Biotech Daily

Monday September 14, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: PRESCIENT UP 18%; DIMERIX DOWN 63%**

*** DIMERIX FALLS 76% ON DMX-200 MISSING DKD PRIMARY ENDPOINT**

*** 3 COMPANIES: 'COVID-19 RECOVERY AHEAD OF EXPECTATIONS'**

*** GI DYNAMICS RAISES $13.7m IN CRYSTAL AMBER FINANCING**

*** ORTHOCELL TREATS 300 ACCESS PATIENTS WITH CELGRO**

*** AVITA ENROLS 1st RECELL FOR VITILIGO TRIAL PATIENT**

*** STARPHARMA: 'SPL7013 KILLS SARS-COV-2, IN-VITRO'**

*** AUSCANN: NEUVIS MARIJUANA CAPSULES MEET ENDPOINTS**

*** ORTHOCELL 10m DIRECTOR OPTIONS AGM**

*** ALTHEA CANADA MARIJUANA LICENCE; BLUM MANUFACTURING DEAL**

*** AGC ASAHI GLASS TAKES 7.5% OF REGENEUS**

*** ALTHEA TO RELEASE 81.6m VOLUNTARY ESCROW SHARES**

MARKET REPORT

The Australian stock market was up 0.68 percent on Monday September 14, 2020, with the ASX200 up 40.1 points to 5,899.5 points. Twenty-three of the Biotech Daily Top 40 stocks were up, 11 fell and six traded unchanged.

Prescient was the best, up 1.1 cents or 17.7 percent to 7.3 cents, with 9.1 million shares traded. Optiscan climbed 15 percent; Amplia and Antisense rose more than 10 percent; Starpharma improved 8.15 percent; Patrys was up 7.7 percent; Paradigm climbed 5.6 percent; Imugene was up 4.4 percent; LBT, Mesoblast, Oncosil and Opthea were up more than three percent; Avita, Pharmaxis and Telix rose more than two percent; Compumedics, Medical Developments, Nova Eye, Orthocell, Polynovo and Volpara were up more than one percent, with Cochlear, Cyclopharm and Genetic Signatures up by less than one percent.

Dimerix led the falls, down as much as 56.5 cents or 76.35 percent to 17.5 cents, before closing down 46.5 cents or 62.8 percent at 27.5 cents, with 68.4 million shares traded. Proteomics lost 8.3 percent; Osprey fell four percent; Resonance retreated 3.45 percent; Cynata, Immutep, Next Science and Uscom shed two percent or more; Clinuvel, Kazia and Pro Medicus were down more than one percent; with CSL and Resmed down by less than one percent.

DIMERIX

Dimerix fell as much as 76.35 percent to 17.5 cents on news that its 45-patient, phase II trial of DMX-200 for diabetic kidney disease did not meet its primary endpoint.

Dimerix said the primary endpoint was the change in 24-hour albuminuria from baseline compared to a placebo, but there was “no significant difference between treatment with DMX-200 and a placebo across the full patient cohort”.

The company said that “although a statistically significant difference in reduction of albuminuria for the primary endpoint was not seen, with overall analysis showing no conclusive benefit of DMX-200 compared to placebo across the entire cohort of diabetic kidney disease patients (2% difference), analysis showed statistically and clinically significant variation in treatment response for patients with higher levels of albuminuria at study baseline”.

Dimerix said a subgroup of 26 patients with a higher starting baseline of albuminuria of at least 57 milligrams per millimole (mg/mmol) showed a statistically significant difference in albuminuria reduction compared to placebo, an overall average of an 18 percent reduction ($p = 0.03$).

The company said that 16 of 26 patients (61.5%) with a higher starting albuminuria level showed a reduction compared to placebo with nine of the 16 patients (56%, or 34.6% of the 26-patient sub-group) achieving a greater than 25 percent reduction, above standard best therapy, irbesarten.

Dimerix said the double-blind, randomized, placebo-controlled, crossover study enrolled 45 patients, with 40 patients meeting criteria for inclusion, and administered 240mg of oral DMX-200 for 12 weeks, preceded or followed by 12 weeks of a placebo and separated by a six-week washout period.

The company said DMX-200 was generally safe and well-tolerated.

Lead investigator Prof Simon Roger said that “a treatment, such as DMX-200, that has a good combination of strong clinical safety records and a demonstrated albuminuria lowering capability and data and that has the potential to delay the onset of end-stage kidney failure would be a significant benefit to patients”.

“With limited treatment options currently available and many patients who do not adequately respond to angiotensin receptor blockers, there remains a significant unmet need for more efficacious and durable therapies for diabetic kidney disease and focal segmental glomerulosclerosis (FSGS),” Prof Roger said.

Dimerix chief executive officer and managing director Dr Nina Webster said the results “provide further supporting and consistent data demonstrating that DMX-200 may benefit patients with inflammatory diseases, including diabetic kidney disease, FSGS and acute respiratory distress syndrome”.

“This is now the third study completed by Dimerix that shows efficacy in a group of patients with active inflammatory disease and is supportive of our plan to progress DMX-200 into a phase III clinical study in FSGS in the first half of 2021, in parallel to partnering discussions and ultimately further testing in later stage diabetic kidney disease patients,” Dr Webster said.

“The collective phase II data is invaluable in informing the design and execution of our single, phase III registration study in FSGS and further increases our confidence that DMX-200 will prove a valuable therapeutic option to patients suffering FSGS and who currently have no approved or effective medication,” Dr Webster said.

Dimerix fell as much as 56.5 cents or 76.35 percent to 17.5 cents, before closing down 46.5 cents or 62.8 percent to 27.5 cents, with 68.4 million shares traded.

AROA BIOSURGERY, NUHEARA, VISIONEERING TECHNOLOGIES

In the last week, three companies, Aroa, Nuheara and Visioneering have reported recovery from the Covid-19 pandemic, ahead of expectations.

In separate announcements, Aroa, Nuheara and Visioneering said that following the negative impact of Covid-19 and government restrictions, they continued to see recovery in sales of Aroa's skin reconstruction product, Nuheara's sound hearing and filtering earbuds and Visioneering's Naturalvue multifocal contact lenses.

Today, Aroa said sales had slowed from late March 2020, but recovery had exceeded expectations, down only nine percent for the year-to-date to August 31, 2020, compared to the previous corresponding period.

Aroa said that with the easing of restrictions, it expected to deliver growth on revenue for the six months to March 31, 2020, which was $NZ11.9 million ($A10.93 million), in the six months to March 31, 2021, "based on the absence of future disruptions".

"The recovery from the Covid-19 downturn has exceeded Aroa's internal expectations," the company said.

Last Wednesday, Nuheara said it had $1.85 million in total invoiced sales for July and August, exceeding sales for the year to June 30, 2020, and had a committed backorder for a further $2.5 million.

Last Monday, Visioneering said that in July and August, it had $US1.2 million ($A1.65 million) in revenue and $US1.1 million ($A1.51 million) in shipments to US eye care professionals, "tracking [the three months to March 31, 2020] which was a record quarter … and exceeding [the three months to September 30, 2019] which was a record quarter for net revenue in North America.

Aroa was up five cents or 3.9 percent to $1.33.

Nuheara was unchanged at 4.8 cents with 4.96 million shares traded.

Visioneering was up 0.3 cents or 11.5 percent to 2.9 cents with 3.9 million shares traded.

GI DYNAMICS

GI Dynamics says it has raised $US10 million ($A13.7 million) through a private placement led by Crystal Amber Fund.

In July, GI Dynamics said Crystal Amber and a related party would finance $US10 million ($A14.3 million), it would lose four directors and delist from the ASX on July 22, 2020 (BD: Jul 20, 2020).

Today, the company said the financing included the conversion of $US1.25 million in outstanding convertible notes into series A preferred stock and the sale of $US3.75 million in additional series A preferred stock.

GI Dynamics said it had cancelled previous warrants and an unsecured convertible promissory note, replaced with a new unsecured convertible promissory note for $US4.9 million.

The company said it also expected a second closing of the financing, including the sale of $US5 million in series A preferred stock on or before October 31, 2020, with Crystal Amber agreeing to purchase shares not purchased by other investors.

GI Dynamics said the funds would be used for operations and to support strategic priorities, including for Conformité Européenne mark approval for its Endobarrier duodenal liner for obesity and type 2 diabetes, initiation of its trial in India and to resume the Step-1 pivotal trial in the US.

GI Dynamics delisted from the ASX last year and is a US based public unlisted company.

ORTHOCELL

Orthocell says it has treated 300 patients with its Celgro collagen medical device under the Australian Therapeutic Goods Administration's special access scheme.
Orthocell said that under the approval, doctors could prescribe Celgro for nerve, tendon, cartilage and dental maxillofacial bone repair, prior to regulatory approval.
Orthocell managing-director Paul Anderson said the number was "an important milestone" demonstrating continued uptake and use of Celgro via the scheme.
"The data collected from these Celgro cases provides important real-world evidence adding to the effectiveness established in clinical studies as we prepare for first [Australian] and US approval."
Orthocell was up half a cent or 1.2 percent to 41.5 cents.

AVITA THERAPEUTICS

Avita says it has enrolled the first patient in its up-to 84 patient, multi-centre, pivotal trial of its Recell system for vitiligo at Florida's Miami Dermatology and Laser Institute.
In June, Avita said it had submitted an investigational device exemption application with the US Food and Drug Administration for the trial (BD: Jun 2, 2020).
Today, the company said the study aimed to evaluate the safety and effectiveness of the Recell system's spray-on skill cells at 24 weeks to repigment skin in patients with stable vitiligo for at least one year.
Avita said vitiligo was an autoimmune disease that attacked the epidermis layer of the skin and resulted in loss of color or pigmentation, it affected up to two percent of the global population, including 6.5 million Americans and there was no cure or universally accepted treatment to limit the spread of disease.
Avita was up 20 cents or 2.8 percent to $7.40 with 358,296 shares traded.

STARPHARMA HOLDINGS

Starpharma says further in-vitro testing of SPL7013 shows that it kills severe acute respiratory syndrome-coronavirus-2 (Sars-Cov-2), the virus that causes Covid-19.
Last month, Starpharma said it had reformulated SPL7013 into nasal antiviral sprays to inhibit Sars-Cov-2 and had completed antiviral testing to confirm that SPL7013, the active ingredient in its Vivagel for bacterial vaginosis and condom coatings "acts early in the viral replication cycle" and rendered Sars-Cov-2 inactive (BD: Aug 25, 2020).
Today, the company said pre-clinical testing at the La Jolla, California-based Scripps Research Institute showed that SPL7013 inhibited infection of host cells when the compound was applied to cells either before or after exposure to the virus.
Starpharma chief executive officer Dr Jackie Fairley said data showed "that at clinically relevant concentrations, at the concentration of the SPL7013 Covid-19 nasal spray, SPL7013 inactivates more than 99.9 percent of Sars-Cov-2".
"This potent virucidal action is consistent with the activity seen for SPL7013 for other viruses, including human immunodeficiency virus and herpes simplex virus," Dr Fairley said.
Starpharma was up 13 cents or 8.15 percent to $1.725 with 7.0 million shares traded.

AUSCANN GROUP HOLDINGS

Auscann says its 25-patient, phase I, pharmaco-kinetic and safety study of its hard-shell marijuana capsules, using the Neuvis platform, achieved all its primary endpoints.
Auscann said the two-arm, randomized, open-label, crossover study enrolled 28 healthy volunteers, with 25 patients completing the study, to compare the effect of a single dose of either its tetrahydrocannabinol (THC) and cannabidiol (CBD) combination capsule, Sativex or a pre-formulation oil comparator, with a 14-day washout period between treatments.
The company said the primary endpoint was to assess the pharmacokinetics of tetrahydrocannabinol and cannabidiol and the main active metabolite of tetrahydrocannabinol, 11-hydroxy-THC.
Auscann said its capsules showed a lower peak concentration than the oil comparator and were significant ($p < 0.05$) at the 2.5mg THC, 2.5mg CBD dose.
The company said the total drug exposure for the 10mg THC, 10mg CBD capsule was similar to the comparator oil and to patients receiving a comparable dose of the Sativex oral spray, which had 10.8mg tetrahydrocannabinol and 10.0mg cannabidiol.
Auscann said 16 patients had adverse events following treatment with the oil comparator, compared to seven patients with its capsules, with events either mild or moderate.
The company said it expected to finalize the full report in October 2020 and would begin an investigator-led phase IIa study for chronic neuropathic pain by the end of the year.
Auscann was up half a cent or 3.1 percent to 16.5 cents with 3.3 million shares traded.

ORTHOCELL

Orthocell says its annual general meeting will vote to and to issue 10,100,000 options to directors, exercisable at 60 cents each within four years.
Orthocell said it would vote to issue 4,000,000 options to managing director Paul Anderson, 2,000,000 options each to chairman Dr Stewart Washer and non-executive director Matthew Callahan, 1,200,000 options to chief financial officer Nicole Telford, 500,000 options to non-executive director Prof Lars Lidgren and 400,000 options to non-executive director Qi Xiao Zhou.
The company said the issue of options was a cost-effective way for the company to remunerate directors “as opposed to cash remuneration”.
Orthocell said it would also vote to adopt its remuneration report, to re-elect Prof Lidgren and elect Mr Callahan and Leslie Wise as directors, approve the employee incentive plan, ratify the prior issue of shares and approve an additional 10 percent placement capacity.
The meeting will be held at Building 191, Murdoch University, South Street, Murdoch, Western Australia on October 14, 2020 at 11am (AWST) or 2pm (AEDT).

ALTHEA GROUP HOLDINGS

Althea says Canada subsidiary Peak Processing Solutions has a standard processing licence from Health Canada and an agreement with Blum Beverage Company.
Althea said the licence would allow it to start operations at its Tecumseh, Ontario facility to manufacture and distribute cannabis-infused beverages, concentrates and topicals.
The company said Peak would manufacture products for third parties and supply products to Althea, aiming for revenue of $C25 million ($A26.07 million) within 18 months.
Althea said the Blum agreement allowed it to place orders for Peak to manufacture and distribute marijuana beverages, containing 5.0mg tetrahydrocannabinol.
The company said the commercial terms of the agreement were confidential.
Althea was up 6.5 cents or 11.2 percent to 64.5 cents with 6.5 million shares traded.

REGENEUS

Tokyo's AGC Asahi Glass says it has become a substantial shareholder in Regeneus with 22,459,393 shares or 7.5 percent of the company.

In December, Regeneus said AGC had agreed to terminate its manufacturing licence and joint venture agreement for Progenza in Japan (BD: Dec 20, 2019).

The company said at that time that as part of the termination arrangements, AGC elected to convert $US2.5 million of the upfront and milestone payments into Regeneus shares at a fixed price of 16 cents a share.

Regeneus said in December that the price was a 100 per cent premium to the price at December 19, 2019, and made AGC the largest shareholder with eight percent.

The company said in December it expected to issue the shares in February 2020.

Last month, Regeneus said it had a $26.4 million agreement with Tokyo's Kyocera Corp for its Progenza platform for knee osteoarthritis (BD: Aug 11, 2020)

Today, AGC said that on September 10, 2020 it acquired the shares for $3,593,503 or 16 cents a share.

Regeneus was up two cents or 11.1 percent to 20 cents with 1.1 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it will release 81,590,361 shares from voluntary escrow on September 21, 2020.

Althea said that chief executive officer Joshua Fegan held 56,250,000 of the escrow shares, Aphria Inc held 12,250,000 escrow shares, Mancann Holdings had 10,000,000 escrow shares, with PAC Partners holding 3,090,261 escrow shares.