHNOLOGIES \(FORMERLY ADMEDUS\)](#)

Constellation Immunotherapy, Everbest City and Fung Yuen Wong (Everbest Group) say they have ceased to be substantial shareholders in Anteris.

Yesterday, the Group said it had become substantial shareholders in Anteris with 326,951 shares or 5.53 percent, buying the shares for \$HK10,000,000 (\$A1,845,728) or \$5.65 a share.

Today, Constellation, Everbest and Mr Wong said they had sold 32,648 shares for \$140,869 or \$4.315 a share.

Last week, Hong Kong's Star Bright, with Constellation, said it had reduced its substantial holding in Anteris from 1,277,155 shares (21.61%) to 730,192 shares or 12.35 percent (BD: Jul 17, 2020).

Anteris fell one cent or 0.3 percent to \$3.80.