Biotech Daily

Tuesday April 21, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 7%; ALTERITY DOWN 23%**
*** DOHERTY STARTS 2,500 PATIENT 'ASCOT' COVID-19 TRIAL**
*** REDHILL PROVIDES RHB-107 TO US AGENCY FOR SARS-COV-2**
*** EMVISION: 'PRELIMINARY BRAIN IMAGES CORRELATE WITH CT, MRI'**
*** POLYNOVO NOVOSORB BTM: 'UP TO 100% WOUND CLOSURE'**
*** VOLPARA PLACEMENT RAISES $28m; $7m SHARE PLAN TO GO**
*** GENETIC TECHNOLOGIES RAISES $2.3m, TOTAL $5.3m**
*** AVITA TO MOVE TO US**
*** VISIONEERING RECEIVES $1.6m US COVID-19 RELIEF LOAN**
*** NSW EXPANDS IMPEDIMED SOZO LYMPHOEDEMA PREVENTION PROGRAM**
*** INVITROCUE WINS CE MARK FOR ONCO-PDO CANCER TEST**
*** US PATENT FOR TALI ATTENTION DEFICIT PRODUCTS**
*** ADHERIUM, PLANET INNOVATION DEVELOP REMOTE SENSORS**
*** LIVECARE TO DISTRIBUTE G MEDICAL PRIZMA DEVICE**
*** CARDIEX REQUESTS 'SENSOR DEVELOPMENT' TRADING HALT**
*** PLATINUM DILUTED TO 10% OF KAZIA**
*** CANN GROUP 5-YEAR MARIJUANA SUPPLY AGREEMENT WITH PURE CANN**
*** NEUROTECH EXTENDS 'ASX PRICE QUERY' SUSPENSION**
*** NOXOPHARM RECEIVES $409k FROM CANCELLED LOAN**
*** ELIXINOL: OLIVER HORN IN, STRATOS KAROUSOS OUT, HELEN WISEMAN**
*** MORE COVID-19 CLAIMS: MEDLAB, NOXOPHARM**

MARKET REPORT

The Australian stock market fell 2.46 percent on Tuesday April 21, 2020, with the ASX200 down 131.7 points to 5,221.3 points. Four of the Biotech Daily Top 40 stocks were up, 30 fell, four traded unchanged and two were untraded. All three Big Caps fell.

Dimerix was the best of the few, up one cent or 6.7 percent to 16 cents, with 1.9 million shares traded. Optiscan climbed 6.25 percent; Antisense rose two percent; with Pro Medicus up 0.2 percent.

Alterity led the falls, down 0.5 cents or 22.7 percent to 1.7 cents, with 648,016 shares traded. LBT lost 20 percent; Neuren fell 19.5 percent; Avita shed 13.1 percent; Amplia lost 12.8 percent; Starpharma retreated 11.4 percent; Medical Developments and Volpara were down more than 10 percent; Compumedics and Immutep lost nine percent or more; Clinuvel fell 7.5 percent; Paradigm was down 6.8 percent; both Ellex and Universal Biosensors fell five percent; Imugene, Kazia, Nanosonics, Oncosil, Orthocell, Pharmaxis and Resonance were down more than four percent; Mesoblast and Telix were down three percent or more; Cochlear, CSL, Impedimed, Opthea, Polynovo and Prescient shed more than two percent; with Cyclopharm and Genetic Signatures down more than one percent.

PETER DOHERTY INSTITUTE

The Peter Doherty Institute has begun a 2,500 patient, randomized, controlled trial to assess lopinavir/ritonavir and/or hydroxychloroquine for patients with Covid-19.

Melbourne's Doherty Institute said that the trial would be conducted at more than 70 Australian hospitals, 11 New Zealand hospitals and Singapore joined the trial today.

The Doherty Institute said that the trial would assess clinical, virological and immunological outcomes in patients with severe acute respiratory syndrome coronavirus 2 (Sars-Cov-2) infection with four arms comparing responses to lopinavir/ritonavir alone, hydroxychloroquine alone, lopinavir/ritonavir and hydroxychloroquine in combination and the standard of care, primarily pain relief and oxygen therapy.

The Institute said that the Australasian covid-19 trial (Ascot) will be led by its clinical research co-lead Prof Steven Tong an infectious diseases clinician at the Royal Melbourne Hospital, which was the first trial site opened.

The Doherty said that there were no treatments with established effectiveness for Covid-19, but "multiple treatment options and combinations … may be effective".

The Institute said laboratory tests showed that lopinavir/ritonavir, which was used to treat HIV, and hydroxychloroquine, used to treat arthritis and prevent and treat malaria, could stop Sars-Cov-2.

Prof Tong said that while the World Health Organization considered both drugs to be promising treatments, more research was needed to be sure they were safe and effective in humans.

"The aim of Ascot is to test whether using these drugs will prevent patients deteriorating to the point of needing a ventilator in the intensive care unit," Prof Tong said.

"We have designed the trial so that it's responsive and adaptive," Prof Tong said.

"This means that if one of the drugs is proving to be effective, we can adapt the trial to focus on that treatment," he said.

"Conversely, if a drug isn't effective, or is causing severe side effects, we can stop it," Prof Tong said.

According to the trial description on the Australian New Zealand Clinical Trials Registry the primary outcome was the proportion of participants alive and not having required intensive respiratory support, such as invasive or non-invasive ventilation or humidified high flow nasal oxygen flow, at 15 days after enrolment.

The ANZCTR said the outcome would be assessed by the number of patients who were not admitted into the intensive care unit 15 days after enrolment.

The website said that secondary endpoints included patients not hospitalized, with no limitations on activities, patients not hospitalized with limitations on activities, hospitalized not requiring supplemental oxygen, hospitalized, requiring supplemental oxygen, hospitalized on non-invasive ventilation or high flow oxygen devices, hospitalized on invasive mechanical ventilation or extra-corporeal membrane oxygenation (ECMO or life support), and death.

The ANZCTR said inclusion criteria for the trial were patients aged 18 years and over with confirmed Sars-Cov-2 infection by nucleic acid testing in the past 12 days, able to be randomized within 12 days of symptom onset and expected to be remain an inpatient for at least 48 hours from the time of randomization.

Trial details are available at ANZCTR: https://bit.ly/3cAn2r4.

The trial is supported by the University of Melbourne, the University of Queensland, Hunter Medical Research, the Pratt Foundation, the Royal Brisbane Women's Hospital Foundation and the Minderoo Foundation.

REDHILL BIOPHARMA

Redhill says it will provide RHB-107 to the US National Institute of Allergy and Infectious Diseases for non-clinical studies of activity against Sars-Cov-2.

Redhill said that RHB-107 (upamostat or WX-671) was an investigational new chemical entity, studied in more than 300 people in 10 clinical trials, including two completed phase II oncology studies and several phase I studies in healthy volunteers and oncology patients.

The company said that RHB-107 was “a serine protease inhibitor active against a number of human trypsins and several other related serine proteases [and] inhibition of serine proteases, including trypsins, may inhibit viral attachment and replication and decrease lung damage from viral pneumonia”.

Redhill said that Institute selected RHB-107 for in-vitro testing, following evaluation of data on the drug’s possible mechanism of action and potential activity against severe acute respiratory disease coronavirus-2 (Sars-Cov-2) the virus that causes Covid-19.

The company said it was the second investigational drug it was evaluating for Covid-19 along with opaganib, also known as Yeliva, which was being administered under a compassionate use program in Israel, “with several patients treated to date, with preliminary positive outcomes” (BD: Apr 7, 2020).

Redhill said an investigational new drug application had been submitted to the US Food and Drug Administration to evaluate opaganib in a clinical study in adults diagnosed with Covid-19 and pneumonia.

On the Nasdaq, Redhill was up 83 US cents or 13.1 percent to $US7.16 ($A11.36) with 847,133 shares traded.

EMVISION MEDICAL DEVICES

Emvision says images from two of its 30-patient portable brain scanner unit pilot trial for stoke patients show a strong correlation with “gold-standard” imaging methods.

Emvision said the primary endpoint of the trial was to generate a dataset of stroke patient scans which improved the understanding of stroke on electromagnetic scattering effects in the brain.

The company said it would use the data to refine and select the optimal imaging algorithms as well as generating early data on correlation with computed tomography (CT) and magnetic resonance imaging (MRI) images.

Emvision said its imaging algorithm team received blinded data and processed the first two sets of ischemic patient datasets.

The company said its brain scanner images demonstrate strong correlation with CT and MRI imaging, including the detection and localization of abnormal brain tissue.

Emvision clinical advisor and stroke specialist Prof Michael O’Sullivan said that “these early results are highly promising”.

“In both cases, the Emvision scans were clearly positive and proved a good guide to the extent of brain tissue damaged or under threat,” Prof O’Sullivan said.

Emvision chief executive officer Dr Ron Weinberger said the company’s “first set of images, while preliminary, is certainly encouraging, demonstrating a strong correlation with mainstay medical imaging outputs, with the potential to add unique functional information”.

“We are confident that as we continue to process further stroke patient data, we will demonstrate our unique value proposition to meet a major unmet clinical need in rapid and portable stroke diagnosis and monitoring,” Dr Weinberger said.

Emvision was up five cents or 6.7 percent to 80 cents.

POLYNOVO

Polynovo says that results from its Novosorb biodegradable temporizing matrix (BTM) feasibility study show up to 100 percent would closure after three months.

Polynovo said the 12-month CP-002 prospective, multi-centre, single-arm, open label feasibility study of Novosorb study for full thickness burns covering 10 percent to 70 percent of total body surface treated 14 patients aged between 21 and 67 years with thermal or contact burns.

The company said that results from 12 patients showed that BTM provided effective temporary wound coverage and integrated into the wound bed with a mean BTM “take” rate at the time of sealing membrane removal of 95.22 percent and a median rate of 98.89 percent within a range of 78.0 to 100.0 percent.

Polynovo said that split-thickness skin graft (SSG) take rates seven to 10 days after application were available for 11 patients and had a mean of 97.53 percent and a median of 100 percent with a range of 75.0 to 100.0 percent.

The company said that mean wound closure rates at one month after treatment varied across anatomical locations from 94.8 percent to 100.0 percent closure.

Polynovo said the closure rate at three months following treatment increased to 99.8 percent to 100.0 percent, “demonstrating success of skin grafting procedures used to provide definitive wound closure in these large wounds”.

The company said that no new risks were identified in the study.

Polynovo said that infections were common and occurred in 12 of 14 subjects, with seven experiencing wound infections at BTM-treated sites, with two subjects requiring removal of BTM.

The company said that seven patients completed their 12-month follow-up assessment and seven patients were withdrawn; two died due to serious adverse events unrelated to BTM, one patient was withdrawn by the investigator, and four were lost to follow-up.

Polynovo said it expected its pivotal study investigation device exemption to be approval by the US Food and Drug Administration in June 2020.

Polynovo chief executive officer Paul Brennan said the results were “outstanding”.

“Not only have Novosorb BTM integrated well, the take of the split skin grafts and closure of these wounds is remarkable,” Mr Brennan said.

“Burns are often contaminated so seeing infections within this cohort is not unusual [but] what is unusual is seeing the matrix continue to integrate and later for the skin graft to take to the matrix with an excellent clinical and cosmetic outcome,” Mr Brennan said.

Polynovo fell six cents or 2.8 percent to $2.06 with 8.05 million shares traded.

VOLPARA HEALTH TECHNOLOGIES

Volpara says it has raised $28 million in a placement at $1.30 a share and hopes to raise a further $7 million in an underwritten share plan.

Volpara said that the placement price was a 10.3 percent discount to the closing price on April 16, 2020.

The company said that eligible shareholders at the record date of April 20 would be able to buy between $2,000 and $30,000 of new shares in the plan, which would open on April 28 and close on May 11, 2020.

Volpara the funds would be used to strengthen its balance sheet and pursue merger and acquisition opportunities.

The company said that Bell Potter Securities and Morgans Corporate were the joint lead managers and bookrunners for the placement and joint underwriters of the share plan.

Volpara fell 15 cents or 10.3 percent to $1.30 with 1.9 million shares traded.

GENETIC TECHNOLOGIES

Genetic Technologies says it will raise $US1.44 million ($A2.29 million) in a placement of American depository shares (ADS) at $US2.00 each.
Genetic Technologies said each ADS represented 600 ASX shares at 0.53 cents a share.
Earlier this month, the company said it raised $US1.8 million ($A3.0 million) at $US1.75 per ADS equivalent to 0.48 cents per ASX share (BD: Apr 2, 6, 2020).
Genetic Technologies said the funds would be used for Covid-19 testing, the development of polygenic risk score testing and general working capital.
Genetic Technologies said HC Wainwright and Co LLC was the placement agent and would be paid 7.5 percent of the aggregate purchase for the ADSs sold and $25,000 for expenses.
Genetic Technologies was unchanged at 0.6 cents with 52.4 million shares traded.

AVITA MEDICAL

Avita says it intends to redomicile to the US to “substantially reduce the costs, burden, resourcing and risks” of operating in both Australia and the US.
Avita said it had a scheme of arrangement with the Delaware-based Avita Therapeutics Inc, which will become the new holding company of Avita and its subsidiaries, subject to shareholder, regulatory and court approvals.
The company said its listing on the Nasdaq would become its primary listing, with the ASX to become its secondary listing.
Avita said that it would save about $400,000 a year in external professional costs alone, if the move was approved.
The company said that a Nasdaq listing was expected to increase its visibility and presence in the US, the largest market for burn treatment.
Avita said that the move would better align its corporate structure with its business operations in the US, where nearly all of the company’s employees were located.
The company said that Avita US would acquire all ASX shares and eligible shareholders would receive five Chess depository interests in Avita US for every 100 ASX shares held in Avita on the record date.
Avita said the record date was June 25 and the implementation date was expected to be June 30, 2020, pending approvals.
Avita fell 6.5 cents or 13.1 percent to 43 cents with 32.3 million shares traded.

VISIONEERING TECHNOLOGIES

Visioneering says it will receive a $US1,035,115 ($A1,640,943) non-dilutive loan from the US Government for financial relief amid the Covid-19 crisis.
Visioneering said it was approved for the loan by the US Small Business Administration under the Paycheck Protection Program and expected to receive the funds by April 26, 2020.
The company said the loan was intended to be used for payroll, rent and utilities.
Visioneering said it expected that the loan would be unsecured, carry a one percent interest rate, have deferred payments for six months and at least a portion of the loan may be forgiven based primarily on the company’s payroll and rent paid in the eight weeks subsequent to the loan disbursement.
The company said that is expected the loan to allow operations to continue until January 2021.
Visioneering fell 0.1 cents or 5.3 percent to 1.8 cents with 1.2 million shares traded.

IMPEDIMED

Impedimed said New South Wales Health will purchase up to eight additional Sozo devices to expand its lymphoedema prevention program for cancer patients.
Yesterday, Impedimed said its Sozo bioimpedance spectroscopy technology could detect lymphoedema when the arm still looked normal and introduce therapy up to 12 months earlier than could be detected by clinical examination (BD: Apr 20, 2020).
Today, the company said that NSW Health operated more than 230 public hospitals.
NSW Health executive Ruth Jones said the organization was “working to increase survival and quality of life for people with cancer”.
“The Sozo technology and lymphoedema prevention model-of-care align well with our goals of improving patient care while decreasing costs associated with chronic lymphoedema treatment”.
Impedimed fell 0.1 cents or 2.6 percent to 3.7 cents with 4.6 million shares traded.

INVITROCUE

Invitrocue says it has Conformité Européenne (CE) mark for its Onco-patient-derived organoid (PDO) test for personalized cancer treatment.
Invitrocue said the Onco-PDO test would be commercially available “soon” to oncologists and patients in Europe, initially in Germany and Spain and other countries such as Brazil.
The company said it would seek to list the test under the German Healthcare reimbursement system “in due course”.
Invitrocue was in a suspension and last traded at six cents.

TALI DIGITAL (FORMERLY NOVITA HEALTHCARE, AVEXA)

Tali says it has been granted its first US patent covering the assessment and training function as well as the technology underpinning its attention deficit product portfolio.
Tali said that the patent, titled ‘System and process for cognitive assessment and training’, provided extensive protection for its products until 2035, with potential extensions.
Tali managing-director Glenn Smith said the “US patent, combined with our extensive [intellectual property] portfolio, further strengthens Tali's position as a global leader in the cognitive assessment and training segment, particularly in the area of early childhood attention”.
“The significance of this patent cannot be understated as it covers both the assessment and training functions,” Mr Smith said.
Tali fell 0.1 cents or 3.2 percent to three cents with 18.7 million shares traded.

ADHERIUM

Adherium says it has contracted Planet Innovation to develop inhaled medication adherence devices and digital software for remote monitoring of asthma.
Adherium said the development with the Melbourne-based Planet would add sensors to its Hailie technology to provide physiological data in both asthma and chronic obstructive pulmonary disease remotely.
The company said the data generated would enable physician monitoring reimbursement in the US current procedural terminology reimbursement code in use in the US for remote patient monitoring, which had increased with the Covid-19 pandemic.
Adherium was up 0.1 cents or 3.2 percent to 3.2 cents with 1.3 million shares traded.

G (GEVA) MEDICAL

G Medical says it has appointed New York's Livecare Corp to distribute its Prizma smartphone case vital sign monitoring device in the US.
G Medical said that the three-year distribution agreement was non-exclusive, with no minimum sales commitments.
The company said it would work with Livecare to integrate the Prizma device into the Livecare Link Plus digital platform, which allowed patients' access to medical devices at home for chronic care monitoring.
G Medical was unchanged at 11 cents with 9.4 million shares traded.

CARDIEX

Cardiex as requested a trading halt pending an announcement in relation to the developing a sensor with Beijing's Mobvoi Information Technology (BD: Sep, 11, 2019).
Trading will resume on April 22, 2020 or at an earlier announcement.
Cardiex last traded at 1.8 cents.

KAZIA THERAPEUTICS

Platinum Investment Management says its 9,078,948 share-holding in Kazia has been diluted from 12.58 percent to 10.06 percent.
Earlier this month, Kazia said it raised $7.2 million at 40 cents a share (BD: Apr 9, 2020).
Kazia fell two cents or 4.65 percent to 41 cents.

CANN GROUP

Cann says it has a five-year agreement to produce and manufacture medical marijuana for the Auckland-based Pure Cann NZ.
Last year, Cann said that through its subsidiary, Botanitech Pty Ltd, it would invest $NZ6 million ($A5.7 million) for a 20 percent stake in Pure Cann (BD: Apr 26, 2020).
Today, the company said it had invested $NZ1 million and held 3.9 percent of Pure Cann and under the agreement it would receive $NZ1 million of Pure Cann shares and increase its holding to 7.7 percent, and it was not obliged to invest the remaining $NZ4 million and would issue Pure Cann $NZ1 million worth of Cann Group shares.
Cann said the share exchange would follow a capital raising of at least $10 million within five years, and it would pay Pure Cann $NZ1 million in lieu of shares if not approved.
Cann Group chief executive officer Peter Crock said that the company's "ability to secure supply agreements with quality long-term partners helps support the value of our expansion plan and reinforces Cann Group as a leader in cannabis genetics, cultivation and manufacture".
Cann Group was up one cent or 1.2 percent to 87.5 cents.

NEUROTECH INTERNATIONAL

Neurotech has requested an extension to its voluntary suspension following a trading halt "pending a response to a price query issued by [the] ASX" (BD: Apr 9, 14, 2020).
Neurotech's share price increased 140 percent from five cents at the close of trading on April 6, 2020 to 12 cents at the time of the halt with more than six million shared traded.
Neurotech said trading would resume on April 28, 2020 or on an earlier announcement.
Neurotech last traded at 1.2 cents.

NOXOPHARM

Noxopharm says it has received $409,477 in cash from 3,688,978 collateral shares issued to the New York-based Lind Partners LLC and CST Investment Fund.
Noxopharm said it had previously issued 4.5 million shares to Lind and CST under a convertible security agreement, which was terminated in February (BD: Feb 14, 2020).
The company said it received $159,727 from CST for 1,438,978 shares at 11.1 cents a share, which reduced the CST liability from 2.25 million shares to 811,022 shares.
Noxopharm said it received $249,750 from Lind for 2,250,000 shares.
Noxopharm was up two cents or 11.8 percent to 19 cents with 2.85 million shares traded.

ELIXINOL GLOBAL

Elixinol says it has appointed Oliver Horn to replace nine-month chief executive officer Stratos Karousos, and Helen Wiseman as a director, effective immediately.
Last year, Elixinol said it had appointed Mr Karousos as chief executive officer, replacing Paul Benhaim (BD: Jul 16, 2019).
Earlier this month, Elixinol said it appointed former Swisse Wellness chief executive officer Mr Horn as a director and appointed Mr Benhaim as chair (BD: April 6, 2020).
Today, the company said Mr Karousos had resigned from the Elixinol board.
Elixinol said Ms Wiseman had experience in food, pharmaceutical, natural healthcare, professional services, energy and natural resources and manufacturing industries, and was a former partner of KPMG.
Elixinol fell 2.5 cents or 6.4 percent to 36.5 cents.

MEDLAB CLINICAL

Medlab says it has applied to use its Nanocelle drug delivery platform to develop a nanoparticle chloroquine oro-buccal membrane spray to treat Covid-19 patients.
Medlab said that chloroquine was an anti-malaria drug under investigation for the treatment of patients with Covid-19 and was not approved for Covid-19 use outside of investigative trials.
The company said that clinical studies in China on patients with Covid-19 showed a “reduction of exacerbation of pneumonia, duration of symptoms and delay of viral clearance”.
Medlab was up two cents or 9.1 percent to 24 cents.

NOXOPHARM

Noxopharm says it will seek US Food and Drug Administration guidance for a clinical trial of its idronoxil suppository for Covid-19 patients.
On April 1, Noxopharm said that Melbourne’s Hudson Institute of Medical Research identified that idronoxil, the active ingredient in Veyonda, or NOX66, inhibited “a key inflammatory pathway involved in a process known as a cytokine storm (BD: Apr 1, 2020).
Today, the company said idronoxil blocked the stimulator of interferon genes (Sting) process, which was thought to contribute to “lethal self-destruction of major organs”.
The company said that any non-cancer studies would require non-dilutive funding.