

Biotech Daily

Monday May 25, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: IMPEDIMED UP 28%; IMUGENE DOWN 6%
- * UNISEED \$3.5m FOR FERRONOVA CANCER DETECTION
- * EXOPHARM: 'PLEXARIS IMPROVES ANTI-CANCER DRUG IN-VITRO'
- * CORRECTION: INVEX
- * MESOBLAST: 3 TRIALS SUPPORT RYONCIL (REMSTEMCEL-L) FOR GvHD
- * MEDICAL DEVELOPMENTS: HUNGARY APPROVES PENTHROX FOR PAIN
- * RESONANCE FILES PROVISIONAL PATENT FOR LIVER DISEASE
- * NYRADA: 'COMPOUNDS REACH MOUSE BRAIN, BLOCK CALCIUM BUILD-UP'
- * GOODBYE ADMEDUS, HELLO ANTERIS
- * PROTEOMICS RECEIVES \$200k FOR COVID-19 RESEARCH
- * AEROFLOW HIRES REGIONAL HEALTH FOR OVENTUS 02VENT
- * BLACKCRANE REDUCES TO 6% OF AVITA
- * CARESTREAM BELOW 5% IN MICRO-X
- * ANTEOTECH PROGRESSES SILICON LITHIUM BATTERIES
- * PRESCIENT TAKES 'MATERIAL LICENCE' TRADING HALT TO SUSPENSION
- * CANN GLOBAL EXTENDS 'RESEARCH INITIATIVES' SUSPENSION

MARKET REPORT

The Australian stock market climbed 2.16 percent on Monday May 25, 2020, with the ASX200 up 118.6 points to 5,615.6 points. Twenty-six Biotech Daily Top 40 stocks were up, eight fell, four traded unchanged and two were untraded. All three Big Caps were up.

Impedimed was the best, again on no news, up 1.7 cents or 27.9 percent to 7.8 cents, with 14.4 million shares traded. Osprey climbed 20 percent; Universal Biosensors was up 18.4 percent; Dimerix improved 11.8 percent; Medical Developments and Volpara rose more than eight percent; Pharmaxis was up 6.7 percent; Avita, Kazia, Opthea and Resonance rose five percent or more; Nanosonics and Proteomics climbed more than four percent; Antisense; Immutep; LBT, Next Science, Polynovo and Resmed were up three percent or more; Clinuvel, Cochlear, CSL, Ellex, Paradigm, Pro Medicus and Starpharma rose more than two percent; with Compumedics up one percent.

Imugene led the falls, down 0.2 cents or 5.9 percent to 3.2 cents, with 26.2 million shares traded. Actinogen, Alterity and Orthocell fell five percent or more; Oncosil lost 4.8 percent; Telix shed 1.4 percent; with Cyclopharm and Mesoblast down by less than one percent.

FERRONOVA PTY LTD, UNISEED

Adelaide's Ferronova says Uniseed has led a \$3.5 million raising to fund clinical trials of its nanoparticles for the detection of secondary cancer during surgery.

Ferronova chief executive officer Stewart Bartlett told Biotech Daily that the Ferronova nanoparticles attached to tumor antibodies which were illuminated when viewed through magnetic resonance imaging before surgery and infra-red cameras during surgery. In the announcement, Mr Bartlett said that "up to 27 percent of colorectal cancer patients have undetected micro tumors or isolated cancer cells in lymph nodes which leads to higher mortality rates".

"This results in 20 percent of those patients having cancer recurrence within five years [and] Ferronova's mission is to provide the tools to solve this problem," Mr Bartlett said. The company said that Artesian Venture Partners and the South Australian Venture Capital Fund invested in the series A financing and the University of Sydney become a shareholder as part of a licencing agreement.

Uniseed chief executive officer Dr Peter Devine said Ferronova had "the potential to move the dial in treatment for early stage cancer patients and improving patient outcomes". Ferronova said it was a spin out from the University of South Australia and New Zealand's Victoria University, established in 2016 with seed funding from Powerhouse Ventures. Ferronova is a private company.

EXOPHARM

Exopharm says its Plexaris exosome combined with anti-cancer drug doxorubicin "significantly" kills more lung cancer cells than the drug by itself in-vitro.

Exopharm said doxorubicin was used in chemotherapy, but caused adverse events, including myelo-suppression, cardio-toxicity, alopecia, nausea and vomiting, with dose levels often limited by the adverse patient response.

The company said the platelet-derived Plexaris in combination with doxorubicin, and called "Plexodox" could increase the ability of doxorubicin to kill cancer cells with a lower dose, while reducing the unwanted side-effects and increasing the therapeutic window. In a graph, Exosome said that Plexodox with an average loading of 0.7 micro-moles (μ M) killed more than 60 percent of lung cancer cells after 72 hours whilst doxorubicin on its own at 0.625 μ M killed about 30 percent of lung cancer cells after 72 hours, which was measured as a statistically significant difference (p < 0.05).

Exopharm chief commercial officer Dr Chris Baldwin said that "cancer patients are commonly transfused with platelets to counteract side-effects from chemotherapy already, so we know that allogeneic platelets are not only safe, but therapeutic".

"Our approach is, rather than treat the patient for side effects, let's use platelet [extracellular vesicles] to get doxorubicin where it belongs," Dr Baldwin said. Exopharm was up four cents or 18.2 percent to 26 cents with 1.4 million shares traded.

CORRECTION: INVEX THERAPEUTICS

Friday's edition incorrectly confused Forrest Capital with Andrew Forrest's Tattarang, formerly known as Minderoo Pty Ltd.

Despite the common name, the two groups are unrelated.

Biotech Daily apologises unreservedly for the error.

The fact-checking sub-editor has been reassigned to the Federal Treasury to assist with their add-ups and subtractions.

Invex fell 17.5 cents or 10.5 percent to \$1.49 with 697,868 shares traded.

MESOBLAST

Mesoblast says three separate trials support the use of its allogeneic mesenchymal stem cell drug Ryoncil in children and adults with acute graft versus host disease.

Mesoblast chief medical officer Dr Fred Grossman said the "results from these three trials show a consistent pattern of safety and efficacy for Ryoncil, [previously] remestemcel-L, in patients with the greatest levels of inflammation and the most severe grades of acute [graft versus host disease]".

"These clinical outcomes provide a compelling rationale for use of remestemcel-L in children and adults with other conditions associated with severe inflammation and cytokine release, including acute respiratory distress syndrome (Ards) and systemic vascular manifestations of Covid-19 infection," Dr Grossman said.

The company said that the results of the trial were presented in peer reviewed articles published in 'Biology of Blood and Marrow Transplantation,' with an editorial of the three trials, titled 'Mesenchymal Stromal Cells for GVHD: A Trilogy', available at: https://www.bbmt.org/article/S1083-8791(20)30109-9/fulltext.

Mesoblast said that in all three trials patients received Ryoncil twice weekly for four weeks through intravenous infusions of 2,000,000 cells per/kg, and "Ryoncil was well-tolerated in all studies with no identified safety concerns".

The company said that one trial, through the expanded access program, enrolled 241 children with GVHD who failed to respond to steroid therapy and saw an overall response in 65 percent of patients at day-28.

The article is at: https://www.bbmt.org/article/S1083-8791(20)30059-8/fulltext.

Mesoblast said the second trial was a phase III, single-arm trial in 55 children who failed to respond to steroids for acute graft versus host disease, across 20 centres in the US, and had a 70 percent overall response rate at day-28.

The article is at https://www.bbmt.org/article/S1083-8791(20)30051-3/fulltext.

The company said the third trial was a phase III, randomized, placebo-controlled trial of 260 patients, including 28 children, across 72 centres in seven countries where Ryoncil or placebo were added to second line therapy in patients with steroid-refractory acute GVHD who failed to respond to steroid treatment.

Mesoblast said that at day-28, high risk patients treated with Ryoncil had a 58 percent overall response rate compared to a 37 percent rate in the placebo group (p = 0.03), with no significant benefit of Ryoncil in standard risk patients, but a 64 percent overall response in paediatric patients treated with Ryoncil, compared to 36 percent in the placebo group (p=0.05).

The article is available at https://www.bbmt.org/article/S1083-8791(19)30573-7/fulltext. Mesoblast fell one cent or 0.3 percent to \$3.68 with 5.5 million shares traded.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says Hungary has approved the sale of Penthrox for emergency relief of moderate to severe pain.

Earlier this month, Medical Development said it had been approved for sale in the Netherlands and Bosnia and Herzegovina, with the approval process in the Netherlands part of a set of four countries, including Greece, Hungary and Malta (BD: May 5, 2020). Today, the company said approvals in Greece and Malta were "expected soon".

Medical Developments said it was yet to achieve government reimbursement in Hungary but could begin sales to the private sector.

Medical Developments rose 65 cents or 8.3 percent to \$8.46 with 375,918 shares traded.

RESONANCE HEALTH

Resonance says it has filed a provisional patent covering the application of novel antisense oligonucleotides to treat liver related disease.

Resonance said the patent was titled 'Method for Treating Liver Related Disease', but did not say where it filed the patent or the expected duration.

The company said antisense oligonucleotides targeted particular human proteins essential to the lifecycle of some human viruses.

Resonance said that in the liver, this particular protein supported the infectivity, growth and maturation of hepatitis-B virus, hepatitis-C virus and HIV.

The company said that in laboratory testing, its antisense oligonucleotides were shown "to significantly reduce the expression of this host protein in liver hepatocellular carcinoma HepG2 cells, a model cell-line commonly used in liver research".

Resonance was up one cent or 5.9 percent to 18 cents.

NYRADA INC

Nyrada says its NYX-242 and NYX-1010 compounds can cross the blood-brain-barrier in mouse brains and block calcium ion build-up in cells.

Nyrada said that in a pre-clinical pharmacokinetic study, therapeutic concentrations of both NYX-242 and NYX-1010 were detected in the uninjured animal brain 30 minutes following a single intravenous dose of 4.2mg/kg in three mice, demonstrating that "both drugs readily cross the intact blood-brain-barrier".

In a graph, the company showed that both compounds blocked calcium ion build-up by 50 percent, 30 minutes after intravenous dosing, with NYX-242 blocking 50 percent of build-up with a dosage of about 1,300 nanogram/millilitre (ng/mL) and NYX-1010 with a dosage of less than 200ng/mL.

Nyrada said that many drugs relied on the compromised blood-brain-barrier to enter the brain, which occurred in severe traumatic brain injury and stroke, but fail to show efficacy in milder forms of brain injury such as concussion, where the blood-brain-barrier was not as greatly compromised.

The company said its compounds did not rely on the breakdown of the blood brain barrier, providing an advantage, and the compounds could be used for treatment of the full spectrum of traumatic brain injury severity, including concussion.

Nyrada chief executive officer James Bonnar said that "having two potent drug candidates that act on distinctly different targets to limit toxic calcium ion build-up in brain cells is a huge achievement."

"It provides a solid scientific foundation and greatly de-risks the Brain Injury program," Mr Bonnar said.

"Nyrada is well positioned to becoming a leader in the field of brain injury drug development," Mr Bonnar said.

Nyrada was up one cent or 6.25 percent to 17 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Anteris says it has changed its name to from Admedus to Anteris Technologies and will trade on the ASX under the code AVR, effective from May 22, 2020.

Anteris said the name change was approved by shareholders at its annual general meeting on May 15, 2020.

Anteris fell four cents or 0.6 percent to \$7.06.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has received \$200,000 to develop a diagnostic for Sars-Cov-2 and to isolate biomarkers to understand Covid-19 disease progression.

Proteomics said the \$200,000 was awarded under the Western Australian Covid-19 Research Grants Program.

The company said the diagnostic would be a saliva-based, rapid, non-invasive immunoassay-based test for direct detection of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2).

Proteomics said that as part of this grant for the diagnostic program it would collaborate with the Perth's Heart and Lung Research Institute of Western Australia on a separate program for serology testing to identify whether people had been exposed to the virus by seeing if they have developed antibodies against it.

The company said the second portion of the grant was for the development of a protein biomarker to understand susceptibility and response to Covid-19, which would be undertaken in collaboration with respiratory physicians at Perth's University of Western Australia Medical School.

Proteomics said the research would analyze blood samples from patients at diagnosis to identify whether there were biomarkers in mild Covid-19 patients that were protective in the individual and determine if there were biomarkers that predicted a severe or critical infection.

The company said it expected the research "to be completed over the next eight to 12 months".

Proteomics was up 1.5 cents or 4.55 percent to 34.5 cents.

OVENTUS MEDICAL

Oventus says Aeroflow Healthcare has sub-contracted Regional Health Diagnostics to provide the Oventus sleep treatment platform lab-in-lab model in the US.

Previously, Oventus said the 'lab-in-lab' model used a scanner to measure the patient's mouth size for a custom-fit for the O2Vent (BD: Jun 24, 2019).

In February, the company said the Asheville, North Carolina-based Aeroflow had begun to sell its products for obstructive sleep apnoea, including the O2Vent, and would offer Oventus products under sub-contracts with regional US sleep groups (BD: Feb 24, 2020). Today, Oventus said that Regional Health operated 12 sleep laboratories in Tennessee, Georgia, Alabama, North Carolina and South Carolina, and would offer lab-in-lab services at two of its Tennessee locations, where the state was "in the process of lifting orders governing sheltering from Covid-19".

Oventus said Regional Health would provide the O2Vent to at least 20 patients at each site every month for minimum term of three years, with an automatic three-year renewal. Oventus was up one cent or 3.9 percent to 26.5 cents.

AVITA MEDICAL

Blackcrane Capital says it has reduced its substantial holding in Avita from the equivalent of 165,187,032 shares (7.80%) to 126,193,878 shares (5.92%).

The Bellevue, Washington-based Blackcrane said it bought and sold shares between February 14 and May 21, 2020, with the single largest sale on May 21 of 9,797,940 shares for \$4,438,467 or 45.3 cents a share and the single largest purchase on March 11 of the equivalent of 4,873,480 shares for \$US1,490,141 or 46.8 Australian cents a share. Avita was up 2.5 cents or 5.7 percent to 46.5 cents with 13.0 million shares traded.

MICRO-X

New York's Carestream Health Inc says it has ceased its substantial shareholding in Micro-X, following a dilution of its 9,405,000 shares.

In April and May, Micro-X said it raised \$8.75 million in a placement and \$1,8 million in an underwritten, one-for-5.6 rights offer at 14 cents a share, and it expected to raise a further \$4.45 million in the shortfall placement (BD: Apr 17, May 11, 2020).

According to the most recent Micro-X Appendix 2A application for quotation of securities, the company had 357,167,839 shares on issue and Biotech Daily calculates that Carestream's 9,405,000 shares represented 2.63 percent of the company.

Micro-X was up one cent or 7.4 percent to 14.5 cents with 2.2 million shares traded.

ANTEOTECH (FORMERLY ANTEO DIAGNOSTICS)

Anteotech says will combine its silicon composite and cross-linker additive anode design to enhance its lithium ion battery program.

Anteotech said it had improved the storage capacity of its silicon composite, and was working on its porosity to absorb expansion and developing its surface coating to improve stability.

The company said the cross-linker additive for use with water-based binders was effective and was working towards external validation and optimization.

Anteotech said it was curating a collaborative network of partners to support the combination of the silicon composite and the cross-linker additive to develop the anode and improve the battery.

The company also produces a range of molecular binders for laboratory use. Anteotech fell 0.1 cents or four percent to 2.4 cents with 10.8 million shares traded.

PRESCIENT THERAPEUTICS

Prescient has requested a voluntary suspension to follow the trading halt requested last week "regarding a material licence agreement" (BD: May 21, 2020).

Trading will resume on May 26, 2020 or on an earlier announcement.

Prescient last traded at 4.5 cents.

CANN GLOBAL

Cann Global has requested an extension to the voluntary suspension, following a trading halt for an announcement "regarding current research initiatives" (BD: May 18, 20, 2020). Cann Global said it expected an announcement to be made by May 27, 2020. Cann Global last traded at 0.7 cents.