Biotech Daily

Wednesday April 28, 2021

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AMPLIA UP 12%; ALTERITY DOWN 12%**

*** PIPER ALDERMAN: PHARMALEX ACQUIRES BRANDWOOD CKC**

*** ALLEGRA $2m LOAN FOR BONE SUBSTITUTE RESEARCH**

*** RESPIRATORY COMPROMISE INSTITUTE TRIALS 4D MEDICAL XV LVAS**

*** ANTEO RAISES $12m FOR EUGENI COVID-19 TEST; PLAN FOR $4m**

*** EMVISION: POTENTIAL STROKE DETECTION ANALYSIS TECHNIQUES**

*** AMPLIA PLANS AMP945 COMBINATION PANCREATIC CANCER TRIAL**

*** RESPIRI: TERRY WHITE CHEMMART TO STOCK WHEEZO**

*** ORTHOCELL: 'CELGRO NERVE REPAIR BEATS MARKET LEADER' IN RATS**

*** RACE, NEWCASTLE UNI STUDY BISANTRENE CARDIAC IMPACT**

*** MGC SUBMITS ARTEMIC TO HEALTH CANADA**

MARKET REPORT

The Australian stock market was up 0.44 percent on Wednesday April 28, 2021, with the ASX200 up 30.9 points to 7,064.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 14 fell and 10 traded unchanged. All three Big Caps were up.

Amplia was the best, up three cents or 12.2 percent to 27.5 cents, with 259,604 shares traded. Optiscan climbed 7.1 percent; Antisense and Cynata were up five percent or more; Orthocell and Patrys improved four percent or more; Paradigm was up 3.5 percent; Avita, Oncosil and Proteomics rose more than two percent; CSL, Nanosonics, Neuren and Pharmaxis were up one percent or more; with Clinuvel, Cochlear, Pro Medicus, Resmed and Volpara up by less than one percent.

Alterity led the falls, down 0.4 cents or 11.8 percent to three cents, with 79.2 million shares traded. Impedimed lost 7.7 percent; Universal Biosensors was down 5.4 percent; Genetic Signatures fell 4.9 percent; Polynovo and Uscom were down three percent or more; Compumedics, Cyclopharm, Medical Developments, Mesoblast, Next Science, Prescient and Starpharma shed more than one percent; with Kazia down 0.7 percent.

PIPER ALDERMAN

Law firm Piper Alderman says Sydney's Brandwood CKC has been acquired by the Frankfurt, Germany-based life sciences consultancy Pharmalex Group.

Piper Alderman said it advised Brandwood on the merger with Brandwood now part of the privately-owned Pharmalex Group, establishing an Australian presence for the advisory firm.

Piper Alderman said that Brandwood CKC was formed in 2019, following the merger of two leading Australian consulting firms Brandwood Biomedical and Capital K Consulting and offered "a range of regulatory, technical and commercial services for developers, manufacturers and suppliers of medical devices, diagnostics and pharmaceutical products.

Piper Alderman said that partner Lis Boyce and associate Bahar Agar advised Brandwood and assisted in the negotiations and implementing the transaction documents, as well as planning for post-completion operations.

The law firm said that Ms Boyce was the deputy chair of Ausbiotech's Ausmedtech advisory group.

Brandwood CKC managing-director Grant Bennett said the merger "allows us to expand the range and geographical reach of services we can provide our clients, as well as supporting Pharmalex by providing global expertise in the medical device and diagnostic sectors".

Piper Alderman has offices in Adelaide, Brisbane, Melbourne and Sydney.

ALLEGRA ORTHOPAEDICS

Allegra says it has a $2 million loan at 13 percent per annum from an undisclosed lender to fund the development of its strontium-hardystonite-Gahnite bone substitute.

Allegra said it could draw-down up-to $2 million in tranches of $300,000 for up to 24 months.

The company said the load could be repaid in cash or in Allergra shares with a purchase price at a 10 percent discount to the 90-day volume weighted average price.

Allegra was unchanged at 32 cents.

4D MEDICAL

4D says the Respiratory Compromise Institute will implement its x-ray velocimetry lung ventilation analysis software (XV LVAS) at eight US clinical sites.

4D said the Alexandria, Virginia-based Respiratory Compromise Institute would conduct an up-to 100 patient pilot program using the XV LVAS to evaluate endo-bronchial valve procedures in treating late-stage chronic obstructive pulmonary disease.

The company said that the institute would use the 4D automated end-to-end workflow to identify additional sources of respiratory insufficiency to inform the course of patient treatment.

4D chief executive officer Prof Andreas Fouras said that the Respiratory Compromise Institute was "comprised of members recognized as world leaders in [chronic obstructive pulmonary disease] clinical practice and research".

"4D Medical is excited to demonstrate the capability of XV LVAS to provide unprecedented insight into pulmonary functioning, critical in analyzing and managing respiratory diseases," Prof Fouras said.

4D Medical was up half a cent or 0.3 percent to $1.59.

ANTEOTECH

Anteo says it has raised $12 million at 26 cents a share and hopes to raise $4 million in a share plan to fund the roll-out of its Eugeni Covid-19 antigen rapid test.

Earlier this month, Anteo said it had Conformité Européenne (CE) approval for the Eugeni severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen rapid test, a single use, disposable, immuno-chromatographic test (BD: Apr 12, 2021).

In a media release today, Anteo chief executive officer Derek Thomson said the launch "would enable the company to start selling tests into the European Economic Area and the United Kingdom, with the aim of having it available in Australia by mid-year".

"This is a major milestone for the company, with our sights set on finalizing approvals here in Australia and in the US where our technology is already being used by another Brisbane company, Ellume, to target the home test market," Mr Thomson said.

Anteo said that the placement share price was a 20.3 percent discount to the 10-day volume-weighted average price.

Mr Thomson said that the company "now has the necessary financial flexibility to scale up operations and accelerate the roll-out of its Eugeni reader platform and Covid-19 [antigen rapid test] test, as well as our growing pipeline of other assay tests which will provide us with a considerable competitive advantage in the current market".

The company said that PAC Partners Securities Pty Ltd was the sole lead manager to the placement.

Anteo said the share plan would allow eligible investors at the record date of April 27, 2021 to buy up-to $30,000 worth of shares at 26 cents a share.

The company said the share plan would open on May 4 and close on May 18, 2021.

Anteo fell 2.5 cents or six percent to 39 cents with 56.7 million shares traded.

AMPLIA THERAPEUTICS

Amplia says mouse studies show that its focal adhesion kinase (FAK) inhibitor AMP945 enhances chemotherapy and impacts biomarkers in pancreatic cancer.

In March, Amplia said it would collaborate with the Sydney-based Garvan Institute of Medical Research to develop AMP945 for pancreatic cancer (BD: Mar 18, 2021).

Today, the company said that a mouse model of pancreatic cancer showed that AMP945 with gemcitabine, or Abraxane, a standard-of-care for pancreatic cancer, enhanced "the activity of the chemotherapy as determined by key indicators of cell death and of cancer cell proliferation".

Amplia said that a single round of AMP945 in combination with Abraxane caused a "significant increase" in levels of cleaved Caspase-3, a marker of cancer cell death.

The company said that Ki67, a marker of cancer cell proliferation, was significantly reduced after dosing with both AMP945 and Abraxane.

Amplia said that data from the research "demonstrated that AMP945 impacts several key markers of disease, including the level of fibrosis and collagen maturity in the tumor environment".

Amplia chief executive officer John Lambert said that the data provided "further validation of our approach of using our proprietary FAK inhibitors to enhance the effectiveness of the current therapies for this difficult to treat disease".

"It is very encouraging to see that AMP945 is able to directly reduce the levels of fibrosis is these tumor models, as well as enhance the activity of gemcitabine/Abraxane," Mr Lambert said.

Amplia said it was planning a phase II trial of AMP945 in pancreatic cancer patients.

Amplia was up three cents or 12.2 percent to 27.5 cents.

EMVISION MEDICAL

Emvision says it has developed two data processing techniques, “dielectric mapping” and “pulsatility”, which could improve the care and diagnosis of stroke patients.

Emvision said dielectric mapping and pulsatility used data collected form its portable electromagnetic imaging brain scanner which provided diagnostic information obtained non-invasively from patients and without using ionizing radiation to rapidly distinguish between ischaemic, or vessel blockage, and haemorrhagic, or bleeding, strokes.

The company said that dielectric mapping could provide high-fidelity anatomical detail to clinicians to assist in assessing stroke impact by mapping and analysing tissue permittivity, a measure of resistance to an electric field, to interpret the effect of anatomical structural changes in the brain.

Emvision said the dielectric maps enabled clinicians to see and image visualizing anatomical electric properties and was similar in appearance to at computed tomography (CT) or magnetic resonance imaging (MRI) scan.

The company said that dialectric maps using electro-magnetic radiation could be used “where CT and MRI [were] not accessible or practical” by the bedside or in road or air ambulances.

Emvision said that pulsatility measures blood flow through electric changes, and could assist in diagnosis of large vessel occlusion, or the blockage of one of the major arteries in the brain.

The company said that about one third of ischaemic strokes were caused by of large vessel occlusion (LVO) and by measuring blood flow through the brain, pulsatility could identify the degree of occlusion or blockage as early as possible, as well as potentially localizing the extent of salvageable tissue and effect of reperfusion therapy, or treatment to restore blood flow.

Emvision said that the pulsatility analysis could be delivered at point-of-care without the need of contrast agents or ionizing radiation and could avoid unnecessary disability as a result of treatment delay, as well as reduce costs.

Emvision chief executive officer Dr Ron Weinberger said that “using [electro-magnetic] imaging, clinicians will be able to make good approximations to the anatomical region at which stroke occurs and will enable a visualization of the [electro-magnetic] image for clinicians that is familiar to them and what they have been looking at for decades, CT and MRI”.

“Pulsatility is a complimentary technique that alongside our existing diagnostic algorithms, has the potential to improve diagnosis and treatment and save more lives,” Dr Weinberger said.

Emvision was up 14 cents or 4.6 percent to $3.17.

RESPIRI

Respiri says it Brisbane’s Terry White Chemmart will stock and market its Wheezo device for asthma management.

Respiri chief executive officer Marjan Mikel said that the “agreement with Terry White Chemmart takes the number of pharmacies contracted to stock and sell Wheezo to approximately 1,000 stores, representing an implied market footprint of 22 percent based on the total number of ex-hospital community pharmacies across the country”.

The company said it was in “active discussions” with other pharmacy retailers to sell the Wheezo device.

Respiri was up 1.5 cents or 13.6 percent to 12.5 cents with 2.7 million shares traded.

ORTHOCELL

Orthocell says its Celgro collagen medical device has outperformed the market-leading nerve repair device for peripheral sciatic nerve regeneration in a rat study.
Orthocell said that the study of four rats with severed sciatic nerves was designed to evaluate the safety and efficacy of Celgro in peripheral nerve repair, to meet the requirements of the US 510(k) regulatory pathway.
The company said the study, led by Dr Zoran Pletikosa at the University of Western Sydney, administered the rats with either Celgro or the US Food and Drug Administration-approved nerve repair device.
Orthocell said that the Celgro nerve repair group had the sciatic nerve restored to its pre-injured state at four weeks post-treatment with no adverse reactions, inflammation, scar tissue formation or fibro-adhesions.
The company said the FDA-approved device group showed significant inflammation with foreign body reactive giant cells, excessive fibro-adhesions to the surrounding soft tissue, as well as fibro-encapsulation and separation of the epineurium to the nerve fibres, and the nerve was not restored to its pre-injured state at the four-week post-treatment point.
Orthocell said Celgro was easier to cut to size, manipulate and position when wrapping around the injured nerve, and hydrated immediately upon contact with tissue fluid, compared to the comparator device which was thicker and not easy to cut to the required size, rubbery in texture and required 15 to 30 minutes pre-soaking to hydrate.
The company said that with the nerve regeneration data, and previously released interim human clinical data, it was evaluating the US regulatory pathways to identify opportunities for expedited approval of Celgro and the best route to the highest reimbursement value.
Orthocell managing-director Paul Anderson said that “Celgro has shown to be the superior product for nerve regeneration when compared to the market leading alternative”.
“Importantly, this evaluation of regulatory and reimbursement pathways positions the company towards a more attractive reimbursement value,” Mr Anderson said.
Orthocell was up 2.5 cents or 4.85 percent to 54 cents with 1.7 million shares traded.

RACE ONCOLOGY

Race says it will collaborate with the University of Newcastle to investigate the heart safety of Bisantrene compared to current anthracycline chemotherapeutics.
Race chief scientific officer Dr Daniel Tillett told Biotech Daily that the research collaboration would conduct in-vitro studies followed by mouse studies of Bisantrene.
The company said the project would be led by New South Wales-based University of Newcastle’s cardiotoxicity researchers Prof Aaron Sverdlov and Prof Doan Ngo.
Race said that the heart safety of Bisantrene had been shown in more than 40 clinical trials but how it avoided causing cardiotoxicity was unknown.
The company said that the aim of this project was to explore Bisantrene’s low cardiotoxicity at the molecular level.
Race said that anthracyclines were a class of chemotherapeutics commonly used in breast cancer that were known to be effective, but also cardiotoxic.
The company said that the University of Newcastle research would begin immediately with results over the next 12 months supporting phase IIb human trials of a Bisantrene in anthracycline naïve breast cancer patients, planned to begin in Europe in 2022.
Dr Tillett said that “understanding how Bisantrene works at a molecular level to avoid damage to the heart will aid all our clinical plans”.
Race was up one cent or 0.3 percent to $3.12.

MGC PHARMACEUTICALS

MGC says its Canadian partner Glow Lifetech has filed a Health Canada application to classify its anti-inflammatory Artemic for Covid-19 as a natural health product.

Last year, MGC said its 50-patient, phase II, safety and efficacy trial of Artemic, an oral spray comprised of artemisinin, vitamin C, curcumin and boswellia serrata, or Indian frankincense, for Covid-19 patients in Israel and India had “successfully met the primary and secondary endpoints” (BD: Dec 15, 2020).

Today, the company said that the Toronto-based Glow Lifetech would market, sell and distribute Artemic as a food additive, if approved by Health Canada.

MGC managing-director Roby Zomer said that “approval of Glow’s application if granted will further highlight the robustness and effectiveness of our clinical trial processes in relation to treatments that we are able to develop and bring to market”.

MGC was up 0.4 cents or seven percent to 6.1 cents with nine million shares traded.