Biotech Daily

Tuesday July 14, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PHARMAXIS UP 21%; DIMERIX DOWN 11%**

*** POLYNOVO: BARDA $21.6m FOR NOVOSORB BTM TRIAL**

*** PHARMAXIS: FDA ORPHAN STATUS FOR PXS-5505 FOR MYELOFIBROSIS**

*** QUEENSLAND UNI: 1st COVID-19 VOLUNTEER DOSED; VACCINE NEXT YEAR**

*** ALCIDION $686k MURRUMBIDGEE MIYA PRECISION, MEMRE CONTRACT**

*** MACH7 COMPLETES $41m CLIENT OUTLOOK ACQUISITION**

*** ZELIRA PHASE I ZTL-103 MARIJUANA PAIN TRIAL 'SAFE, TOLERABLE'**

*** IMUGENE PHASE I PD1-VAXX TRIAL FOR LUNG CANCER APPROVED**

*** NEUROSCIENTIFIC: EMTIN B INCREASES MYELIN FORMATION, IN-VITRO**

*** HERAMED SHARE PLAN RAISES $233k, TOTAL $2.55m**

*** NUHEARA PLEADS SCHULTZ TO ASX 75% PRICE QUERY**

*** ATO SIENNA-BARD1 MERGER CAPITAL GAINS TAX RELIEF**

*** MGC LICENCE TO GROW MARIJUANA FOR RMIT RESEARCH**

*** BLUECHIIP TAKES 'LABCON AGREEMENT' HALT TO SUSPENSION**

*** ANTEOTECH REQUESTS 'LIFE SCIENCES DEVELOPMENT' TRADING HALT**

*** GI DYNAMICS REQUESTS CRYSTAL AMBER NOTE TRADING HALT**

*** REGAL FUNDS BELOW 5% IN MEDICAL DEVELOPMENTS**

*** RECCE'S DR GRAHAM, OLGA MELROSE TAKE 25.3%**

*** PLATINUM TAKES 19.89% OF AMPLIA**

*** ALLAN MOSS, BLUEFLAG TAKE 8.7% OF AMPLIA**

*** RACE DIRECTOR DR WILLIAM GARNER DILUTED TO 11.4%**

*** RECCE APPOINTS DR ALAN DUNTON DIRECTOR**

*** IMAGION LOSES CFO BRIAN CONN; CFO WANTED**

MARKET REPORT

The Australian stock market fell 0.61 percent on Tuesday July 14, 2020, with the ASX200 down 36.4 points to 5,941.1 points. Five of the Biotech Daily Top 40 stocks were up, 30 fell and five traded unchanged. All three Big Caps fell.

Pharmaxis was the best, up 1.6 cents or 20.5 percent to 9.4 cents with 18.4 million shares traded. Amplia and Patrys climbed eight percent or more; Nova (Ellex) improved 4.7 percent; with Antisense up 3.1 percent.

Dimerix led the falls, down four cents or 10.96 percent to 32.5 cents, with 2.2 million shares traded, followed by LBT down 10.8 percent and Alterity 10.3 percent. Actinogen, Kazia and Prescient lost more than eight percent; Mesoblast and Next Science were down seven percent or more; Paradigm, Telix and Uscom fell more than six percent; Avita and Orthocell shed more than five percent; Oncosil, Opthea, Osprey and Universal Biosensors retreated four percent or more; Immutep, Neuren and Proteomics were down more than three percent; Clinuvel, Cynata and Starpharma shed more than two percent; Cyclopharm, Nanosonics, Polynovo, Resmed and Volpara were down one percent or more; with Cochlear, CSL, Genetic Signatures, Medical Developments and Pro Medicus down by less than one percent.

POLYNOVO

Polynovo says the US Government has provided $US15 million ($A21.6 million) for its pivotal trial of Novosorb biodegradable temporizing matrix (BTM) for full thickness burns.
Polynovo said the funding was from the US Biomedical Advanced Research and Development Authority (BARDA) and it would make a modest co-funding and in-kind contribution for the trial.
The company said it aimed to gather data on the effectiveness of Novosorb BTM for full thickness burns, which would enable it to apply for pre-market approval from the US Food and Drug Administration approval for the indication.
Polynovo managing-director Paul Brennan said the BARDA's "substantial non-dilutive funding for this and other programs better enables Polynovo to bring our innovative, life-saving products to the US and the rest of the world."
Polynovo fell four cents or 1.7 percent to $2.30 with 6.2 million shares traded.

PHARMAXIS

Pharmaxis says it has been granted US Food and Drug Administration orphan drug designation for its oral lysyl oxidase (LOX) inhibitor PXS-5505 for myelofibrosis.
Pharmaxis said myelofibrosis was a rare cancer, in which normal bone marrow was gradually replaced with a fibrous scar-like material and led to progressive bone marrow failure.
Pharmaxis chief executive officer Gary Phillips said the company was "very pleased with the FDA orphan-drug designation for PXS-5505".
"Pharmaxis believes that the current treatments for myelofibrosis can be augmented by a pan-LOX inhibitor and be disease modifying in a market with high unmet need and significant deal values for programs with clinical proof of concept," Mr Phillips said.
"We expect to file an investigational new drug application with the FDA shortly and will provide an update on the clinical trial plans at that time".
Pharmaxis was up 1.6 cents or 20.5 percent to 9.4 cents with 18.4 million shares traded.

UNIVERSITY OF QUEENSLAND, CSL

The University of Queensland says the first two of 120 healthy adult volunteers have been dosed in its phase I safety and dose escalation trial of a vaccine for Covid-19.

University of Queensland vaccine project co-leader Prof Paul Young told ABC Radio National the phase I trial was looking for safety and the production of antibodies and a combined phase II/III, to be run by CSL, could be completed by the middle of 2021.

Prof Young said that "nothing is guaranteed … we're really just saying next year is our hope that we'll be able to roll-out the first batches of vaccine".

In a media release, Prof Young said the first human trial would evaluate the safety of the vaccine and the immune response it generates in a group of healthy volunteers.

"The green light to move into this first phase of human trials follows extensive pre-clinical testing that started when we first selected our lead vaccine candidate on February 14," Prof Young said.

"This testing showed that the vaccine was effective in inducing antibodies that were able to neutralize the virus," Prof Young said. "Further studies have shown that the vaccine was safe to give to people."

In February, CSL said it partnered with the University of Queensland for its coronavirus disease-19 (Covid-19) vaccine program to combine with its influenza subsidiary Seqirus's MF59 adjuvant (BD: Feb 12, 2020).

Last month, CSL said it would manufacture, develop, and distribute the University of Queensland's Covid-19 vaccine with the Oslo-based Coalition for Epidemic Preparedness Innovations (BD: June 5, 2020).

Prof Young said he expected to have preliminary results "after about three months, and if all goes well, we can move as fast as we can to the next stage in the vaccine's development".

University of Queensland vaccine co-leader Prof Keith Chappell said the pace of the project had been "relentless and … a fantastic achievement to move so quickly into clinical trials".

Prof Chappell said the University had reached this stage with help from collaborators at the Australian National University and the Doherty Institute.

Project director Prof Trent Munro said that "if things go to plan, CSL will rapidly advance production of tens of millions of doses and move the program into later stage clinical testing, regulatory approval, large-scale manufacture and distribution".

Prof Young told Biotech Daily that the first data from the phase I, placebo-controlled, dose-escalation trial would be unblinded in September and the volunteers would be monitored for 12 months.

Prof Young said the phase II/III trial and its start date was "really a question for CSL who will be taking on oversight of the phase II/III studies, but I expect [by the end of] this year".

Prof Young said the primary endpoints were to be worked out by CSL, "however immunogenicity and efficacy are the likely primary endpoints".

"If you are looking for a date, as I said below there are still too many variables to be sorted, but from the middle to latter part of 2021 would be desirable," Prof Young said.

A CSL spokesperson told Biotech Daily the "the exact production timelines are subject to safety and efficacy data generated by phase I, II and III trials as well as regulatory approval".

"Vaccine development is a complex process and this stage of research development contains a high risk of failure," the spokesperson said.

"As soon as we have more information, we will provide an update," CSL said.

The University said that the Queensland Government provided $10 million for the project, the Federal Government $5 million and more than $10 million came from donors.

ALCIDION GROUP

Alcidion says the Murrumbidgee Local Health District has contracted $686,000 for its Miya Precision patient management platform and Memre mobile application.
Alcidion said that earlier this year, the Wagga Wagga, New South Wales -based Murrumbidgee Local Health District elected to use Miya Precision for an initial 12 months from January 1, 2020, but the platform now incorporated a Covid-19 monitoring dashboard for positive and at-risk patients and out-of-hospital monitoring capabilities.
The company said it would roll out its Miya Memre application, which provided access to test results and risk indicators, to up to 200 clinicians and its Miya Precision to the Wagga Wagga Base Hospital.
Alcidion was unchanged at 15 cents with 3.3 million shares traded.

MACH7 TECHNOLOGIES

Mach7 says it has completed the $40,942,776 acquisition of the Waterloo, Ontario-based Client Outlook Inc.
Earlier this month, Mach7 said it had raised a total of $34.8 million through a placement and rights offer at 68 cents a share to buy Client Outlook (BD: Jul 1, 2020).
Today, the company said it had paid $40,836,431 in cash to vendor, with $106,345 withheld to meet certain liabilities.
Mach7 fell six cents or 6.8 percent to 82 cents with 1.8 million shares traded.

ZELIRA THERAPEUTICS

Zelira says its seven-patient, phase I, dose escalation study of its marijuana-based ZTL-103 for chronic pain has met its primary and secondary safety endpoints.
Zelira said the study, at Melbourne's St Vincent's Hospital in conjunction with the Perth, Western Australia-based Emerald Clinics, assessed safety in patients already using high doses of opioids.
The company said nine patients were enrolled and seven patients completed the study and were administered a single sublingual dose of ZTL-103 containing five milligrams (mg) of total cannabinoids including 2.5mg tetrahydrocannabinol (THC) and 2.5mg cannabidiol (CBD), followed by a seven day washout period, another single dose and then two daily doses for seven days, before escalating to 20mg for seven days, 30mg for seven days and a single dose of 25mg.
Zelira said ZTL-103 was well tolerated with no serious adverse events and the study provided details on the rate of cannabinoid uptake after dosing, which could help inform dosing strategy.
The company said there was no significant change in pain severity, but pain interferences scores showed a dose responsive and statistically significant reduction at daily doses of more than 10mg ($p = 0.043$).
Zelira said it also found statistically signification reductions in patient reported scores for anxiety ($p = 0.007$), stress ($p = 0.03$) and depression ($p = 0.002$), at doses of 30mg or more of THC and CBD.
The company said that at daily doses of 10mg or more ZTL-103 "reduced median scores from 'severe or moderate' to 'mild or normal' category for anxiety, stress and depression".
Zelira fell 0.1 cents or 1.8 percent to 5.4 cents with 1.1 million shares traded.

IMUGENE

Imugene says the Chris O'Brien Lifehouse cancer hospital has approved a 32-patient, phase I trial of its anti-cancer immunotherapy candidate PD1-Vaxx for lung cancer.
In April, Imugene said it planned to begin first-in-human, phase I trials by the end of 2020, including a multi-centre, dose escalation study of PD1-Vaxx, or IMU-201, to test different doses on patients with non-small cell lung cancer as a monotherapy and in combination with immune checkpoint inhibitors (BD: Apr 27, 2020).
Today, the company said the primary aim of the trial was to determine safety and optimal biological dose, but efficacy, tolerability and immune response would also be measured.
Imugene said additional clinical sites would be opened in Australia and in the US following US Food and Drug Administration investigational new drug approval.
The company said it expected to begin patient screening in August.
Imugene was unchanged at 3.4 cents with 48.6 million shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says its Emtin B for multiple sclerosis increases myelin formation more effectively than Copaxone, in-vitro.
Neuroscientific said the study, conducted by the Marseilles-based contract research organization Neuron Experts, compared Emtin B to the leading marketed drug for multiple sclerosis, Copaxone.
The company said multiple sclerosis was a chronic neurodegenerative disease in which the immune system mistakenly attacked the myelin sheath surrounding nerve fibres.
Neuroscientific said it analyzed Emtin B's effect on myelin formation by measuring the area of the myelin sheaths surrounding the nerve cell axons.
The company said it found that Emtin B significantly increased myelin formation compared to a control at concentrations of 30 micrograms/millilitre (µg/ml) to 150µg/ml and was more effective than Copaxone at 60µg/ml, 120µg/ml and 150µg/ml; and increased myelin formation by more than 30 percent at 150µg/ml and more than 25 percent at 120µg/ml.
Neuroscientific said it expected to make the full report available this month.
Neuroscientific rose three cents or 15 percent to 23 cents with 9.7 million shares traded.

HERAMED

Heramed says it has raised $2.55 million through a $2.32 million placement and $233,000 share purchase plan at nine cents a share.
Last month, Heramed said it had commitments to raise $2.32 million in a placement at nine cents a share and hoped to raise a further $1.5 million in a share plan at the same price (BD: Jun 5, 2020).
Today, the company said that with Henslow Pty Ltd, it would seek to place the shortfall and had firm indicative bids to place more than half of the shortfall.
Heramed fell 0.4 cents or 4.3 percent to 8.9 cents.

NUHEARA

Nuheara 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 rose 75 percent from 2.0 cents on July 9, 2020 to 3.5 cents yesterday July 13 and noted a significant increase in the trading volume.
Nuheara fell half a cent or 13.9 percent to 3.1 cents with 28.7 million shares traded.

SIENNA CANCER DIAGNOSTICS

Sienna says it has received a draft class ruling from the Australian Taxation Office for capital gains tax rollover relief for shareholders to exchange shares for Bard1 shares.
In April, Sienna and Bard1 said they had agreed for Bard1 to acquire Sienna through a scheme of arrangement to combine their cancer diagnostic tests, later approved by the Federal Court of Australia (BD: Apr 9, Jun 11, 2020).
Today, the company said a final ruling would be provided following shareholder approval at a July 15 meeting, following Federal Court approval scheduled for July 17 and following the expected July 28, 2020 final merger.
Sienna was unchanged at 6.7 cents.

MGC PHARMACEUTICALS

MGC says the Australian Office of Drug Control has issued a cultivation permit to grow marijuana for research with the Royal Melbourne Institute of Technology.
MGC said the botanical research projects included cultivating and breeding strains to test against cancer cells to optimize efficacy.
The company said it would focus on identifying new cannabinoids and formulas to find new treatments, initially screening for anti-cancer activity for melanoma, prostate and other cancer cells.
MGC was unchanged at 2.3 cents with 24.7 million shares traded.

BLUECHIIP

Bluechiip has requested a suspension to follow the trading halt regarding the Labcon North America “long term development and supply agreement” (BD: Jul 10, 2020).
In 2018, Bluchiip said it had a three-year deal worth $US11.6 million ($A15.9 million) to supply its tracking chips, hardware and services to the San Francisco-based Labcon (BD: Aug 29, 2018).
Trading will resume on July 16, 2020 or on an earlier announcement.
Bluechiip last traded at 5.7 cents.

ANTEOTECH

Anteotech has requested a trading halt “pending an announcement by the company concerning a development in our life sciences division”.
Trading will resume on July 16, 2020 or on an earlier announcement.
Anteotech last traded at 2.2 cents.

GI DYNAMICS

GI Dynamics has requested a trading halt pending an announcement on the potential conversion of the … 2017 senior secured convertible note issued to Crystal Amber”.
Earlier this month, GI Dynamics said it had further extended the maturity date of its $US5,000,000 ($A6,595,767) Crystal Amber convertible note to July 31, 2020, and said that if funding was not secured, it “would need to cease operations” and delist from the ASX (BD: Jun 15, 2017; May 4, 18, Jun 17, Jul 1, 2020).
Trading will resume on July 16, 2020 or on an earlier announcement.
GI Dynamics last traded at 0.3 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Regal Funds Management says it has ceased to be a substantial shareholder in Medical Developments selling 40,000 shares at $6.82 a share.
Yesterday, the Sydney-based Regal Funds said that it had reduced its holding to 3,307,076 shares or 5.04 percent (BD: Jul 13, 2020).
Today, Regal Funds said that on July 9, 2020 it sold 40,000 shares and Biotech Daily calculates that Regal Funds holds 3,267,076 shares or 4.98 percent of the company.
Medical Developments fell six cents or 0.9 percent to $6.40 with 236,000 shares traded.

RECCE PHARMACEUTICALS

Recce founder Dr Graham Melrose and Olga Melrose say they have increased their holding from 30,375,003 shares (22.70%) to 36,450,003 shares (25.28%).
The Mount Claremont, Western Australia-based Dr and Ms Melrose said that on July 9, 2020 they converted 6,075,000 class C performance shares.
Recce was up 15 cents or 16.1 percent to $1.08.

AMPLIA THERAPEUTICS

Platinum Investment Management says it has increased its substantial shareholding in Amplia from 5,715,000 shares (8.60%) to 17,169,000 shares (19.89%).
The Sydney-based Platinum said that on July 10, 2020 it acquired 11,454,000 shares for $1,145,400 or 10 cents a share.
This month, Amplia said it hoped to raise $4 million through an underwritten, rights offer at 10 cents a share and confirmed the institutional part raised $2 million (BD: Jul 1, 3, 2020).
Amplia was up one cent or eight percent to 13.5 cents with 3.4 million shares traded.

AMPLIA THERAPEUTICS

Former Macquarie Group managing-director Allan Edward Moss and Blueflag Holdings say they have become substantial in Amplia with 7,500,000 shares or 8.69 percent.
The Sydney-based Blueflag said that on July 14, 2020 it acquired the shares for $750,000 or 10 cents a share (see above).

RACE ONCOLOGY

Race director Dr William Garner says his 13,930,078 share-holding has been diluted from 12.75 percent to 11.41 percent.
The San Juan, Puerto Rico-based Dr Garner said that on July 14, 2020 he was diluted in the company's $3 million placement at 60 cents a share a share and as the result of an exercise of options In March, June and July, 2020 (BD: Jul 13, 2020).
Race was up 5.5 cents or 5.7 percent to $1.02 with 2.4 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has appointed Dr Alan Dunton as an independent non-executive director and as a member of its audit, risk and remuneration and nomination committees.
Recce said Dr Dunton had more than 30 years of pharmaceutical experience, including as chief executive officer of Panacos Pharmaceuticals, Metaphor Pharmaceuticals and chief operating officer of Emisphere Technologies.
The company said he was currently a director for Oragenics Inc, Palatin Technologies, Cormedix Inc and Regeneus.
Recce said Dr Dunton previously worked for Johnson & Johnson, including as president and managing director of the Janssen Research Foundation and vice president of research and development at the RW Johnson Pharmaceutical Research Institute.
The company said Dr Dunton held a Doctor of Medicine from the New York University School of Medicine and a Bachelor of Biochemistry from the Buffalo-based State University of New York.

IMAGION BIOSYSTEMS

Imagion says chief financial officer Brian Conn has resigned effective from August 1, 2020 “to take a full time chief financial officer position with another of his clients”.
Imagion executive chairman Bob Proulx thanked Mr Conn for his work over the past three years and said he had “been instrumental in our early formative period”.
The company said it had begun the search for an Australian-based replacement.
Imagion fell 0.1 cents or 2.3 percent to 4.3 cents with 13.8 million shares traded.