Biotech Daily

Monday July 20, 2020

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: IMUGENE UP 16%; ACTINOGEN DOWN 9%**

*** UNIQUEST, CSL COLLABORATE ON SJÖGREN'S SYNDROME**

*** MICRO-X: US FDA 510(k) APPROVAL FOR ROVER MOBILE X-RAY**

*** ECOFIBRE RECEIPTS UP 27% TO $43.0m**

*** OPTISCAN: FEDERAL $971k FOR ORAL CANCER SCREENING TRIAL**

*** USCOM: 1A DETECTS EARLY PRE-ECLAMPSIA**

*** ADALTA: DATA, PHASE I DESIGN 'SUFFICIENT FOR FDA APPLICATION'**

*** IMMURON: FDA GUIDANCE TO US NAVY FOR CAMPYLOBACTER, E COLI**

*** FEDERAL COURT OKAYS SIENNA, BARD1 MERGER; GOODBYE SIENNA**

*** NOXOPHARM: 'NOX66 INCREASES IMMUNE CELLS IN TUMORS'; PATENT**

*** CORRECTION RECCE: 327 FOR CSIRO SARS-COV-2 PROGRAM, NOT 529**

*** GENETIC TECHNOLOGIES TO ASX: 'COVID-19 DETAILS IN PROSPECTUS'**

*** GI DYNAMICS: CRYSTAL AMBER $14m, 4 DIRECTORS TO GO, QUIT ASX**

*** MGC: $1.4m FOR CANNVALATE'S MEDICINAL CANNABIS CLINIC**

*** RESPIRI: BUY-NOW-PAY-LATER ZIP CO FOR WHEEZO**

*** LITTLE GREEN MARIJUANA PERMIT**

*** PRESCIENT REQUESTS 'COLLABORATION' TRADING HALT**

*** ZELIRA REQUESTS US LICENCE AGREEMENT TRADING HALT**

*** HERAMED TAKES 'MATERIAL COLLABORATION' HALT TO SUSPENSION**

*** PETER MEURS DILUTED TO 12.6% OF DIMERIX**

*** CREDIT SUISSE BELOW 5% IN KAZIA**

*** EVERBEST, CONSTELLATION TAKE 5.5% OF ANTERIS**

MARKET REPORT

The Australian stock market fell 0.53 percent on Monday July 20, 2020, with the ASX200 down 32.0 points to 6,001.6 points. Twenty of the Biotech Daily Top 40 stocks were up, 13 fell, six traded unchanged and one was untraded.

Imugene was the best, up 0.6 cents or 15.8 percent to 4.4 cents, with 114.9 million shares traded. Nova Eye (Ellex) climbed 14 percent; Proteomics was up 10.9 percent; Paradigm rose seven percent; Amplia was up 6.25 percent; Cynata and Genetic Signatures were up more than five percent; Kazia improved four percent; Opthea and Resonance rose more than three percent; Cyclopharm, Optiscan and Universal Biosensors climbed more than two percent; Dimerix, Impedimed, Pharmaxis, Pro Medicus and Resmed rose more than one percent; with Cochlear, Mesoblast, Neuren and Volpara up by less than one percent.

Actinogen led the falls, down 0.2 cents or 8.7 percent to 2.1 cents, with 10.9 million shares traded. Orthocell fell 4.35 percent; LBT and Telix were down more than three percent; Alterity and Uscom shed more than two percent; Avita, Clinuvel, Next Science, Polynovo and Starpharma were down more than one percent; with CSL, Medical Developments and Nanosonics down by less than one percent.

UNIQUEST, CSL

Uniquest says that with CSL it will develop and commercialize antigen-specific immune tolerance induction technology for the auto-immune disease Sjögren's syndrome.
Uniquest said CSL would fund a research and development collaboration and have an option to licence the rights to develop the University of Queensland antigen-specific immune tolerance induction (ASITI) technology for the auto-immune disease, characterized by dry eyes, mouth and other mucous membranes.
The University's commercialization division said that the technology addressed the immunological cause of auto-immune disease, by re-establishing disease-causing antigen-specific tolerance in patients, without impairing normal immunity and the ability to fight infections.
Uniquest said that the collaboration with CSL involved the identification of a liposome-encapsulated antigen candidate and subsequent progression of the lead candidate towards clinical development.
Uniquest chief executive officer Dr Dean Moss said the partnership built on the University's ongoing relationship with CSL.
"This partnership will bring together CSL's expertize in the development of treatments for autoimmune diseases and [the University's] excellence in life sciences research, following two earlier research collaborations between the partners relating to immune modifying therapies".
Uniquest said that the research team, led by Prof Ranjeny Thomas, discovered that the body's immune response could be "re-educated" to turn-off, rather than react to a self-antigen responsible for an autoimmune disease.
Prof Thomas said that the "liposome-encapsulated antigen, DEN-181 for rheumatoid arthritis, has been developed to the end of a first-in-human clinical trial".
"From that first clinical trial, we learnt a lot about DEN-181, its ability to modulate antigen-specific T cells in [rheumatoid arthritis] patients … which we are now applying to the Sjogren's syndrome program" and other pre-clinical programs.
CSL fell 72 cents or 0.25 percent to $282.70 with 378,606 shares traded.

MICRO-X

Micro-X says it has 510(k) clearance from the US Food and Drug Administration for its Rover mobile medical x-ray for military medical facilities.
Micro-X said the Rover system weighed 95 kilograms and had the higher power needed for trauma imaging, previously only available with conventional technology more than five times the Rover's weight.
The company said the FDA clearance was "a significant step forward in [its] commercialization plan for its second product.
Micro-X said the US had the world's largest defence budget, was the single largest market for the Rover system and it had been in active discussions with the US Army Medical Material Agency for some time.
The company said it planned to seek Conformité Européenne (CE) mark and Australian Therapeutic Goods Administration approval within the next 12 months.
Micro-X managing-director Peter Rowland said that "securing FDA clearance for the Rover is a hugely exciting milestone for us as we can now start full marketing and demonstration activities for this unique product to the US Army, Navy and Air Force".
"As the only deployable product with this full x-ray performance, our focus is now on ramping up sales and commercialization activities in the US to convert the interest into sales," Mr Rowland said.
Micro-X was up 1.75 cents or 11.9 percent to 16.5 cents with 13.8 million shares traded.

ECOFIBRE

Ecofibre says receipts from customers for the year to June 30, 2020 were up 26.95 percent to $42,954,000 compared to the previous corresponding period.
Ecofibre said receipts were from its Ananda Health hemp-derived cannabidiol (CBD) products and its Hemp Black hemp-based personal protective equipment.
The company said it had cash and cash equivalents of $18,252,000 at June 30, 2020 compared to $25,740,000 at June 30, 2019.
Ecofibre was up two cents or 0.9 percent to $2.27.

OPTISCAN IMAGING

Optiscan says it has received a $971,000 Federal Government grant for a trial of its confocal microscopic three-dimensional screening technology for oral cancer.
Optiscan said its imaging technology of human tissue at the cellular level allowed physicians to view tissue at 1,000-times better resolution than a magnetic resonance imaging scan and eliminated the need to have biopsies sent to a laboratory for analysis.
The company said the University of Melbourne Dental School would undertake a trial of about 150 patients over 12 months and was due to begin in September 2020.
Optiscan said the funding was part of the Medical Research Future Fund's Biomedtech Horizons Program, operated by MTP Connect.
Optiscan executive chairman Darren Lurie said that oral cancer was "one of the most common cancers globally, with a five-year mortality rate of approximately 50 percent, particularly if not detected and treated early".
"Despite this, there are currently limited tools to identify individuals who are likely to develop oral cancer, and patients are subjected to invasive biopsies," Mr Lurie said.
"Our technology is making cancer screening less invasive and more efficient, enabling early diagnosis and surgical treatment," Mr Lurie said.
Optiscan was up 0.1 cents or 2.1 percent to 4.8 cents with 2.2 million shares traded.

USCOM

Uscom says its Uscom 1A is able to detect haemodynamic changes in pre-eclampsia at five to 11 weeks, rather than the routine 20 to 25 weeks, aiding treatment.
Uscom said a research paper on the use of its ultra-sonic cardiac output monitor, co-authored by executive chair Prof Rob Phillips and titled, 'Maternal Hypertension, Advanced Doppler Haemodynamics and Therapeutic Precision: Principles and Illustrative Cases', was published in the journal Current Hypertension Reports and was available at https://link.springer.com/article/10.1007/s11906-020-01060-2.
The company said the research was the result of a collaboration with the University of Queensland and China's Shandong Maternal and Child Health Hospital.
The company said the study found that the haemodynamic changes of pre-eclampsia could be accurately detected at five to 11 weeks of pregnancy using the Uscom 1A, with treatment starting immediately, rather than the routine 20 to 25 weeks, when the changes of hypertension might be more difficult to reverse.
Uscom fell half a cent or 2.4 percent to 20 cents.

ADALTA

Adalta says the US Food and Drug Administration deems its pre-clinical data and phase I trial design "sufficient to support an investigational new drug application".
Adalta said the FDA had indicated that its phase I trial design for AD-214 for interstitial lung disease and idiopathic pulmonary fibrosis was "reasonable" and it would incorporate FDA guidance into its current phase I trial protocol and ongoing development plans.
The company said the trial design included healthy volunteers, interstitial lung disease patients and idiopathic pulmonary fibrosis patients.
Adalta said the Australian protocol had been amended to include two sentinel cohorts of two participants receiving either AD-214 or a placebo at two lower doses than the originally proposed 1mg/kg starting dose.
Adalta said it did not require FDA approval to conduct its phase I program in Australia, but it ensured that FDA-specific requirements could be incorporated before top-line safety results from part one of the trial, expected in early 2021.
The company said it had begun screening healthy volunteers in Australia.
Adalta fell 0.8 cents or eight percent to 9.2 cents with 1.65 million shares traded.

IMMURON

Immuron says the US Navy has received US Food and Drug Administration guidance for a new drug for campylobacter and enterotoxigenic Escherichia coli.
In June, Immuron said its collaboration on campylobacter and Escherichia coli (Etec or E-coli) with the US Naval Medical Research Center was back on-track, after a Covid-19 delay, to develop and evaluate a cow colostrum-based drug for moderate to severe campylobacter and E coli (BD: Jun 9, 2020).
Today, the company said the Naval Centre met with the FDA, which provided additional guidance and comments to support a planned investigational new drug (IND) application.
Immuron said it would conduct two human phase II clinical trials in 2021, with one to focus on the ability of its oral hyperimmune product to protect volunteers against moderate to severe campylobacter capsule and a second against E coli.
Immuron chief executive officer Dr Jerry Kanellos said the meeting was "an important milestone in the development of any new drug for therapeutic evaluation".
Immuron was up 2.5 cents or 11.4 percent to 24.5 cents with 1.3 million shares traded.

SIENNA CANCER DIAGNOSTICS, BARD1 LIFE SCIENCES

Sienna and Bard1 say the Federal Court of Australia has approved their scheme of arrangement for Sienna to be acquired by Bard1.

Sienna and Bard1 said that following lodgment with the Australian Securities and Investment Commission, it expected its shares to be suspended from the close of trading today, with Sienna shares to be transferred to Bard1 on July 28.

In April, the companies said that they had a merger agreement for Bard1 to acquire Sienna through a scheme of arrangement to combine their cancer diagnostic tests (BD: Apr 9, 2020).

Bard1 fell 0.1 cents or 3.3 percent to 2.9 cents with 4.4 million shares traded.

Sienna last traded at seven cents, having listed on the ASX at 20 cents in August 2017 (BD: Aug 3, 2017).

NOXOPHARM

Noxopharm says it has in-vitro evidence that its idronoxil increased the immune cell count in cancer micro-tumors and has filed a patent application.

Noxopharm said that pre-clinical data from two independent research groups confirmed that idronoxil, or NOX66, the active ingredient in Veyonda, restored cancer-fighting immune function within 'cold' micro-tumors, by converting them to 'hot' tumors.

The company said this would enable immune checkpoint inhibitors to work in more patients and in more cancer types.

Noxopharm said in-vitro data from Frankfurt, Germany-based Goethe-University Institute of Biochemistry and Hong Kong University's Department of Clinical Oncology showed that a low dose of idronoxil-activated T-cells caused them "to proliferate and to infiltrate the cancer cell spheroids … [which] positively correlated with increased killing of the … cells.

The company said that it was "close to claiming the first drug capable of converting 'cold' tumors to 'hot' tumors across multiple cancer types in a well-tolerated way".

Noxopharm chief executive officer Dr Graham Kelly said that Veyonda "could hold the answer to arguably the biggest challenge currently facing the oncology world, that of restoring the cancer-fighting ability of the body's immune system in order to achieve higher response rates to immune-oncology drugs".

Dr Kelly said that to respond to enable immune checkpoint inhibitors, individual tumors needed "to contain cancer-fighting immune cells, something that the majority of human tumors lack".

Noxopharm said it had filed a patent on July 16, 2020 with the Australian Patent Office under the international Patent Cooperative Treaty, titled 'Immuno-oncology therapy' and if granted it would provide intellectual property protection until July 17, 2040.

Noxopharm head of drug discovery and research Dr Olivier Laczka said that one of the ways that tumors became 'cold' was by increasing levels of the molecule sphingosine-1-phosphate (S1P).

"That sets up a chemical barrier that expels immune cells and then keeps them excluded," Dr Laczka said.

"[Idronoxil] is an S1P inhibitor, so it was a logical question to ask whether removing this S1P barrier … would turn cold tumors into hot tumors," Dr Laczka said.

"I am excited to report that the data released today confirms this," Dr Laczka said.

Noxopharm was unchanged at 33 cents with 4.9 million shares traded.

RECCE PHARMACEUTICALS

Recce says Recce-529 has not been accepted for the CSIRO and Doherty Institute's severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) antiviral program.
Earlier this month, Recce said Recce-327 and Recce-529 had both been selected by the Commonwalth Scientific and Industrial Research Organisation and Melbourne's Doherty Institute as "priority 1 candidates" (BD: Jul 8, 2020).
Today, the company said both compounds were delivered to the "fee for service Sars-Cov-2 antiviral screening program" but only Recce-327 had been accepted.
Recce fell three cents or 2.2 percent to $1.36 with 887,220 shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies has told the ASX that information about its planned Covid-19 test was on page 10 of a 158-page prospectus in May 2020.
The ASX noted Genetic Technologies announcements on its breast cancer test, Covid-19 testing capacity, patent announcements and a Youtube interview with acting chief executive officer Dr George Muchnicki.
The ASX said that in the video interview, Dr Muchnicki disclosed the $US1.0 million to US1.5 million cost of developing the test, that six people were working on its development in Melbourne and that it expected to develop the test in three to six months.
The ASX noted the change in price from 0.5 cents on July 15, 2020 to 1.3 cents on July 16, 2020, a significant increase in trading volumes and asked the company when the video was first published and if it had previously announced information about the cost and timeframe to develop the test.
Genetic Technologies told the ASX that the video was first announced as a link on June 12, 2020 and disclosed to the ASX that it expected to use funds for development of a Covid-19 severity test on page 10 of its prospectus on May 29, 2020.
The company said that individual comments referred to in the video may not in and of themselves be considered to be material on their own, but reference to reoccurring research and development spending and product development costs were contained in its annual reports and appendix 4C updates.
Genetic Technologies was up 0.05 cents or 4.35 percent to 1.2 cents with 243.1 million shares traded.

GI DYNAMICS

GI Dynamics says Crystal Amber and a related party will finance $US10 million ($A14.3 million), it will lose four directors and delist from the ASX on Wednesday.
GI Dynamics said it would offer Crystal Amber series A preferred shares at 17.56 cents a share, a new class of shares to be created subject to shareholder approval, for $US5 million by mid-August and a further $US5 million by October 31, 2020.
The company said the four current board members would resign following the company's removal from the ASX and would appoint new directors prior to resigning.
GI Dynamics said the proposed financing would be subject to shareholder approval, its removal from the ASX on Wednesday July 22, 2020 and a restructuring of the outstanding $US10 million August 2019 convertible note to an August 2020 note, with five percent interest and a June 30, 2022 maturity date (BD: Aug 22, 2019).
GI Dynamics was unchanged at 0.2 cents with 2.1 million shares traded.

MGC PHARMACEUTICALS

MGC says it will pay Cannvalate Pty Ltd $1 million in shares and $400,000 in cash for its Melbourne subsidiary Medicinal Cannabis Clinic Pty Ltd.
MGC said it would incorporate a new company to hold all operating clinic-based assets, data and intellectual property and Medicinal Cannabis Clinic staff would continue operations.
The company said the new company would obtain relevant state and federal licences to import and distribute medical marijuana products and move its supply chain.
MGC said the acquisition would allow it to wholesale and distribute products directly to other clinics and pharmacies to reduce storage and distribution costs, and to reduce logistics and operational costs.
MGC was unchanged at 2.4 cents with 5.55 million shares traded.

RESPIRI

Respiri says it has a merchant services agreement with Zip Co subsidiary and buy now pay later provider Zip Money Payments Pty Ltd.
Respiri chief executive officer Marjan Mikel said the agreement would provide financial flexibility to asthmatic patients seeking access to its Wheezo platform.
Respiri was up half a cent or 3.45 percent to 15 cents with 11.3 million shares traded.

LITTLE GREEN PHARMA

Little Green says the Office of Drug Control has granted it a marijuana cultivation and production permit for its expanded cultivation and manufacturing facility.
Little Green Pharma said the permit was for its expanded facility, permitting and including nine flowering rooms, two mother plant rooms and two vegetation rooms.
Little Green was up two cents or 6.1 percent to 35 cents.

PRESCIENT THERAPEUTICS

Prescient has requested a trading halt “pending an announcement by the company to the market regarding a collaboration announcement”.
Trading will resume on July 22, 2020 or on an earlier announcement.
Prescient last traded at 5.8 cents.

ZELIRA THERAPEUTICS

Zelira has requested a trading halt “pending an announcement by the company in relation to a licencing agreement in the United States of America”.
Trading will resume on July 22, 2020 or on an earlier announcement.
Zelira last traded at 5.3 cents.

HERAMED

Heramed has requested a voluntary suspension to follow the trading halt requested last week “for … a material collaboration agreement” (BD: Jul 16, 2020).
Trading will resume on July 22, 2020 or on an earlier announcement.
Heramed last traded at 8.9 cents.

DIMERIX

Peter Meurs says his 24,819,309 share-holding in Dimerix has been diluted from 13.67 percent to 12.55 percent of the company.
The Melbourne-based Mr Meurs said that he was diluted on June 29, 2020 following the $5.8 million placement at 36 cents a share (BD: Jun 22, 2020).
Dimerix was up half a cent or 1.5 percent to 34 cents with 1.1 million shares traded.

KAZIA THERAPEUTICS

Credit Suisse Holdings says it has ceased to be a substantial shareholder in Kazia.
In April, the Sydney-based Credit Suisse said that it had become substantial with 5,289,148 shares or 5.86 percent of the company.
Today, Credit Suisse said that it bought and sold shares between April 24 and July 15, 2020, with the single largest sale of 238,101 shares on June 25, 2020 for $119,664 or 50.26 cents a share.
Kazia was up two cents or four percent to 52 cents.

ANTERIS TECHNOLOGIES (FORMERLY ADMEDUS)

Constellation Immunotherapy, Everbest City and Fung Yuen Wong (Everbest Group) say they have become substantial shareholders in Anteris with 326,951 shares or 5.53 percent.
Last week, Hong Kong's Star Bright, with Constellation, said it had reduced its substantial holding in Anteris from 1,277,155 shares (21.61%) to 730,192 shares or 12.35 percent (BD: Jul 17, 2020).
Today, the Everbest Group said that on July 14, 2020 it acquired the shares for $HK10,000,000 ($A1,845,728) or $5.65 a share.
Anteris fell 49 cents or 11.4 percent to $3.81.