Biotech Daily

Monday June 15, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: PATRYS UP 7%; PROTEOMICS DOWN 19%**

*** PROTEOMICS: 'PROMARKERD SIGNIFICANTLY PREDICTS RENAL DECLINE'**

*** AVITA OVERWHELMING BACKS US MOVE**

*** NOXOPHARM UNDERWRITTEN RIGHTS RAISE $7.9m**

*** MEDLAB RAISES $5.4m, SHARE PLAN FOR $4m MORE**

*** AZURE (INVICTUS) PREPARES IVB001 NAFLD, NASH STUDY**

*** CELLMID: WONDFO COVID-19 TEST 86% SENSITIVE; DOHERTY SAYS 69%**

*** PERENNIAL TAKES 7.4% OF ATOMO**

*** ONE FUNDS TAKES 8.4% OF BLUECHIIP**

*** CANN GROUP ISSUES CSIRO 325k SHARES FOR MARIJUANA R&D**

*** CANN GLOBAL: MARIJUANA STRAIN STOPS MS IN-VITRO, MICE**

*** MGC, IM CANNABIS TO SELL MARIJUANA CANNEPIL IN ISRAEL**

*** THC: CANNATREK TO SUPPLY DRIED MARIJUANA FLOWER**

*** ESENSE, ANC J-V FOR SKIN CARE, HAIR CARE, SANITIZER**

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

*** PHARMAUST TAKES 'SARS-COV-2 TEST RESULTS' TO SUSPENSION**

MARKET REPORT

The Australian stock market fell 2.19 percent on Monday June 15, 2020, with the ASX200 down 128.0 points to 5,719.8 points. Six of the Biotech Daily Top 40 stocks were up, 29 fell, four traded unchanged and one was untraded. All three Big Caps fell.

Patrys was the best, up 0.1 cents or 7.1 percent to 1.5 cents, with 35,000 shares traded. Uscom climbed 4.8 percent, Clinuvel and Volpara improved more than three percent; Kazia was up 1.2 percent; with Mesoblast up 0.3 percent.

Proteomics led the falls, down 10.5 cents or 18.6 percent to 46 cents with 2.6 million shares traded. Amplia lost 12.5 percent; Imugene fell 11.1 percent; Prescient shed 10.3 percent; LBT and Osprey lost more than nine percent; Alterity, Next Science and Pharmaxis fell more than six percent; Compumedics and Paradigm were down more than five percent; Actinogen, Avita, Cynata and Universal Biosensors fell four percent or more; Immutep, Impedimed and Starpharma were down three percent or more; Cochlear, Dimerix, Medical Developments and Resonance shed two percent or more; with CSL, Ellex, Genetic Signatures, Neuren, Orthocell and Resmed down one percent or more.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says a 2,972-patient sample analysis shows Promarkerd can predict “a clinically significant decline in kidney function up to four years in advance”.

Proteomics said that the retrospective analysis of the Johnson & Johnson 4,330-patient, phase III ‘Canvas’ trial of canagliflozin for type 2 diabetes patients with cardiovascular risk, was presented on the weekend at the American Diabetes Association’s Scientific Sessions, which ran from June 12 to 16, 2020.

In 2017, Proteomics said its four-year, 792-patient validation study showed that the Promarkerd blood test could predict diabetic kidney disease onset better than any current measure (BD: Jun 13, 2017).

Today, the company said the study, conducted with the University of Western Australia Medical School and Janssen Research and Development, was a randomized, global multi-centre study of type 2 diabetes patients with a high-risk of cardiovascular disease.

The company said that 926 patients or 31.1 percent of all patients developed chronic kidney disease (CKD) in the follow-up period.

Proteomics said the study showed that moderate and high-risk test scores were increasingly prognostic for chronic kidney disease compared to low-risk test scores.

The company said patients predicted by Promarkerd to be high-risk were 13.5 times more likely to develop the disease, with “high statistically significance” ($p = 1.3 \times 10^{-104}$).

Proteomics said an increase in Promarkerd score was significantly associated with poor patient chronic kidney disease outcomes.

The company said Promarkerd achieved positive predictive value at the high-risk cut-off of 74 percent and a negative predictive value at the moderate-risk cut-off of 83 percent.

Proteomics managing-director Dr Richard Lipscombe said the results were “far-reaching for the commercial roll-out of the test because they substantiated the effectiveness of Promarkerd as a prognostic test for diabetic kidney disease in a globally recognized clinical cohort”.

“Promarkerd works, it’s safe and it can be run by accredited laboratories now as a laboratory developed test,” Dr Lipscombe said. “This is really a green light for using this simple blood test, globally.”

“This technology has the ability to improve the lives of the 31 million Americans living with diabetes,” Dr Lipscombe said.

“If patients know that they’re on the path to diabetic kidney disease, they can intervene sooner to treat the condition,” Dr Lipscombe said.

Proteomics said the result paved the way for future US Food and Drug Administration approval of the test and complemented the recent Conformité Européenne (CE) mark registration of the Promarkerd immunoassay in the European Union (BD: April 16, 2020).

The company said it would undertake further research to determine if patients displayed lower Promarkerd risk scores after treatment and to examine the performance of Promarkerd for cardiovascular disease.

Proteomics said it was focused on partnering to take Promarkerd to US patients.

Proteomics fell 10.5 cents or 18.6 percent to 46 cents with 2.6 million shares traded.

AVITA MEDICAL

Avita says shareholders overwhelmingly supported the redomicile to the US at its scheme meeting (BD: Apr 21, 2020).

Avita said 926,498,581 votes (97.75%) approved the move, with 21,357,290 votes (2.25%) opposed.

Avita fell two cents or 4.65 percent to 41 cents with 20.3 million shares traded.

NOXOPHARM

Noxopharm says it has raised $7,918,876.42 through a fully-underwritten, non-renounceable, pro rata rights issue at 13 cents a share.
Noxopharm said the 13 cents issue price was a 33 percent discount to the 15-day volume-weighted average price to May 6, 2020.
The company said that 42,395,545 shares or 69.6 percent of the total 60,914,434 share entitlements were taken up, with shares worth $2,407,456 allocated to the underwriter.
Noxopharm said shareholders would be allotted one option for every three new shares subscribed for, exercisable at 30 cents each by June 18, 2023.
The company said the funds would be used for working capital for Veyonda, Darrt-2, Lupin and Covid-19 clinical programs.
Noxopharm fell 1.5 cents or 7.7 percent to 18 cents.

MEDLAB CLINICAL

Medlab says it has commitments to raise $5.4 million in a placement and hopes to raise a further $4 million through a share purchase plan at 15 cents a share.
Medlab said the offer price was at a 26.8 percent discount to the last closing price of 20.5 cents on June 10, 2020 and the share plan was not underwritten.
The company said that the share plan record date was June 12, the offer would open on June 17 and would close on July 3, 2020.
Medlab said the funds would be used the ensure its marijuana-derived Nanabis path to phase III trials was uninterrupted, “to bridge multiple research catalysts over the next 12 months”, for working capital for Nanabis, its vitamins, minerals and supplements inventory and to cover potential Covid-19-related regulatory delays.
The company said Acova Capital and Morgans Corporate were joint lead managers to the placement.
Medlab fell 3.5 cents or 17.1 percent to 17 cents with 1.6 million shares traded.

AZURE HEALTH TECHNOLOGY (MERGED WITH INVICTUS BIOPHARMA)

Azure says it is preparing for an up to 80-patient phase II clinical study of IVB001 for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH).
Earlier this month, Azure said it had raised $1,686,000 through the issue of convertible notes at $1.00 each to sophisticated investors to fund the acquisition of Invictus Biopharma for its tocotrienols pharmaceuticals, food additive and supplements business (BD: Jun 4, 2020).
Today, the company said the study would be randomized, double-blind and placebo-controlled, and would analyze the safety and efficacy of IVB001, a drug candidate based on non-invasive and direct delivery of tocotrienols using its proprietary transmucosal delivery platform.
The company said the study would be conducted at eight sites in Australia and New Zealand, with Datapharm Australia its clinical research organization.
Azure said tocotrienols acted as strong antioxidants, had anti-fibrotic activity, distributed preferentially to the liver, and addressed the abnormal retention of fat in liver cells, called steatosis, inflammation caused by steatosis and the generation of scar tissue, called fibrosis, as a result of inflammation.
The company said that non-alcoholic fatty liver disease and steatohepatitis had no approved treatments and if left unchecked could progress to live cirrhosis and liver cancer.
Azure is a public unlisted company.

CELLMID, THE DOHERTY INSTITUTE

Cellmid says Melbourne's Doherty Institute evaluates the Wondfo Covid-19 test as 68.6 percent sensitive across all time points, compared to Wondfo's 86.4 percent claim.
In May, Cellmid requested a voluntary suspension to respond to a media article on the accuracy or otherwise of Covid-19 tests following its announcements of importing 600 Wondfo test kits (BD: Mar 30, Apr 7, 14, 22, May 7, 15, 2020)
Cellmid said the Doherty Institute interim evaluation of the test for antibodies to the severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) was produced for the Australian Therapeutic Goods Administration as part of its post market review of all serology-based Covid-19 point-of-care tests on the Australian Register of Therapeutic Goods (ARTG) to verify their ability to detect antibodies to Sars-Cov-2, the virus that causes Covid-19.
The company said the Doherty Institute results "indicate testing against polymerase chain reaction-tested patient samples and do not represent evaluation in a clinical setting, unlike Wondfo's own validation".
Cellmid said that comparing sensitivity, or the likelihood of true positives, at nine to 14 days after the expected development of antibodies, was found by the Doherty Institute to be 76.2 percent, compared to the Wondfo claim of 85.2 percent.
The company said that at 15 days and more, the Doherty Institute said the test was 93.8 percent sensitive, compared to the Wondfo 94.3 percent evaluation.
Cellmid said that specificity, or true negatives, were evaluated at 97.8 percent by the Doherty Institute and 99.6 percent by Wondfo, across all time points.
Cellmid chief executive officer Maria Halasz said while "there are still 17 other tests listed on the ARTG to be reviewed, we are very pleased to see that the results of the review outlined in the interim Doherty Report make the Wondfo Test one of the best performing of the five antibody tests reviewed to date across all specificity and sensitivity metrics".
"The testing showed performance results which are consistent with the manufacturer's claims in the meaningful period of 14 [or more] days following onset of symptoms, when antibodies are expected to be present in most patients," Ms Halasz said.
Cellmid said the Doherty Report concluded that the Wondfo test "achieves the manufacturer's stated performance when serum samples collected greater than 14 days following the onset of symptoms are included only" and had the highest overall sensitivity of five devices tested.
Cellmid fell 5.5 cents or 29.7 percent to 13 cents with 2.7 million shares traded.

ATOMO DIAGNOSTICS

Perennial Value Management says it has increased its substantial shareholding in Atomo from 36,020,169 shares (6.42%) to 41,762,504 shares (7.44%).
The Sydney-based Perennial said that between June 9 and 11, 2020 it bought 5,742,335 shares for $1,853,866 or 32.3 cents a share.
Atomo fell one cent or 3.3 percent to 29 cents with 2.5 million shares traded.

BLUECHIIP

One Funds Management says it has increased its substantial shareholding in Bluechiip from 40,000,000 shares (6.74%) to 50,000,000 shares (8.43%).
The Sydney-based One Funds said that it bought and sold shares between September 10, 2018 and June 12, 2020, with the single largest purchase 21,185,441 shares for $1,250,000 or 5.9 cents a share.
Bluechiip fell 0.6 cents or 10.2 percent to 5.3 cents with 1.3 million shares traded.

CANN GROUP

Cann Group says it will issue the Commonwealth Scientific and Industrial Research Organisation 325,272 shares for “the provision of research and development services”.
In 2018, Cann Group said it had a three-year research and development agreement with the CSIRO to develop technology for the manufacture and sale of its medical marijuana products (BD: Oct 25, 2018).
Last year, the company said the CSIRO received 91,164 shares as settlement of an invoice for services rendered (BD: Jan 20, 2019).
Cann Group fell 6.5 cents or 6.6 percent to 92.5 cents.

CANN GLOBAL

Cann Global claims it has identified a marijuana strain that can stop the progression and reverse the damage of multiple sclerosis through in-vitro and mouse studies.
Cann Global said the studies, conducted in a laboratory at the Haifa, Israel-based Technion, aimed to match marijuana extracts that regulated or modulated immune function in order to optimize multiple sclerosis treatment.
The company said it compared five marijuana strain ‘chemovars’, or chemical entities, with a control for one hour of treatment in a petri dish on human CD4 T-cells.
Cann Global said that CD4 T-cells played a central role in immune protection.
The company said that it found that different chemovars had different killing abilities and identified one chemovar that could effectively kill CD4 T cells that had become destructive and could cause damage to the body by the immune system.
Cann Global said it found that proliferating human CD4 T cells were more sensitive to treatment with marijuana chemovars than resting T cells.
The company said that a study of more than 150 mice evaluated the effect of four chemovars on the progression of experimental autoimmune encephalomyelitis.
Cann Global said that three chemovars reduced paralysis and one chemovar was detrimental and inhibited natural recovery potential.
The company said the Technion was working to isolate and identify molecules within the marijuana strain responsible for the therapeutic effect to develop a pharmaceutical product to safely treat multiple sclerosis without side effects.
Cann Global was up 0.1 cents or 14.3 percent to 0.8 cents with 44.2 million shares traded.

MGC PHARMACEUTICALS

MGC says it has a five-year, exclusive, binding term sheet with Israel’s IM Cannabis Corp to import, sell and distribute its marijuana-based Cannepil for epilepsy in Israel.
MGC said it was in discussions with Israel’s Ministry of Health for phase IIb clinical trial approval and for early access scheme approval to sell Cannepil.
MGC fell 0.1 cents or 4.2 percent to 2.3 cents with 2.1 million shares traded.

THC (THE HYDROPONICS CO) GLOBAL GROUP

THC says it has a supply and manufacturing agreement with Brisbane’s Cannatrek to produce its Canndeo marijuana and Cannatrek medicines at its Southport facility.
THC said Cannatrek would supply a minimum of 480kg of dried marijuana flower, including 240kg for Canndeo and 240kg for Cannatrek medicines.
THC was up half a cent or 1.3 percent to 38 cents.

ESENSE-LAB

Esense says it has a joint venture agreement with ANC Enterprises to produce a range of skin care, hair care and hand sanitizer products with its terpene mix.
Esense said that under the agreement, it would provide terpenes for each product category and Melbourne's ANC would manufacture the resulting products.
The company said the 700,000-initial order for terpenes would be split into 500,000 hand sanitizer units, 100,000 skin care units and 100,000 hair care products.
Esense said it would continue further research into terpenes' anti-viral qualities to reduce the ethanol content in sanitizers.
Esense fell 0.2 cents or 10 percent to 1.8 cents with 4.5 million shares traded.

GI DYNAMICS

GI Dynamics has requested a trading halt "pending an announcement … in relation to the company's 2017 senior secured convertible note issued to Crystal Amber Fund".
Last month, GI Dynamics said it had further extended the maturity date of the $US5,000,000 ($A6,595,767) Crystal Amber Fund convertible note from May 15 to June 15, 2020 (BD: May 18, 2020).
Trading will resume on June 17, 2020 or on an earlier announcement.
GI Dynamics last traded at 0.7 cents.

PHARMAUST

Pharmaust has requested a voluntary suspension to follow the trading halt requested last week pending an announcement regarding "results from the Sars-Cov-2 repeat experiments" (BD: Jun 11, 2020).
Earlier this month, Pharmaust said results from tests by Melbourne's Walter and Eliza Hall Institute showed that monepantel and monepantel sulfone reduced severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) replication and cell-to-cell infectivity in tissue culture by 50 percent to 95 percent, in-vitro (BD: Jun 4, 2020).
Pharmaust has been trialling the Elanco monepantel sheep round worm drench, previously PPL-1, for human cancer since June 2014, and for dog cancer since September 2014 (BD: Jun 23, Sep 9, 2014).
Trading will resume on June 16, 2020 or on an earlier announcement.
Pharmaust last traded at 11 cents.