

Biotech Daily

Wednesday March 3, 2021

Daily news on ASX-listed biotechnology companies

* ASX UP, BIOTECH DOWN: AVITA UP 12%; ANTISENSE DOWN 11%

- * DOHERTY: 'RAPID SARS-COV-2 TESTS NEED PCR CONFIRMATION'
- * ORTHOCELL CELGRO APPROVED FOR ARTG PROSTHESES LIST
- * STARPHARMA: ANTIMICROBIAL SPL7013 'KILLS CORONAVIRUSES'
- * GENETIC TECHNOLOGIES \$3.7m INFINITY US COVID RISK TEST DEAL
- * MGC: SWISS PHARMACAN ARTEMIC ORDER INCREASE TO \$425k
- * DR DEXTER CHEUNG REPLACES TRUSCREEN'S CHRIS LAWRENCE

MARKET REPORT

The Australian stock market was up 0.82 percent on Wednesday March 3, 2021, with the ASX200 up 55.7 points to 6,818.0 points.

Eleven of the Biotech Daily Top 40 stocks were up, 19 fell and 10 traded unchanged. All three Big Caps were down.

Avita was the best, up 71 cents or 12.3 percent to \$6.47, with 1.6 million shares traded.

Paradigm climbed 7.9 percent; Osprey was up 5.9 percent; Actinogen improved 4.55 percent; LBT was up 3.1 percent; Pharmaxis and Resonance rose more than two percent; Mesoblast, Nova Eye and Orthocell were up one percent or more; with Neuren up by 0.8 percent.

Antisense led the falls, down two cents or 11.1 percent to 16 cents, with 3.6 million shares traded.

Impedimed lost 8.3 percent; Amplia was down 7.7 percent; Immutep and Optiscan fell more than four percent; Cochlear, Genetic Signatures and Prescient were down more than three percent; Alterity, Clinuvel, Dimerix and Medical Developments shed more than two percent; CSL, Cyclopharm, Nanosonics, Pro Medicus, Resmed, Universal Biosensors and Volpara were down more than one percent; with Next Science, Polynovo and Telix down by less than one percent.

DOHERTY INSTITUTE, ROYAL MELBOURNE HOSPITAL

The Doherty says that rapid "Covid-19" antigen tests are best used for hospital triaging with confirmatory polymerase chain reaction tests in low-Covid-19 prevalence countries. The Doherty Institute said that researchers at the Royal Melbourne Hospital, Austin Health and Monash Health studied the performance and feasibility of rapid severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen tests compared to polymerase chain reaction (PRC) tests to detect Covid-19 in countries with a low Covid-19 prevalence. The Institute said that antigen tests rapidly detected the viral protein of Sars-Cov-2, the virus that caused Covid-19, directly from clinical samples, while PCR tests detected the viral RNA of Sars-Cov-2 "making them significantly more sensitive".

The Doherty said that antigen tests, including the Abbott Panbio Sars-Cov-2 antigen test, had 99.96 percent specificity with sensitivity rates varying based on Covid-19 symptoms. The Institute said the 2,413-patient study, titled 'Multi-site assessment of rapid, point-ofcare antigen testing for the diagnosis of Sars-Cov-2 infection in a low-prevalence setting: A validation and implementation study' was published in the Lancet regional Health -Western Pacific journal and the full text of the article was available at

https://www.thelancet.com/journals/lanwpc/article/PIIS2666-6065(21)00024-9/fulltext.

The article said that the specificity of the Abbott PanBio Covid-19 antigen test was 99.96 percent with sensitivity among participants with RT-PCR-confirmed infection "dependent upon the duration of symptoms reported, ranging from 77.3 percent (duration 1 to 33 days) to 100 percent in those within seven days of symptom onset".

The article said that a range of implementation challenges were identified which might inform future Covid-19 testing strategies in a low prevalence setting.

Co-lead author of the study Prof Deborah Williamson said that the antigen tests performed best in the first few days after symptom onset and the tests had shown utility in settings with a high-prevalence of Covid-19, such as the UK or the US.

"Given the high specificity, antigen-based tests may be most useful in rapidly triaging public health and hospital resources while expediting confirmatory PCR testing," Prof Williamson said.

"But considering the limitations in test sensitivity and the potential for rapid transmission in susceptible populations, particularly in hospital settings, careful consideration is required for implementation of antigen testing in a low prevalence setting," Prof Williamson said.

ORTHOCELL

Orthocell says its collagen-based Celgro Dental, or Striate+, for tissue repair has been included on the Australian Register of Therapeutic Goods Prostheses List.

Orthocell said inclusion on the Prostheses List enabled dental practitioners to receive reimbursement from private insurers for use of Celgro Dental in approved dental bone and soft tissue repair procedures, reducing costs to the patient.

Last year, the company said the Therapeutic Goods Administration approved the sale of Celgro (BD: Dec 17, 2020; Jan 17, 2021).

Last month, Orthocell said a Federal advisory committee recommended Celgro's inclusion on the Australian Register of Therapeutic Goods Prostheses List (BD: Feb 5, 2020).

Today, Orthocell managing-director Paul Anderson said that the "inclusion of Celgro Dental on the Prostheses List is the culmination of translational research and a regulatory program to bring this product to the Australian market".

"I am delighted that patients now have access to a premium dental membrane product designed, manufactured and reimbursed in Australia," Mr Anderson said.

Orthocell was up half a cent or 0.98 percent to 51.5 cents.

STARPHARMA

Starpharma says its SPL7013, recently launched as the Viraleze nasal spray, has shown anti-viral activity "against other pandemic coronaviruses".

Last month, Starpharma said Viraleze had been registered for sale in Europe and the UK and laboratory studies had shown it could "inactivate a broad spectrum of respiratory viruses, including more than 99.9 percent of [severe acute respiratory syndrome coronavirus-2] ... the virus that causes Covid-19" (BD: Feb 23, 2021).

Today, the company said testing at the La Jolla, California-based Scripps Research Institute confirmed that SPL7013 blocked the spike proteins of severe acute respiratory syndrome coronavirus (Sars-Cov) and the Middle East respiratory syndrome coronavirus (Mers-Cov) or Mers, both of which caused significant mortality and did not have a vaccine. Starpharma said that SPL7013 reduced the number of cells infected with either Sars-Cov-2, Sars or Mers by about 80 percent, compared to infected cells left untreated.

Starpharma chief executive officer Dr Jackie Fairley said that "the increasingly broad spectrum of antiviral activity for SPL7013, including against Sars, Mers and influenza virus [subtypes] ... adds to the appeal for Viraleze [and] given this, the product also has the benefit of likely utility in future viral pandemics".

The company said its anti-microbial SPL7013 was the active ingredient in Vivagel BV for bacterial vaginosis and its Vivagel condom coatings.

Starpharma was unchanged at \$2.10 with 1.1 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it has a minimum \$US2.9 million (\$A3.7 million) three-year distribution agreement with Infinity Biologix LLC for its Covid-19 Risk Test in the US. Genetic Technologies said the test might enable the risk assessment of an individual developing a serious disease should they contract the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

The company said the test was intended to predict disease severity using a combination of genetic and clinical information and it was in the "final stages to submit the Covid-19 Risk Test for clearance under the 1988 US Federal standards for clinical laboratories, known as Clinical Laboratory Improvement Amendments (CLIA).

Genetic Technologies said that the Piscataway New Jersey-based Infinity Biologix, formerly Rutgers University Infinity, was a leading laboratory providing sample collection and processing, storage, analytical services, and scientific and technical support. The company said it would receive an initial upfront payment of \$US50,000 followed by minimum payments of \$US850,000 in the first year and \$US1.0 million in each of the second and third years.

Genetic Technologies said that Infinity had the capacity to process more than 100,000 Covid-19 Risk Tests a day at its two major labs, with underlying royalty structure based on \$US10 a unit, with Infinity deciding the sales and end-to-consumer pricing.

Genetic Technologies chief executive officer Simon Morriss said the agreement was "a significant milestone ... representing the first multi-year commercial agreement the company has entered into for the sale and distribution of one of its developed products".

"Our Covid-19 Risk Test is designed to provide individuals with the ability to understand their personal risk associated with contracting a serious case of this disease," Mr Morriss said. "Alongside existing treatment options and vaccines, we believe this test will enable more insightful decisions for states, workplaces and individuals on pathways forward in managing this pandemic."

Genetic Technologies was up 0.1 cents or 1.4 percent to 7.1 cents.

MGC PHARMACEUTICALS

MGC says Swiss Pharmacan AG has increased the value of its initial purchase order of food additive Artemic Rescue by about 85 percent to \$425,000.

Last month, MGC Pharma said it had a three-year agreement with the Niederrohrdorf, Switzerland-based Swiss Pharmacan for the sale and distribution of its anti-inflammatory Artemic product line in Germany (BD: Feb 18, 2021).

Today, the company said the Artemisinin, Curcumin, Boswellia serrata, and Vitamin Cbased Artemic was safe and could prevent the deterioration of Covid-19 patients and achieve faster clinical improvement, based on a 50-patient phase II clinical trial (BD: Dec 15, 2020).

MGC was unchanged at eight cents with 18.5 million shares traded.

TRUSCREEN GROUP (FORMERLY POLARTECHNICS)

Trusceen says it has appointed Dr Dexter Cheung to replace Chris Lawrence as a director, with Mr Lawrence retiring from the board for health reasons.

Last year, the Auckland-based Truscreen said it hoped to raise up-to \$NZ2 million (\$A1.86 million) to dual-list on the ASX for its cervical cancer test (BD: Nov 9, 2020).

Today, the company said Dr Cheung had more than 20 years' experience in medical device research and development and was currently the research and development manager of the respiratory humidification division of Fisher & Paykel Healthcare.

Truscreen said Dr Cheung held a Bachelor of Technology, a Master of Engineering and a Doctor of Philosophy from New Zealand's University of Auckland.

On the NZX, Truscreen was unchanged at 10.5 NZ cents (9.8 Australian cents) with 357,562 shares traded.