Biotech Daily

Thursday June 21, 2018

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: AIRXPANDERS UP 13%; USCOM DOWN 9%**

*** MESOBLAST 75% DAY-100 PAEDIATRIC GVHD SURVIVAL**

*** CYNATA 2nd COHORT 86% DAY-28 ADULT GVHD IMPROVEMENT**

*** RACE WINS UK 'UNLICENSED MEDICINE' FOR BISANTRENE FOR AML**

*** RHINOMED UP 28% AS COLUMBIA TAKES IT TO CANNABIS CORNER**

*** QUEENSLAND BAUXITE BUYS MEDCAN AUSTRALIA, MEDICAL CANNABIS**

*** EUROPEAN PATENT FOR USCOM BLOOD FLOW, PRESSURE MONITOR**

*** ESENSE: 'MARIJUANA TERPENES ARREST CELL GROWTH IN-VITRO'**

*** AUSCANN PLEADS SCHULTZ TO ASX 14.5% FALL QUERY**

MARKET REPORT

The Australian stock market was up 0.96 percent on Thursday June 21, 2018 with the ASX200 up 59.5 points to 6,232.1 points.

Nineteen of the Biotech Daily Top 40 stocks were up, eight fell and 13 traded unchanged. All three Big Caps were up.

Airxpanders was the best, up 1.5 cents or 13.0 percent to 13 cents with 1.1 million shares traded.

Avita and Benitec climbed more than seven percent; Mesoblast and Prescient were up more than six percent; Dimerix was up five percent; Compumedics, Factor Therapeutics and Neuren improved more than four percent; Cynata and Telix were up more than three percent; Cochlear, CSL, Ellex, Medical Developments and Oncosil rose more than two percent; Clinuvel, Starpharma and Volpara were up more than one percent; with Nanosonics, Resmed and Sirtex up by less than one percent.

Yesterday's 9.7 percent best, Uscom, led today's falls, down 1.5 cents or 8.8 percent to 15.5 cents with 185,477 shares traded.

Admedus, Cyclopharm and LBT lost more than six percent; Imugene fell 3.6 percent; ITL shed 2.4 percent; with Impedimed and Pro Medicus down by less than one percent.

MESOBLAST

Mesoblast says that 41 of 55 children (74.5%) in its open-label phase III trial of remestemcel-L for acute graft versus host disease have survived to 100 days.
Mesoblast said that 33 of the 38 children (86.8%), who responded to treatment at day-28, were alive at day-100 and the multi-infusion regimen was well-tolerated.
The company said that day-100 mortality could reach 70 percent in patients who fail to respond to initial steroid therapy, with 12-month mortality approaching 90 percent.
Mesoblast said that the day-100 data was presented today at the International Society for Stem Cell Research meeting in Melbourne.
In February, the company said the trial met its primary endpoint of day-28 overall response rate with 69 percent (38 patients) surviving, compared to the 45 percent historical control rate (p = 0.0003) (BD: Feb 22, 2018).
Mesoblast said that acute graft versus host disease was associated with significant morbidity and was a leading cause of mortality after allogeneic hematopoietic stem cell transplantation for blood cancers or other conditions.
The company said mesenchymal stem cells had anti-inflammatory and immunemodulatory biological activity supporting their investigational use in acute graft versus host disease.
Mesoblast said that successful results from the phase III trial, with day-180 data, might provide sufficient evidence to file for accelerated approval of remestemcel-L in the US.
Mesoblast chief executive Prof Silviu Itescu said it was “wonderful” that the trial showed “such promising survival rates at day-100 … [and] our objective is to bring this new therapy to market and make it available to patients who are in desperate need with this life-threatening complication of an allogeneic bone marrow transplant.”
Mesoblast was up nine cents or 6.1 percent to $1.565 with 2.7 million shares traded.

CYNATA THERAPEUTICS

Cynata says that six of seven cohort B patients (85.7%) in its phase I trial of CYP-001 for graft versus host disease improved by at least one grade compared to baseline.
Cynata said that cohort B adult patients received a higher dose of its CYP-001 mesenchymal stem cell product candidate, with four patients (57.1%) having a complete response rate and all seven surviving to day-28.
The company said that by day-28, the eight-patient cohort A had a complete response rate of 12.5 percent or one patient, compared to 57 percent in cohort B.
Cynata chief executive officer Dr Ross Macdonald told Biotech Daily that one of the eight patients enrolled in cohort B discontinued prior to treatment.
Dr Macdonald said that cohort A received two infusions of CYP-001 at a dose level of one million cells per kilogram of body weight, up to a maximum of 100 million cells per infusion and cohort B received two infusions of CYP-001 at a dose level of 2 million cells per kilogram of body weight, up to a maximum of 200 million cells per infusion.
Cynata said that there were no treatment-related serious adverse events or safety concerns identified and the data support moving to a phase II trial.
Dr Macdonald said the 28-day results for cohort B were “highly encouraging and, together with the excellent data from cohort A, support the advancement of CYP001 into a phase II trial in graft versus host disease”.
“Importantly, CYP-001’s strong safety profile may enable us to advance the therapy directly into phase II trials in other indications beyond [graft versus host disease] where there is a high unmet medical need for a consistent and scalable source of high-quality [mesenchymal stem cells],” Dr Macdonald said.
Cynata was up four cents or three percent to $1.365.

RACE ONCOLOGY

Race says that the UK Medicines and Healthcare Products Regulatory Agency has approved the import and distribution of Bisantrene as an unlicensed medicine.
Race said the Agency told its London-based distributor Durbin PLC that Bisantrene for acute myeloid leukaemia could be supplied, subject to Agency approval and in response to unsolicited requests from doctors for treating patients with unmet medical needs.
The company said the approval allowed Durbin to import and supply Bisantrene to UK-based doctors and hospitals in response to such requests, with the initial approval for 75 courses of treatment of 14 vials per course, but Durbin could apply for further approvals.
Race said that no further approval was needed to begin supply of Bisantrene in response to physician requests or to invoice hospitals that received the drug, with the use of unlicenced medicines in the UK typically funded by the hospital administering the drug.
The company said the approval allowed Durbin to supply Bisantrene to all 28 other countries in the European Economic Area, subject to local approval and import rules.
Race said that in France, an autorisations temporaires d'utilisation, or temporary authorization for use, was required to import and supply an unlicenced medicine.
Race was unchanged at 24 cents.

RHINOMED (FORMERLY CONSEGNA GROUP)

Rhinomed climbed 28 percent to 16 cents on news that it has an agreement with New York's Columbia Care LLC for nasally-delivered medical marijuana.
Rhinomed has been commercializing its Mute nasal dilators for snoring and the Turbine sports version of the plastic nasal inserts claiming an increased oxygen supply, with trial showing mixed results (BD: Feb 13, 2014; Sep 30, 2016).
In 2013, the then Consegna said it intended that the nasal inserts would carry a drug payload and in 2014, Rhinomed said it had was targeting acute migraine by including low-dose sumatriptan in its Breatheassist nasal inserts (BD: Sep 19, 2013; Feb 14, 2014).
Today, Rhinomed chief executive officer Michael Johnson told Biotech Daily that the non-binding term sheet with Columbia Care was to develop a range of micro-low dosing of marijuana-based drugs in the nasal inserts and delivered through nasal, transdermal, mucosal or vapor routes to the patient.
In a media release to the ASX, Rhinomed said that Columbia Care was "the largest medical marijuana operator in the US" and the agreement would "leverage Rhinomed's patented nasal technology platform and Columbia Care's research and manufacturing capabilities to create a patent protected and exclusive range of reliable, dose-controlled, cannabis-based nasally administered medicines" for over-the-counter and clinical applications to address significant unmet needs in cancer, sleep apnoea, post-traumatic stress disorder (PTSD), severe and chronic pain and anti-nausea.
The company said it expected to complete a binding agreement in the next 90 days.
Rhinomed said that the companies believed that "nasally-delivered, dose-controlled, targeted medical cannabis formulations open up a new pathway and opportunity across a range of indications for this class of medication within the clinical and over-the-counter consumer health settings".
Columbia Care chief executive officer Nicholas Vita said that Rhinomed was "a leader in the development of nasal and respiratory technology and Columbia Care is the leading medical cannabis product innovator and distributor in the US".
"Marrying our respective core competencies gives us an immediate leadership position in the largest market in the world," Mr Vita said.
Rhinomed closed up 1.5 cents or 12 percent to 14 cents with 1.7 million shares traded.

QUEENSLAND BAUXITE

Queensland Bauxite says it will acquire the remaining 45 percent of subsidiary Medical Cannabis and it has an agreement to buy Brisbane's Medcan Australia Pty Ltd.
Queensland Bauxite first called a trading halt for the marijuana deal in May, later requesting a voluntary suspension and four extensions of the suspension followed by three updates on the progress of the deal (BD: May 2, 4, 18, 25, 2018).
Today, Queensland Bauxite said the two-part acquisition included a binding agreement to buy Medcan Australia, which held a Federal Office of Drug Control medical cannabis production licence and had "an experienced management and production team with a contract to supply already in place, [enabled] the Medical Cannabis group to legally grow and cultivate high [tetrahydrocannabinoid] and [cannabidiol] medicinal cannabis products in Australia to supply the new Australian and the burgeoning global markets".
The company said it and Medical Cannabis had an agreement with the other shareholders of Medcan, Craig Cochran and Gareth Ball to acquire the company, subject to conditions.
Queensland Bauxite said it would issue of 250 million shares to the vendors and following the acquisition the Medcan vendors would hold eight percent of Queensland Bauxite.
The company said that Mr Cochran and Mr Ball would be contracted as part of the management team for the first two years and their remuneration would include quarterly issues of 1.25 million shares for Mr Cochran and one million for Mr Ball for the first two years following settlement, including an inflation adjustment in the second year, as well as 10 percent of Medcan's net profit, pending shareholder, ASX and other approvals.
Queensland Bauxite said it would acquire the remaining 45 percent of its Medical Cannabis subsidiary for 1,195,000,000 of its shares.
Queensland Bauxite executive chair Pnina Feldman said "the value of [Medical Cannabis] and Medcan combined is greater than the sum of the individual businesses".
"Both parties achieve value uplift with clear and deliverable synergies," Ms Feldman said.
"[Medical Cannabis], with this acquisition, is now able to fulfil its vision to become a fully vertically-integrated cannabis company," Ms Feldman said.
Queensland Bauxite was up 0.4 cents or 8.2 percent to 5.3 cents with 164.8 million shares traded.

USCOM

Uscom says the European Patent Office intends to grant a patent relating to its combined blood flow and pressure monitoring system.
Uscom said the patent, titled 'Combined Blood Flow and Pressure Monitoring System and Method', would provide intellectual property coverage until January 14, 2034.
The company said the patent described "a new method for measuring the work the heart and vessels generate to deliver oxygen to the cells … an improved predictor of outcome and guide for cardiovascular therapy … [and described] a new system and method for monitoring cardiovascular function which incorporates blood flow and blood pressure".
Uscom said that current technologies for measuring cardiovascular function monitored either blood pressure or blood flow, or lesser measures such as bio-impedance.
The company said that prior studies described methods for incorporating the blood pressures and flow parameters, but the new method "improves on these by measuring the load on the heart more accurately".
"Cardiac work and power better predict cardiovascular events and survival than conventional monitoring and the new Uscom system and method improves on these measures again," the company said.
Uscom fell 1.5 cents or 8.8 percent to 15.5 cents.

ESENSE-LAB

Esense says that laboratory testing of its terpene marijuana blends shows “signs of cellular growth arrest, with results showing low cell proliferation”.

The Israel-based Esense said that the study of the aromatic organic hydrocarbons by the Dead Sea and Arava Science Centre showed that “the composition and profiles of cannabis terpenes have been shown to possess added pharmaceutical and cosmetic values … [but] due to the high cost of the plants and regulatory issues, the elution of its terpenic fraction is not feasible”.

The company said that this was addressed by in-vitro reconstruction of its terpene profile after analytical verification and the new compositions were homologous to the original plant.

Esense said that “most formulations attenuated the capability of the cells to proliferate rather than mediate a cell death effect” with a dose-response effect in most tested formulations with one formulation demonstrated an outstanding potency of up to 90 percent inhibitory effect following exposure to a low dose of the formulation.

Esense fell 0.3 cents or 3.7 percent to 7.9 cents.

AUSCANN

Auscann has told the ASX that it is not aware of any information it has not announced which, if known, could explain recent trading in its securities.

The ASX said the company’s share price fell 18 cents or 14.5 percent from an intra-day high of $1.24 to an intra-day low of $1.06, yesterday June 20, 2018, and noted a significant increase in trading volume.

Auscann climbed 17.5 cents or 16.2 percent to $1.255 with 2.2 million shares traded.