Biotech Daily

Monday July 6, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 11%; ALTERITY DOWN 14%**

*** MESOBLAST: US ALLOWS REMESTEMCEL-L FOR COVID-19 CHILDREN**

*** NYRADA: 'ORAL NYX-PCSK9I EQUALS INJECTABLES FOR LDL, IN-VITRO'**

*** COGSTATE: $66m CLINICAL TRIALS SALES CONTRACTS**

*** BIOTRON: 'BIT225 ENHANCES HIV-1 IMMUNE RESPONSE'**

*** MAYNE: NOVAST SUPPLY AGREEMENT FOR 13 CONTRACEPTIVES**

*** DIMERIX ADVANCES DMX-700 PROGRAM FOR COPD**

*** ALLEGRA ACQUIRES SYDNEY UNI SR-HT-GAHNITE PATENTS**

*** CARDIEX RESTRUCTURES INHEALTH COLLABORATION**

*** CRESO REDEEMS 1.2m KUNNA NON PERFORMANCE SHARES**

*** RECCE REQUESTS 'RESEARCH AGREEMENT' TRADING HALT**

*** THORNEY, TIGA INCREASE, DILUTED TO 27% OF VISIONEERING**

*** ELEANORE GOODRIDGE BELOW 5% IN NOXOPHARM**

*** ERLYN DALE, WINTON WILLESEE REPLACE ESENSE CO-SEC JAMES BAHEN**

MARKET REPORT

The Australian stock market fell 0.71 percent on Monday July 6, 2020, with the ASX200 down 43.3 points to 6,014.6 points. Thirteen of the Biotech Daily Top 40 stocks were up, 22 fell and five traded unchanged. All three Big Caps fell.

Mesoblast was the best, up 38 cents or 11.3 percent to $3.75, with 10.8 million shares traded. Resonance climbed 6.45 percent; Cyclopharm and Oncosil improved four percent or more; Immutep and Orthocell were up three percent or more; Imugene, Kazia and LBT rose more than two percent; Pro Medicus was up 1.5 percent; with Avita, Next Science and Starpharma up by less than one percent.

Alterity again led the falls, down 0.7 cents or 14.3 percent to 4.2 cents, with 55.0 million shares traded. Osprey lost 12 percent; Amplia fell 8.3 percent; Patrys shed 7.7 percent; Optiscan and Universal Biosensors fell more than four percent; Cynata and Polynovo were down more than three percent; Compumedics, CSL, Nanosonics, Neuren, Pharmaxis and Uscom shed more than two percent; Antisense, Cochlear, Genetic Signatures, Paradigm, Proteomics, Resmed, Telix and Volpara were down more than one percent; with Clinuvel, Medical Developments and Nova Eye (Ellex) down by less than one percent.

MESOBLAST

Mesoblast says it has expanded its US protocol for remestemcel-L to children with cardiovascular and other complications of multi-system inflammatory syndrome.
Mesoblast said it filed the protocol with the US Food and Drug Administration to provide physicians with access to its remestemcel-L for an intermediate-size patient population with multi-system inflammatory syndrome caused by Covid-19, under its existing investigational new drug application.
In April, the company said it had begun a 300-patient, phase II/III trial of remestemcel-L for Covid-19-related acute respiratory distress syndrome (Ards) in adults (BD: Apr 30, 2020).
Today, Mesoblast said it would administer either one or two doses of its allogeneic mesenchymal stem cell product remestemcel-L to patients between two months and 17 years of age, within five days of referral under the expanded access protocol.
The company said multi-system inflammatory syndrome included massive simultaneous inflammation of multiple critical organs and their vasculature.
Mesoblast said that in about 50 percent of cases the inflammation was associated with significant cardiovascular complications leading to decreased cardiac function, and could result in dilation of coronary arteries with unknown consequences.
Mesoblast chief medical officer Dr Fred Grossman said the safety and efficacy data generated to date using remestemcel-L in children with graft versus host disease suggested it could provide a therapeutic benefit in multi-system inflammatory syndrome complications patients, especially if the heart was a target organ for inflammation.
“Use of remestemcel-L in children with Covid-19 builds on and extends the potential application of this cell therapy in Covid-19 cytokine storm beyond the most severe adults with acute respiratory distress syndrome.”
Mesoblast climbed 38 cents or 11.3 percent to $3.75 with 10.8 million shares traded.

NYRADA

Nyrada says that its oral NYX-PCSK9i equals injectable alirocumab and evolocumab in lowering low density lipoprotein in healthy human white blood cells, in-vitro.
Nyrada said it tested its PCSK9 inhibitor against two US approved monoclonal PCSK9 antibodies, evolocumab marketed as Repatha and alirocumab marketed as Praluent, and the results confirmed that with and without the presence of the statin Mevastatin, high dose NYX-PCSK9i was equal to the two approved drugs.
The company said the results opened “the potential for NYX-PCSK9i to be used alone, or in combination with [a] statin” for low density lipoprotein (LDL), or “bad cholesterol”.
Nyada said that the laboratory results confirmed that both with and without the addition of the statin Mevastatin, it had “the potential to develop a combined PCSK9-statin single pill treatment for high LDL cholesterol”.
Nyrada scientific advisory board member Dr Gilles Lambert said the “results demonstrate that our PCSK9 inhibitor works just as well as the FDA approved injectable medications Repatha and Praluent in this cell model, marking the achievement of an exciting scientific milestone for the Company”.
Nyrada chief executive officer James Bonnar said that “having a drug candidate that works as well as the two market-leading monoclonal PSCK9 antibodies in a human cell model is a huge achievement”.
“It represents a big step forward in our mission to develop the first-ever small molecule PCSK9 inhibitor to treat high cholesterol and provide a compelling cost-competitive and convenient treatment alternative,” Mr Bonnar said.
Nyrada was up six cents or 34.3 percent to 23.5 cents with 21.1 million shares traded.

COGSTATE

Cogstate says $US8.4 million in clinical trials sales contracts in the three months to June 30, 2020 takes the total signed for the year to $US46 million ($A66.1 million).
Cogstate said this was a record result and an increase on the $US18 million for the year to June 30, 2019.
The company said sales contracts did not equal revenue but was recognized based on achievement of pre-determined milestones over the life of a contract.
Cogstate said clinical trials could vary from several months for a phase I study to up to four or five years for a phase III study.
The company said that due to Covid-19 and resulting isolation orders, there was a general slowing of new clinical trials during the three months to June 30, 2020, with $US5 million of the $US8.4 million was recognized prior to April 15, 2020.
Cogstate was up 3.5 cents or nine percent to 42.5 cents.

BIOTRON

Biotron says its BIT225 enhances the immune response to human immunodeficiency virus type-1 (HIV-1) by inhibiting the viral protein Vpu.
Biotron said the data was from a phase II study that compared wild-type virus with the HIV-1 virus with the Vpu protein removed and was presented at the International AIDS Conference in San Francisco July 6 to 10, 2020.
The company said it showed that BIT225 restored cell surface markers, which normally signaled the immune system to attack the virus but was downregulated in HIV, back to normal.
Biotron said it indicated that BIT225 increased a key marker linked to functionality so that T cells were able to move around the body and restore immune function.
Biotron said the presentation, titled 'Vpu inhibitor BIT225 alters T cell activation and homing plasma membrane receptor expression on CD4+ T cells (CD28 and CCR7) and monocyte -derived macrophages (CD80 and CD86)' was co-authored by Biotron chief executive officer Dr Michelle Miller.
The presentation concluded that BIT225 treatment could counteract Vpu-mediated downregulation of membrane expressed CD28 and CCR7 and CD80 and CD86 monocyte derived macrophages infected with HIV-1.
"The latest results provide key information on how BIT225 directly modifies immune responses to HIV-1 infection," Dr Miller said. "It helps explain the immune changes that we saw in the phase II clinical trial and gives us even more confidence in our product."
Biotron was up three cents or 30 percent to 13 cents with 71.5 million shares traded.

MAYNE PHARMA GROUP

Mayne says it has a long-term supply agreement with the Nantong, China-based Novast Laboratories for 13 US oral contraceptive products, including five not previously marketed.
Mayne said four of the products were US Food and Drug Administration approved and a fifth product was pending with the FDA.
Mayne chief executive officer Scott Richards said that Novast had "an outstanding quality track record manufacturing and supplying oral contraceptives to the US market".
"This transaction expands our women's health portfolio and secures supply on more favorable terms of eight products previously acquired from Teva Pharmaceuticals to continue to drive growth of our women's health franchise," Mr Richards said.
Mayne was up 1.5 cents or 3.7 percent to 42.5 cents with 16.4 million shares traded.

DIMERIX

Dimerix says it has advanced its understanding of how receptors may contribute to lung damage in its DMX-700 program for chronic obstructive pulmonary disease.
Dimerix said its research showed that due to the functional interaction of receptors there was an increased presence and activation of the receptor complex at the cell surface.
The company said it expected this to result in an increased pro-inflammatory effect.
Dimerix said it identified the receptor interaction with its receptor-heteromer investigation technology (Receptor-HIT) discovery tool,
The company said the understanding would allow it to move its DMX-700 program to the next stage of development to optimize DMX-700 to limit signaling of these receptors and for in vivo dose ranging studies.
Dimerix chief executive officer Dr Nina Webster said, “it is very pleasing to report that our program for chronic obstructive pulmonary disease has been making strong progress in the background to our three clinical phase programs, with all programs advancing despite Covid-19”.
Dimerix was unchanged at 37.5 cents with 1.2 million shares traded.

ALLEGRA ORTHOPAEDICS

Allegra says it has issued the University of Sydney 4,806,000 shares to acquire patents and applications for strontium-hardystonite-Gahnite (Sr-HT-Gahnite).
Allegra said Sr-HT-Gahnite simulated the performance of natural bone by achieving mechanical strength required for load bearing and bioactivity for bone regeneration, and had a variety of applications, including as a synthetic bone substitute.
The company said it began working with the University of Sydney in 2014 for the exclusive licence to Sr-HT-Gahnite and commenced commercialization of an interbody cervical spinal cage as its first product.
Allegra chief executive officer Jenny Swain said the company was “very excited by the acquisition of these patents as we believe this material will enable us to create and commercialize highly desirable implants with unique properties that we can bring to the market”.
Allegra climbed 44.2 cents or 502.3 percent to 53 cents with 2.5 million shares traded.

CARDIEX

Cardiex says it has restructured its investment and collaboration agreement with the Los Angeles-based Inhealth to develop hypertension and cardiovascular programs.
In 2018, Cardiex said it would pay more than $4.6 million through three convertible notes and 12 times the three months revenue to either June 30, 2021 or the earlier date of exercise, for up to 50.5 percent of Inhealth’s “health coaching and Telehealth services” (BD: Oct 16, 2018).
Today, Cardiex said it had extended the maturity and conversion date from July 2020 to July 1, 2021 and reduced the balance for repayment of the $US5 million convertible note from $US3 million to $US2.5 million, and a further $US1 million could be repaid from a new Inhealth 2020 capital raising.
Cardiex said conversion of the notes would be at the lower of a discount to a qualified financing or $US9 million, and the option to take 50.5 percent of Inhealth would be exchanged for one percent of fully diluted capital, which would increase its shareholding in Inhealth from 7.7 percent to between 8.7 and 37 percent, prior to new capital being raised.
Cardiex was up 0.3 cents or 12.5 percent to 2.7 cents with 16.2 million shares traded.

CRESO PHARMA

Creso says it has redeemed 1,212,120 performance shares after Kunna Canada failed to cultivate, extract and sell 10 kilograms of cannabis extract within 18 months.
In 2018, Creso said it had completed the acquisition of Kunna Canada and its Medellin, Colombia-based registered subsidiary Kunna Colombia and paid for the acquisition with 8,212,121 shares and 1,212,120 performance shares (BD: Dec 21, 2018).
Today, the company said the shares had been automatically redeemed at 0.001 cent a share following the June 20, 2020 milestone date.
Creso was up 0.1 cents or 3.2 percent to 3.2 cents with three million shares traded.

RECCE PHARMACEUTICALS

Recce has requested a trading halt “pending the release of an announcement relating to a material research agreement”.
Trading will resume on July 8, 2020 or on an earlier announcement.
Recce fell two cents or 2.9 percent to 68 cents.

VISIONEERING TECHNOLOGIES

Thorney Technologies and Tiga Trading say they have increased and been diluted in Visioneering from 240,292,371 shares (28.93%) to 244,578,085 shares (26.97%).
The Melbourne-based Thorney and Tiga said that on June 30, 2020 they acquired 2,142,857 shares and were diluted in the $1,067,000 share purchase plan at 1.4 cents per Chess depository interest (BD: Jun 25, 2020).
Visioneering was unchanged at 1.9 cents with 10.7 million shares traded.

NOXOPHARM

Eleanore Goodridge says she has ceased to be a substantial shareholder in Noxopharm.
Last month, the Darling Point, New South Wales-based Ms Goodridge said she held 13,574,144 shares or 6.37 percent of the company (BD: Jun 23, 2020).
Today, Ms Goodridge said that between June 23 and 26, 2020 she sold 3,838,155 shares in three off-market sales for 13 cents a share.
Biotech Daily calculates that Ms Goodridge holds 9,735,989 shares or 4.6 percent of the company.
Noxopharm was up one cent or five percent to 21 cents with 2.2 million shares traded.

ESENSE-LAB

Esense says it has appointed Erlyn Dale and Winton Willesee as joint company secretaries, replacing James Bahen effective from July 6, 2020.
Esense said both Ms Dale and Mr Willesee had experience in governance roles with ASX listed and other companies.
Esense fell 0.1 cents or 4.8 percent to two cents with 13.0 million shares traded.