Biotech Daily

Thursday June 4, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 67%; PATRYS DOWN 6%**

*** DIMERIX DMX-200 JOINS REMAP-CAP GLOBAL COVID-19 ARDS STUDY**

*** ASIC: INSIDER TRADING - EX-SIRTEX CEO GILMAN WONG 3 YEAR BOND**

*** AZURE NOTES RAISE $1.7m FOR INVICTUS**

*** CORRECTION: PARADIGM**

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*** LBT APAS INDEPENDENCE FOR MRSA 6-MONTH FDA DELAY**

*** OSPREY REQUESTS 'SHORTFALL PLACEMENT' TRADING HALT**

*** PFIZER AUSTRALIA HOSTS 'POST-COVID-19' WEBINAR**

*** LAZARD TAKES 5% IN MAYNE**

*** REGENEUS LOSES 5-YEAR DIRECTOR DR GLEN RICHARDS**

*** ZELIRA US CEO DR OLUDARE ODUMOSU STARTS ON $217k**

*** CELLMID: 'EMERGENCE DEAL FOR COVID-19 TESTS'**

*** PHARMAUST: 'MONEPANTEL SUPPRESSES SARS-COV-2 50-95% IN-VITRO'**

MARKET REPORT

The Australian stock market was up 0.84 percent on Thursday June 4, 2020, with the ASX200 up 50.2 points to 5,991.8 points. Fourteen of the Biotech Daily Top 40 stocks were up, 17 fell, eight traded unchanged and one was untraded. All three Big Caps rose.

Dimerix was the best, up 18 cents or 66.7 percent to 45 cents, with 10.3 million shares traded. Telix climbed 8.55 percent; Optiscan was up 7.1 percent; Imugene and Proteomics improved more than five percent; Prescient was up 4.7 percent; CSL and Kazia were up more than three percent; Clinuvel, Oncosil and Resmed rose more than two percent; Ellex and Nanosonics were up more than one percent; with Cochlear, Cyclopharm, Pro Medicus and Volpara up by less than one percent.

Patrys led the falls, down 0.1 cents or 6.25 percent to 1.5 cents, with 610,001 shares traded. Compumedics lost 5.9 percent; Actinogen fell 4.35 percent; Genetic Signatures, LBT, Paradigm, Pharmaxis and Polynovo were down three percent or more; Antisense, Immutep, Neuren, Opthea, Starpharma and Universal Biosensors shed more than two percent; Medical Developments and Next Science were down more than one percent; with Mesoblast down by 0.3 percent.

DIMERIX

Dimerix says its DMX-200 for kidney disease will be included in the Remap-Cap protocol for Covid-19 acute respiratory distress syndrome (Ards).

Dimerix said that the randomized, embedded, multifactorial adaptive platform trial for community-acquired pneumonia (Remap-Cap) study first began in 2013 and started recruitment in 2016.

According to the Remap-Cap website the World Health Organisation-endorsed trial included a pandemic protocol which was activated following the outbreak of the severe acute respiratory syndrome coronoavirus-2 (Sars-Cov-2) outbreak and the subsequent spread of the Covid-19 disease https://www.remapcap.org/coronavirus.

The Remap-Cap website said there were more 200 participating sites in 14 countries.

Dimerix said that subject to regulatory and ethics approval in each territory, it would supply drug product from its existing good manufacturing practice (GMP) batch of DMX-200 and has lodged provisional patent applications in all key jurisdictions for use of any CCR2 inhibitor, including DMX-200, in acute respiratory distress syndrome.

Dimerix chief executive officer Dr Nina Webster told Biotech Daily that DMX-200, or propagermanium, had been approved in Japan in a different formulation and dose for hepatitis B and the US Food and Drug Administration accepted the existing safety data.

Last year, Dimerix said the FDA had confirmed that the proposed non-clinical package and proposed specifications for the manufacturing of its pharmaceutical-grade drug were "appropriate for registration of DMX-200" for its proposed phase III clinical program for focal segmental glomerulosclerosis (FSGS) (BD: Nov 25, 2019).

Today, Dr Webster said that DMX-200 targeted the chemokine receptor type 2 (CCR2) pathway and "blocking this receptor at the same time as the renin angiotensin receptor may limit the cytokine storm associated with Covid-19 Ards'.

Dr Webster said Dimerix was ready to supply DMX-200 for up to 1,000 patients and had contracted an FDA-approved manufacturer in the US should more quantities be required.

Dr Webster said that DMX-200 was an oral capsule but was highly soluble and could be made into a liquid injectible.

In a media release, Dimerix said that DMX-200 "could be the only investigational new drug in the study since all of the other selected candidates are a repurposing of existing approved drugs with potential for Covid-19".

The company said that details on the study design would become available following regulatory submission and approval.

Dimerix said DMX-200 was being trialled as a renal therapy to reduce damage from inflammatory cells by blocking their signalling and limiting subsequent onset of fibrosis, a process that was discovered by Dimerix in Prof Kevin Pfleger's laboratory at the Harry Perkins Institute of Medical Research and the University of Western Australia.

The company said that DMX-200 might also benefit Ards patients with Covid-19 by reducing the inflammatory response in the lungs and thus reducing inflammation and subsequent fibrosis.

Dimerix said it had lodged four different provisional patent applications for the use of any CCR2 inhibitor in Ards, titled 'Treatment for Virus Induced Acute Respiratory Distress Syndrome' or 'Treatment for Acute Respiratory Distress Syndrome' were filed in the US in May 2020, and if granted, would expire after 2040.

In 2017, Dimerix said its 27-patient, phase IIa trial of DMX-200 for chronic kidney disease met its safety primary endpoint and showed efficacy, with six patients achieving a greater than 50 percent reduction in proteinuria, or blood in their urine, beyond that achieved with the highest dosage of current standard of care therapy (BD: Jul 12, 2017).

Dimerix was up 18 cents or 66.7 percent to 45 cents with 10.3 million shares traded.

AUSTRALIAN SECURITIES AND INVESTMENTS COMMISSION
SIRTEX MEDICAL, GILMAN WONG

ASIC says former Sirtex chief executive officer Gilman Wong has received an 18-month non-custodial sentence and is subject to a $10,000 three-year good behavior bond.
ASIC told Biotech Daily that in the District Court of New South Wales at Downing Centre Judge James Bennett sentenced Mr Wong to 18 months imprisonment "to be released forthwith on recognizance of $10,000 to be of good behavior for three years".
ASIC said that no fine or penalty was imposed, but that Mr Wong would be disqualified from acting as a company director for five years.
Last year, ASIC said Mr Wong had pleaded guilty to insider trading (BD: Jul 3, 2019).
In 2018, ASIC said Mr Wong had been charged with one count of insider trading under the Corporations Act (BD: Sep 26, 2018).
ASIC said the Commonwealth Director of Public Prosecutions prosecuted Mr Wong at Sydney's Downing Central Local Court and alleged that "Mr Wong was in possession of inside information, concerning Sirtex's sales, when he sold 74,698 shares in Sirtex on October 26, 2016".
In November 2016, Mr Wong said he sold 74,968 of his 274,968 shares "to cover the tax incurred in relation to the recently vested tranche of rights" (BD: Nov 7, 2016).
In December 2016, Sirtex downgraded its SIR-Spheres growth estimates leading to a significant fall in the share price (BD: Dec 9, 2016).
Shortly afterwards, Mr Wong took leave while his sale of shares was investigated and in January 2017, he was dismissed from the company (BD: Dec 19, 2016; Jan 25, 2017).
In 2018, Sirtex was acquired by CDH Genetech and China Grand Pharmaceuticals for $1.87 billion or $33.60 a share (BD: May 4, Jun 15, Sep 12, 2018).
ASIC previously said that the maximum penalty for an insider trading offence was 10 years' imprisonment.

AZURE HEALTH TECHNOLOGY, INVICTUS BIOPHARMA

Azure says it has raised $1,686,000 through the issue of convertible notes at $1.00 each to sophisticated investors.
Azure said that the proceeds would fund the acquisition of Invictus Biopharma and be used for working capital, debt repayments and the preparation for an initial public offer.
Earlier this year, Azure said it hoped to raise up to $10 million to acquire Invictus for its tocotrienols pharmaceuticals, food additive and supplements business, but the capital raising did not meet the minimum 300 investors rule and it was subsequently removed from the ASX official list (BD: Feb 4, Apr 28, 2020).
Azure and Invictus are both public unlisted companies.

CORRECTION: PARADIGM BIOPHARMACEUTICALS

Last night's edition said that Paradigm had appointed Dr Jeannie "Joughlin" as chief operating officer, incorrectly spelling Dr Joughin's name.
Biotech Daily is embarrassed by the error by the former Wednesday sub-editor and apologizes unreservedly to both Dr Joughin and Paradigm.
Paradigm fell 11 cents or 3.4 percent to $3.10 with 2.1 million shares traded.

CLARIFICATION: IMPEDIMED

Last night's edition quoted Impedimed saying it had "statistically significant" results from its bioimpedance spectroscopy detection trial, without providing p-values.
Today, Impedimed said the ASX requested a clarification and said the association between its L-Dex and the symptom cluster score lymphoedema symptom intensity and distress survey was p = 0.031, while the association between the L-Dex and the symptom cluster score of functional assessment of cancer therapy breast was p= 0.044.
No sub-editors were hurt in making this clarification.
Impedimed was unchanged at 7.5 cents with 2.9 million shares traded.

LBT INNOVATIONS

LBT says the US Food and Drug Administration approval of its APAS Independence for methicillin-resistant Staphylococcus aureus will be delayed for up to 180 days.
In March, LBT said it had filed for FDA 510(k) approval of its automated plate assessment system (APAS) Independence methicillin-resistant Staphylococcus aureus (MRSA or golden staph) analysis module (BD: Mar 30, 2020).
Today, the company said the FDA had requested clarification and additional information and the "submission will be on hold pending receipt of new information requested".
LBT said it had a teleconference with the FDA to discuss "the feedback" and a response was being assessed and prepared to minimize the expected delay in regulatory clearance.
The company said it had 180 days to provide a formal response or the FDA would consider the application withdrawn.
LBT said that "the specific matters raised by the FDA are commercial in confidence and the company expect to lodge a formal response with the FDA within the 180-calendar days provided".
The company said that the matters raised by the FDA would not impact the availability of the MRSA analysis module in other regions and would have no impact on existing regulatory clearances, including the FDA clearance of urine analysis module and Conformité Européenne (CE) mark of the MRSA analysis module.
LBT said that prospective sales opportunities in the US were not impacted.
LBT chief executive officer Brent Barnes said that "at this stage the planning of our response is still a work in progress so we cannot accurately assess the likely timing to resubmit to the FDA".
LBT fell half a cent or 3.3 percent to 14.5 cents.

OSPREY MEDICAL

Osprey has requested a trading halt pending an announcement regarding the placement of Chess depository interests (CDIs) and options from the April rights offer.
In April, Osprey said it raised $10.2 million of a hoped-for $15.5 million in a partly underwritten three-for-one rights offer at 1.2 cents per CDI and received applications for 482,602,345 CDIs or $5,791,228, with each new CDI having an attaching unquoted option exercisable at 1.4 cents by February 15, 2021 (BD: Apr 29, 2020).
In April, Osprey said Brandon Capital Partners had underwritten the shortfall for up to $4,453,692, and the company reserved the right to place the shortfall of 441,648,780 shares worth $5,299,785 within three months (BD: Apr 3, 29, 2020).
Trading will resume on June 9, 2020 or on an earlier announcement.
Osprey last traded at 1.4 cents.

PFIZER AUSTRALIA

Pfizer Australia says it will host a webinar, titled ‘Life on the Other Side’, discussing what the life sciences sector will look like post-Covid-19 on June 18, 2020.
Pfizer said panellists would include Lung Foundation Australia chief executive officer Mark Brooke, Medicines Australia chief executive officer Elizabeth de Somer, University of New South Wales professor of global biosecurity Prof Raina MacIntyre, Pfizer executive director Sam O'Connor and Pharmacy Guild of Australia head George Tambassis.
Pfizer said the webinar would discuss the sustainability of Australia’s healthcare and economy, medicine access and availability, patient challenges and collaboration.
Pfizer Australia and New Zealand managing-director Anne Harris said it was “important to have a panel of this calibre debating the unique and pressing challenges facing our healthcare industry, economy and community more broadly in a post-Covid-19 world”.
“Healthcare, and the way we engage with it, is rapidly evolving,” Ms Harris said. “While patients, providers and the pharmaceutical industry have access to more medicines, more knowledge and more technology than ever before, the critical question post-pandemic will centre on how we adapt to our new reality to thrive beyond the Covid-19 crisis.”
The webinar will be held from 11am until 12.15pm on Thursday June 18, 2020.
To attend the webinar, email: pfizerinvites@pfizer.com.

MAYNE PHARMA GROUP

Lazard Asset Management Pacific Co says it has become a substantial shareholder in Mayne Pharma with 84,728,442 shares or 5.05 percent of the company.
Last month, the Sydney-based Lazard said it had become substantial in Mayne Pharma with 84,379,755 shares or 5.03 percent of the company (BD: May 26, 2020).
Earlier this week, Lazard said it had ceased to be a substantial shareholder in Mayne, and Biotech Daily calculated that Lazard held 82,700,219 shares or 4.93 percent of the company (BD: Jun 2, 2020).
Today, Lazard said that on June 1, 2020 it bought 2,028,223 shares for $867,123 or 42.8 cents a share.
Mayne was up one cent or 2.25 percent to 45.5 cents with 13.2 million shares traded.

REGENEUS

Regeneus says non-executive director Dr Glen Richards has resigned “to focus on his other commitments” after five years with the company.
Regeneus chairman Barry Sechos said the board thanked Dr Richards “for his tremendous efforts and deep business knowledge during his tenure as a director”.
Regeneus was up 0.2 cents or 2.9 percent to seven cents.

ZELIRA THERAPEUTICS (FORMERLY ZELDA THERAPEUTICS)

Zelira says its US chief executive officer and managing-director Dr Oludare Odumosu will receive a base salary of $US150,000 ($A217,361).
Zelira said Dr Odumosu would be entitled to bonuses of up to 30 percent of the base salary, subject to revenue performance targets.
The company said that Dr Odumosu would receive 25,000,000 unlisted options, subject to shareholder approval, with the options in five equal portions, exercisable at 10 cents, 15 cents, 20 cents, 28 cents, and 30 cents, within three years from issue.
Zelira was up half a cent or 8.1 percent to 6.7 cents with 3.9 million shares traded.

CELLMID

Cellmid says it has an agreement to introduce its customers to Melbourne's Emergence Technology Pty Ltd for the supply of new Covid-19 tests.
Cellmid said the tests had Conformité Européenne (CE) mark approval, and included an immunoglobulin-G and immunoglobin-M (IgG/IgM) antibody test from the Nanping, China-based Zhuhai Livzon Diagnostics and a fluorescent polymerase chain reaction nucleotide detection analyzer and kits from the Binjiang District, China-based Ustar Biotechnologies.
The company said Livzon IgG/IgM test had 90.6 percent sensitivity and 99.2 percent specificity, while the Ustar test had 96.3 percent sensitivity and 100 percent specificity.
Cellmid said Emergence would be responsible for the supply of the tests to its customers and Cellmid expected to receive an unspecified commission on sales.
Cellmid was in a suspension and last traded at 18.5 cents (BD: May 7, 11, 2020).

PHARMAUST

Pharmaust says monepantel and monepantel sulfone reduce Sars-Cov-2 replication and cell-to-cell infectivity in tissue culture by 50 percent to 95 percent, in-vitro.
Pharmaust has been trialling the Elanco monepantel sheep round worm drench, previously PPL-1, human cancer since June 2014, and for dog cancer since September 2014, with the most recent trial showing that one of seven dogs had a 60 percent reduction in tumor size after treatment (BD: Jun 23, Sep 9, 2014; May 12, 2020).
Today, the company that Melbourne's Walter and Eliza Hall Institute trialled monepantel in-vitro using severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) viral infections of African green monkey vero cells.
Pharmaust said that "relatively low concentrations of monepantel blocked the infectious capacity" of in tissue culture.
The company said the lowest inhibition value from the tissue culture infectious dose (TCID50) assay was about 50 percent and the highest value was about 95 percent.
Pharmaust said that the quantitative polymerase chain reaction (QPCR) individual assays, the degree of suppression was up to 55 percent.
The company said TCID50 data was more valuable than QPCR data on infectivity, as it measured how the virus life-cycle had been inhibited and QPCR data did not.
Pharmaust said QPRC measured virus RNA content and showed whether virus was being made and released, but not whether the virus was capable of infecting new targets.
The company said that based on the in-vitro data, it would broaden and extend its intellectual property in the area of anti-viral activity through the filing of a patent application specifically covering monepantel in the treatment of Covid-19.
Walter and Eliza Hall Institute researcher Prof Marc Pellegrini said that "these early signs demonstrating that monepantel can block Sars-Cov-2 infectivity in-vitro are encouraging".
Pharmaust chief scientific officer Dr Richard Mollard said that "continuation will involve repetition of these experiments for validation and comparisons with other [mammalian target of rapamycin] inhibitors and treatments currently in the clinic".
The company said it planned to further validate the preliminary results "as soon as possible".
Pharmaust was up 1.8 cents or 18.6 percent to 11.5 cents with 16.2 million shares traded.