Biotech Daily

Tuesday December 15, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: AMPLIA UP 6.5%; MESOBLAST DOWN 15%**

*** MESOBLAST: 'REVASCOR MISSES ENDPOINT, REDUCES HEART EVENTS'**

*** CLARITY PLACEMENT RAISES $25m**

*** ALTHEA PLACEMENT RAISES $6m; SHARE PLAN HOPES FOR $3m**

*** COCHLEAR: US SUPREME COURT DENIES APPEAL; $472m CLAIM, FEES**

*** CARDIEX H1 SALES UP 'MORE THAN 30%'**

*** TGA DROPS CANNABIDIOL TO O-T-C SCHEDULE 3, BUT NO PRODUCTS**

*** MGC: 'ARTEMIC COVID-19 TRIAL MEETS ENDPOINTS'**

*** INCANNEX: IHL-216A BEATS CBD FOR BRAIN INJURY IN RATS**

*** IMMURON, MONASH TEST COW COLOSTRUM AGAINST SARS-COV-2**

*** HERAMED: TELEPERINATAL TO DISTRIBUTE FOETAL MONITORS**

*** AUSTRALIAN ETHICAL TAKES 15% OF NOVA EYE**

*** CREDIT SUISSE TAKES 5% IN DORSAVI**

*** REGAL FUNDS REDUCES TO 14% OF ELIXINOL**

*** REGAL FUNDS BELOW 5% IN MEDADVISOR**

*** DIRECTOR JIM MCDOWELL REJOINS MICRO-X**

*** COCHLEAR APPOINTS STU SAYERS ACTING CFO**

MARKET REPORT

The Australian stock market fell 0.43 percent on Tuesday December 15, 2020, with the ASX200 down 28.9 points to 6,631.3 points. Nine of the Biotech Daily Top 40 stocks were up, 19 fell and 12 traded unchanged. All three Big Caps were up.

Amplia was the best, up 1.5 cents or 6.5 percent to 24.5 cents, with 112,983 shares traded. Osprey improved 4.8 percent; Uscom was up 3.1 percent; Nanosonics rose 2.1 percent; CSL was up 1.2 percent; with Clinuvel, Cochlear, Cyclopharm, Pro Medicus, Resmed, Telix and Volpara up by less than one percent.

Mesoblast led the falls, down 69 cents or 15.2 percent to $3.85, with 19.0 million shares traded. Kazia, LBT and Proteomics lost more than 10 percent; Resonance retreated 6.5 percent; Avita and Immutep were down more than five percent; Compumedics, Imugene and Optiscan fell more than four percent; Cynata and Opthea were down more than three percent; Dimerix and Universal Biosensors shed more than two percent; Pharmaxis and Starpharma were down more than one percent; with Medical Developments, Next Science and Polynovo down by less than one percent.

MESOBLAST

Mesoblast says its 537-patient phase III trial of Revascor mesenchymal precursor cells for chronic heart failure reduces cardiac events, but has not met its primary endpoint.

Mesoblast said that with a mean 30 months of follow-up, its randomized, controlled trial of rexlemestrocel-L showed that patients with advanced chronic heart failure receiving a single endo-myocardial treatment with rexlemestrocel-L on top of maximal therapies had a statistically significant 60 percent reduction of heart attacks or strokes ($p = 0.002$) and a statistically significant 60 percent reduction in death from cardiac causes ($p = 0.037$), "when treated at an earlier stage in the progressive disease process".

The company did not provide specific data on patient numbers for the primary endpoint of "reduction in recurrent non-fatal decompensated heart failure events".

"Despite significant reduction in the pre-specified endpoint of cardiac death, there was no reduction in recurrent non-fatal decompensated heart failure events, which was the trial's primary endpoint," Mesoblast said. "This suggests that [Revascor] reduces mortality by mechanisms that are distinct from those of existing drugs that reduce hospitalization rates but do not significantly impact cardiac mortality."

Mesoblast has renamed Revascor, previously known as MPC-150-IM, "rexlemestrocel-L".

Mesoblast said the reduction in death but not hospital visits "suggests that rexlemestrocel-L reduces mortality by mechanisms that are distinct from those of existing drugs that reduce hospitalization rates but do not significantly impact cardiac mortality".

Mesoblast chief executive Prof Silviu Itescu said there was "an urgent need for new therapies that can reduce the high death rates in heart failure patients by different modes of action from existing drugs which reduce hospitalization rates but have not significantly reduced mortality rates".

"The reduction in mortality seen with rexlemestrocel-L in … heart failure underlines the power of this technology and the commitment of Mesoblast to address diseases in patients with high unmet need which are refractory to existing therapies," Prof Itescu said.

Mesoblast said that the single injection of rexlemestrocel-L, on top of maximal therapy, resulted in a "significant reduction in the incidence of non-fatal ischemic major adverse cardiac events [MACE] due to a heart attack [myocardial infarction] or stroke [cerebrovascular accident] by 60 percent relative to controls ($p = 0.002$).

The company said there was a reduction in MACE seen consistently across both New York Heart Association class II or III populations and irrespective of whether the underlying cause of heart failure was ischemic or non-ischemic.

Mesoblast said there was a "significant reduction in death from all cardiac causes" in the 206 NYHA class II heart failure patients by 60 percent relative to controls ($p = 0.037$), which was evident in both ischemic and non-ischemic subgroups.

The company said rexlemestrocel-L saw a prevention of NYHA class II patients progressing to cardio-vascular death rates of NYHA class III patients ($p = 0.004$), but control group NYHA class II patients progressed to cardio-vascular death rates of NYHA class III patients after a mean period of 20 months of disease stability.

Mesoblast said that there was a significant reduction in MACE outcomes in heart failure patients with NYHA class II disease by 55 percent relative to controls ($p = 0.009$).

Texas Heart Institute medical director Dr Emerson Perin said "rexlemestrocel-L significantly reduces cardiovascular mortality when used early in heart failure patients … and provides durable protection from heart attacks or strokes".

Mesoblast chief medical officer Dr Fred Grossman said the mortality benefit supported "a potential path for approval of rexlemestrocel-L in patients with advanced chronic heart failure".

Mesoblast fell 69 cents or 15.2 percent to $3.85 with 19.0 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says it has raised $25,000,410 in a placement to fund ongoing trials and clinical development of its products for brain, breast and prostate cancer.
The placement share price was not disclosed.
Clarity said the funds would go to its copper-64 and copper-67 Sartate programs for neuroblastoma, its copper-64 Bombesin breast and prostate cancer programs, the diagnostic and therapy prostate cancer program and developing new diagnostic and therapeutic products.
Clarity executive chairman Dr Alan Taylor said that 2020 “has been a pivotal year for Clarity with numerous critical milestones achieved in the development of our main products, advancement of our platform, as well as accelerated corporate and strategic activities despite facing an unprecedented global environment”.
“The money raised will enable us to keep the momentum from 2020 going”, Dr Taylor said.
Clarity is a public, unlisted company.

ALTHEA GROUP HOLDINGS

Althea says its institutional placement has raised $6 million at 44 cents a share and it hopes to raise a further $3 million in a share plan at the same price.
Althea said the share price was a 10.2 percent discount to the last closing price on December 11, 2020 and it would use the funds for marijuana research and development, to expand its patient research through Myaccess Clinics in the UK, develop and expand its Althea Concierge online sales platform, and increase its inventory capacity.
The company said that the share plan would allow holders at the record date of December 14, 2020 to purchase up-to $30,000 worth of shares.
The company did not specify the open and closing dates of the plan but said the offer document would be dispatched “in the coming days”.
Althea was up one cent or two percent to 50 cents with three million shares traded.

COCHLEAR

Cochlear says the US Supreme Court has denied its final appeal against a $US280 million ($A371.7 million) patent lawsuit and will pay $US75 million ($A99.6 million) in fees.
In March, Cochlear said the Court of Appeals affirmed the US District Court decision in the lawsuit of the Alfred E Mann Foundation for Scientific Research and Advanced Bionics LLC against Cochlear and its US subsidiary Cochlear Americas, ruling that Cochlear must pay $US268 million in patent infringement damages (BD: Mar 17, 2020).
In May, the company said the US Court of Appeals for the Federal Circuit in Washington, DC denied its petition for a rehearing and it was ordered to pay about $US280 million for the judgment amount and post judgment interest (BD: May 19, 2020)
In August, Cochlear said it has settled claims of $US75 million to be paid to Alfred E Mann and Advanced Bionics for pre-judgment interest and attorneys’ fees, which would be placed in escrow and paid following the outcome of the final appeal against the $US280 million patent infringement lawsuit (BD: Aug 17, 2020).
Today, the company said it had previously paid the $US280 million to Alfred E Mann and Advance Bionics and would pay the escrowed $US75 million.
Cochlear said the court appeals proceed was finished and the payment of the settlement liability was provided-for in its year to June 30, 2020 financial statements.
Cochlear was up $1.17 or 0.6 percent to $196.89 with 201,000 shares traded.

CARDIEX

Cardiex says its sales for the six months to December 31, 2020 have “surpassed 30 percent growth” compared to the previous corresponding period.
Cardiex said that sales of its Atcor Xcel pulse wave velocity measurement device and its Oscar 2 ambulatory blood pressure monitoring device were “strong despite the pandemic” and the increase came from sales to the research market and clinical trial contracts.
In February, Cardiex said that revenue for the six months to December 31, 2019 was $2,302,757 (BD: Feb 28, 2020).
Cardiex was up 0.1 cents or two percent to 5.2 cents with 2.7 million shares traded.

AUSTRALIAN THERAPEUTIC GOODS ADMINISTRATION

The Therapeutic Goods Administration says it has down-scheduled “certain low dose cannabidiol preparations” to over-the-counter but there are no products available.
The TGA said it had moved low-dose cannabidiol (CBD) containing products, up to a maximum of 150mg/day, from schedule 4 (prescription medicine) to schedule 3 (pharmacist only medicine).
“The decision will allow low-dose CBD containing products, up to a maximum of 150mg/day, for use in adults that have been approved by the TGA, to be supplied over-the-counter by a pharmacist, without a prescription”.
Biotech Daily asked the TGA to explain how adults could be approved by the TGA, and the TGA said products needed to be approved by the TGA without further explanation.
The Administration said that the decision limited over-the-counter supply “to only those products that are approved by the TGA and included on the Australian Register of Therapeutic Goods … [and] outlines additional limits on dosage form and packaging requirements, including pack size and child resistant closures”.
“There are currently no TGA-approved products on the Australian Register of Therapeutic Goods that meet the schedule 3 criteria,” the TGA said.
The Administration said that the decision was made following an earlier TGA safety review of low dose CBD which indicated that the known adverse events of CBD at low doses were not serious.
The TGA said the decision was made by a senior medical officer at the TGA acting as a Delegate of the Secretary of the Department of Health, following extensive public consultation.
The Administration said that the Delegate increased the maximum daily dose proposed in the interim decision from 60mg/day to 150mg/day following further consideration of safety information, the public submissions on the interim decision and the advice of the Joint Committee of the Advisory Committees for Medicines Scheduling and Chemicals Scheduling at the November 2020 meeting.
The TGA said that companies could apply for inclusion of schedule 3 CBD preparations on the ARTG.
The Administration said medicines not included on the ARTG were 'unapproved' and had not been evaluated by the TGA for quality, safety and effectiveness, but could be accessed via the special access or authorized prescriber scheme on prescription only.
The Lambert Initiative for Cannabinoid Therapeutics at the University of Sydney has been previously reported saying that typical CBD therapeutic doses range from 300mg to 1,500mg (BD: Dec 10, 2020).
Emyria executive chair Dr Stewart Washer told Biotech Daily that his company had found that doses of 40mg to 300mg CBD had been shown “to be effective in treating disease like anxiety, post-traumatic stress disorder, pain and depression”.

MGC PHARMACEUTICALS

MGC says its 50-patient phase II trial of its Artemic for Covid-19 patients in Israel and India has “successfully met the primary and secondary endpoints”.

In April, MGC said it ethics approval for a 14-day double-blind, placebo-controlled trial of its anti-inflammatory Artemic, comprised of artemisinin, vitamin C, curcumin and boswellia serrata, or Indian frankincense, which would evaluate the safety and efficacy of Artemic on patients diagnosed with Covid-19 (BD: Apr 17, 2020).

Today, MGC said the primary endpoint was clinical improvement, as defined by the UK national early warning score 2 (News2), maintained for 24 hours in comparison to routine treatment.

The company said News2 measured a patient’s degree of illness to prompt critical care intervention and all 33 patients in the Artemic group met the primary endpoint with News2 scores of less than 2.0 when discharged from hospital.

The company said that “the average News score of patients in the placebo group was 2.25; statistically significantly higher than in the treatment group” ($p < 0.04$).

MGC said that all patients in the Artemic group achieved the secondary endpoints, with one of the 17 placebo patients experiencing life-threating condition.

The company said that no adverse events related to the study drug were reported.

MGC was unchanged at 3.2 cents with 181.7 million shares traded.

INCANNEX HEALTHCARE (FORMERLY IMPRESSION HEALTHCARE)

Incannex says a study in 108 rats shows that its cannabidiol and isoflurane-based IHL-216A “exhibits stronger neuroprotective properties” that cannabidiol alone.

In July, Incannex said it had started a study of IHL-216A for traumatic brain injury and concussion in eight cohorts of rats with induced head injuries with the hope of reducing neuro-excitation, neuro-inflammation, cerebral blood flow and cerebral oxygen consumption (BD: Jul 23, 2020).

Today, the company said the rats were treated with either cannabidiol (CBD) and isoflurane alone, or in combination using the same doses.

Incannex said that isoflurane was administered one to two hours after the injury for 30 minutes and CBD was administered by intra-peritoneal injection every day for seven days post-injury with the first dose administered 15 to 30 minutes post injury.

The company said the study included a control group of uninjured rats.

Incannex said IHL-216A outperformed isoflurane alone and CBD alone in reducing neuronal damage by up-to 53 percent for the brain region cornu-ammonis-1 (CA1) and 60 percent for cornu-ammonis-2 (CA2) in the hippocampus.

The company said IHL-216A reduced the Iba1 neuro-inflammation marker protein by 35 percent more than CBD alone and 123 percent more than isoflurane alone, outperforming CBD and isoflurane alone in the Morris water maze and the Rotarod behavior tests.

Incannex managing-director Joel Latham said the results showed “significant improvements in the key markers of secondary brain injury in a highly-controlled environment”.

“Our intent is for IHL-216A to be the first line of defence to dampen the short and long-term effects of traumatic brain injury caused by any means, but particularly in contact sports,” Mr Latham said.

Incannex said it was assessing clinical trial program options and planned to pursue a US Food and Drug Administration new drug application, subject to further clinical success.

The company said it expected the clinical program to be “established in early 2021”.

Incannex was unchanged at 17 cents with 8.9 million shares traded.

IMMURON

Immuron says Melbourne's Monash University will develop assays to evaluate the efficacy of its bovine colostrum, IMM-124E, against Sars-Cov-2.

Immuron said the research agreement with Monash had been signed following in-vitro studies of its "hyper-immune" bovine colostrum, or the first form of milk produced by cattle, which demonstrated anti-viral activity against severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2), the disease that caused Covid-19.

The company said that the research team, led by Dr Melanie Hutton and Prof Dena Lyras, would use Sars-Cov-2 recombinant proteins provided by Melbourne's Peter Doherty Institute to determine the efficacy of IMM-124E.

Immuron was up three cents or 12.5 percent to 27 cents with 4.4 million shares traded.

HERAMED

Heramed says it will integrate its Herabeat at-home foetal heartrate monitor and its Heracare pregnancy care platform into Teleperinatal's telehealth pregnancy service.

Heramed said it had a letter of intent with the Austin, Texas-based Teleperinatal maternal tele-health service, which operated through workplaces connecting pregnant women with virtual access to physicians and "designed to reduce the cost of pregnancy care".

The company said it would provide Herabeat and Heracare for a six-month paid pilot period, focussed on US Fortune 500 companies with the launch by April 2020, with several contracts secured and it expected to reach 10,000 women by the end of 2021.

Heramed said it would be paid $US5.00 ($A6.65) a month for every active Heracare user, with access to Herabeat for an additional $US29 ($A38.58) a month.

Heramed was up 1.5 cents or 13.0 percent to 13 cents with 1.9 million shares traded.

NOVA EYE MEDICAL (FORMERLY ELLEX MEDICAL LASERS)

Australian Ethical Investment says it has increased its substantial shareholding in Nova Eye from 21,993,912 shares (15.32%) to 23,564,224 shares (16.40%).

The Sydney-based Australian Ethical said that between October 2 and December 10, 2020 it bought 1,570,312 shares for $520,561 or an average of 33.15 cents a share.

Nova Eye was unchanged at 33 cents.

DORSAVI

Sydney's Credit Suisse Holdings says it has become a substantial shareholder in Dorsavi with 15,911,645 shares or 5.33 percent of the company.

Credit Suisse said between August 13 and December 10, 2020 it bought and sold shares with the single largest purchase 7,619,159 shares for $493,609 or 6.48 cents a share.

Dorsavi fell 0.8 cents or 15.7 percent to 4.3 cents with 27.5 million shares traded.

ELIXINOL GLOBAL

Regal Funds Management says it has reduced its substantial shareholding in Elixinol from 36,426,732 shares (15.11%) to 33,662,287 shares (13.97%).

The Sydney-based Regal Funds said that between November 27 and December 10, 2020 it sold 2,764,445 shares for $674,246 or an average of 24.4 cents a share.

Elixinol fell 2.5 cents or 10.4 percent to 21.5 cents with 7.8 million shares traded.

MEDADVISOR

The Sydney-based Regal Funds Management says it has ceased it substantial shareholding in Mesoblast.
Regal Funds said that on December 10 it sold 400,000 shares for $150,480 or 37.62 cents a share.
Last week, Regal Fund said it had increased but been diluted in Medadvisor to 17,779,990 shares (5.10%) and Biotech Daily calculates that Regal Funds retains 17,379,990 shares or 4.98 percent of Medadvisor (BD: Dec 11, 2020).
Medadvisor was unchanged at 37 cents.

MICRO-X

Micro-X says it has re-appointed Jim McDowell as a non-executive director, effective from January 1, 2021.
Micro-X said Mr McDowell was previously a director but resigned in 2018 when he was appointed chief executive of the South Australian State Government's Department of Premier and Cabinet, which required his retirement from commercial appointments and external directorships (BD: Sep 11, 2017; Aug 22, 2018).
Today, a spokesperson for Mr McDowell said he had ceased working for South Australia Premier Steven Marshall on December 11, 2020.
Micro-X said Mr McDowell was currently the chief executive officer of defence and aerospace technology company Nova Group, and previously worked for defence and aerospace companies including British Aerospace Systems Australia and BAE Systems Saudi Arabia, as well as working for the Australia Department of Defence.
Micro-X said Mr McDowell held a Bachelor of Law from the England's University of Warwick and an honorary Doctor of Philosophy from the University of South Australia.
Micro-X was up half a cent or 1.45 percent to 35 cents.

COCHLEAR

Cochlear says it has appointed Stu Sayers as acting chief financial officer to replace Brent Cubis.
In July, Cochlear said Mr Cubis would will leave the role by December 31, 2020 and a search had begun for his replacement (BD: Jul 13, 2020).
Today, Cochlear said Mr Sayers would assume the role effective from January 1, 2020 with a permanent chief financial officer expected to be appointed by June 30, 2021.
The company said Mr Sayer joined the company as head of services in July 2016 and had been a member of the executive team since his appointment.
Cochlear said that prior to joining the company, Mr Sayer had run Audible Asia Pacific, E-Trade and Yahoo in Australia and New Zealand, and previously worked for the ANZ bank, Procter & Gamble and McKinsey Consultancy.
The company said Mr Sayer held a Bachelor of Economics and Accounting and a Master of Business Administration from the Wharton business school of the University of Pennsylvania in Philadelphia.