

Biotech Daily

Thursday June 18, 2020

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: CYNATA UP 9%; OSPREY DOWN 18%
- * VICTORIA, FIRST STATE, ROC \$250m BUSINESS FUND
- * OVENTUS 'OVER-SUBSCRIBED' SHARE PLAN RAISES \$2m, TOTAL \$6.65m
- * CYNATA 440-PATIENT, PHASE III CYMERUS OSTEOARTHRITIS TRIAL APPROVED
- * ANTERIS (ADMEDUS) RECEIVES \$735k R&D TAX INCENTIVE
- * LIFESPOT PLACEMENT RAISES \$300k
- * TELIX RESUMES PHASE III ZIRCON TRIAL IN EUROPE
- * ACRUX, AMRING UNNAMED GENERIC DRUG DEAL
- * RESAPP, RECKITT BENCKISER COUGH DIAGNOSTIC MOU
- * DIMERIX REQUESTS CAPITAL RAISING HALT
- * PATRYS REQUESTS CAPITAL RAISING TRADING HALT
- * OPYL REQUESTS CAPITAL RAISING TRADING HALT
- * EMERALD REQUESTS 'REAL WORLD EVIDENCE PLATFORM' HALT
- * PIE FUNDS TAKES 5% OF PROBIOTEC
- * DIRECTOR DENNIS ECK TAKES 10% OF CELLMID
- * NOXOPHARM CHAIR DR GRAHAM KELLY INCREASES, DILUTED TO 17%
- * ELEANORE GOODRIDGE TAKES 8% OF NOXOPHARM
- * ESENSE. WISE WINE J-V FOR TERPENE-INFUSED SANITIZER
- * MGC SELLS NUTRACEUTICALS TO ONASSIS FOR \$9m IN SHARES
- * PHARMAUST: 'WEHI CONFIRMS MONEPANTEL FOR SARS-COV-2 IN-VITRO'
- * RESPIRI PAYS EX-CEO MARIO GATTINO 'IMMATERIAL' SETTLEMENT

MARKET REPORT

The Australian stock market fell 0.92 percent on Thursday June 18, 2020, with the ASX200 down 55.3 points to 5,936.5 points. Ten of the Biotech Daily Top 40 stocks were up, 22 fell, five traded unchanged and three were untraded.

Cynata was the best, up 5.5 cents or nine percent to 66.5 cents with 1.5 million shares traded. Oncosil and Paradigm climbed more than four percent; Kazia was up 3.3 percent; Optiscan rose 2.2 percent; Antisense, Clinuvel, Neuren and Resmed were up more than one percent; with Ellex and Mesoblast up by less than one percent.

Osprey led the falls, down 0.2 cents or 18.1 percent to 0.9 cents, with 7.0 million shares traded. Proteomics lost 9.6 percent; Uscom fell 8.5 percent; Starpharma shed 6.5 percent; Polynovo and Volpara fell more than five percent; Avita, Impedimed and Orthocell were down more than four percent; Actinogen, Genetic Signatures, LBT, Medical Developments and Next Science lost more than three percent; Imugene, Nanosonics, Pharmaxis, Pro Medicus and Resonance shed more than two percent; Cochlear, Immutep and Telix were down more than one percent; with CSL and Opthea down by less than one percent.

VICTORIA GOVERNMENT

Victoria Treasurer Tim Pallas says a \$250 million State Government Fund will support small-to-medium enterprises that can't raise funds or find the right investment partner.

A media release from Mr Pallas said that the Victorian Business Growth Fund was a partnership with First State Super (Superannuation) to invest in businesses on commercial terms and take an equity stake in business, rather than providing a grant.

The media release said that decisions about investments would be made by independent fund manager Roc Partners.

The Department of Treasury and Finance website said that "all investment decisions will be made by Roc Partners based on a commercial assessment about the potential growth and return profile for the business, governed by an investment mandate agreed by the Victorian Government and First State Super".

"The Victorian Government will have no involvement in investment decisions," the websote said.

A State Government media officer told Biotech Daily that although Roc was currently headquartered in Sydney, it would open a Melbourne office.

The media release said that as businesses dealt with the economic impacts of coronavirus, "accessing the capital they need to grow is likely to become an even greater barrier than it was before".

The Victoria Government said it would partner with the superannuation industry to back these businesses, to boost productivity, increase employment and help stimulate the business sectors.

The State Government said that to deal with the economic crisis caused by the coronavirus pandemic, there was an opportunity for the Government to work with the private sector "to deliver the growth the economy needs, such as superannuation funds, banks, businesses and not-for-profits".

"This is a Victorian-first program that finds a new way of backing our local businesses to become bigger and better," Mr Pallas said.

"We know access to capital is often a handbrake on growth; we're fixing that," Mr Pallas said.

"As we continue to recover from this crisis, we'll continue to pursue more opportunities to work closely with the private sector to grow the economy," Mr Pallas said.

First State Super chief executive officer Deanne Stewart said that small to medium-sized businesses were "the lifeblood of the Australian economy, and in the current environment supporting them to grow and flourish has never been more important".

"This investment will support economic recovery, create new jobs and help stimulate growth across the Victorian communities that need it the most," Ms Stewart said. For more information about the Victorian Business Growth Fund or to apply online, go to: www.dtf.vic.gov.au/businessgrowthfund.

OVENTUS

Oventus says its share plan at 24 cents a share received subscriptions for \$12.64 million which will be scaled back to the hoped-for and capped \$2 million.

Oventus said it had raised a total of \$6.65 million, including the \$4.65 million raised last month through a placement at 24 cents a share (BD: May 1, 2020).

The company said that subscribers in the share plan and placement would receive one free unlisted attaching option for every two shares purchased, exercisable at 36 cents by June 30, 2021.

Oventus fell one cent or three percent to 32 cents with 1.1 million shares traded.

CYNATA THERAPEUTICS

Cynata says it has ethics approval for a 440-patient, randomized, controlled, phase III trial of its CYP-004 mesenchymal stem cell product for osteoarthritis.

Last year, Cynata said it was preparing for a 448-patient, phase II trial of CYP-004, or Cymerus, the third phase II indication for the product, which was expected to begin by April 2020 (BD: Oct 3, 2019).

Today, the company said it had "originally described [the trial] as a phase II clinical trial, but it has since been determined that a phase III trial will be performed".

Cynata said the change was approved by the University of Sydney's human research ethics committee.

The company said the trial would assess the effect of Cymerus mesenchymal stem cells compared to placebo on clinical outcomes and knee joint structure in 440 patients with osteoarthritis of the knee, over two years.

Cynata said that preclinical research had shown that mesenchymal stem cells could improve outcomes in patients with osteoarthritis through a number of functions, including the release of cytokines and growth factors that reduced inflammation and promoted tissue repair, the formation of new blood vessels, and the regeneration of compromised cartilage.

The company said the Australia Therapeutics Goods Administration had allowed the trial to be conducted under the clinical trial notification scheme, subject to Cynata supplying appropriate good manufacturing practice compliance documentation to the trial sponsor, the University of Sydney.

Cynata said the clinical trial notification scheme required only the submission of a notification of the trial to the TGA, as opposed to a formal review and approval process. The company said the trial was sponsored by the University of Sydney and funded by a Federal Government National Health and Medical Research Council (NHMRC) grant. In 2018, Cynata said the NHMRC had approved a \$1,982,802 grant for the proposed phase II trial of Cymerus for osteoarthritis (BD: Dec 13, 2018).

Today, the company said the trial would be held at study centres in Sydney and Tasmania, and would be led by the University of Sydney's Prof David Hunter.

Cynata said that clinical trial restrictions imposed by the University of Sydney, which were aligned with Federal and state government recommendations in response to Covid-19, remained in place.

The company said it expected patient recruitment to begin "once the restrictions are lifted and final procedural and administrative arrangements are completed".

Cynata chief operating officer Dr Kilian Kelly said the company was "delighted to gain ethics approval for this important phase III clinical trial in osteoarthritis patients".

"Approval by the [ethics committee] is a key milestone toward commencement of the trial," Dr Kelly said.

"We look forward to providing further information around the timing of commencement of patient recruitment once more clarity is available regarding the lifting of Covid-19-related restrictions," Dr Kelly said.

Cynata was up 5.5 cents or nine percent to 66.5 cents with 1.5 million shares traded.

ANTERIS (FORMERLY ADMEDUS)

Anteris says it has received \$734,899 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Anteris said the rebate related to expenditure for the year to December 31, 2019. Anteris was up two cents or 0.4 percent to \$5.05.

LIFESPOT HEALTH

Lifespot says it has raised \$300,000 in a private placement to sophisticated and professional investors at 3.3 cents a share.

Lifespot said the funds would be used to establish and consolidate its Bodytel software, to develop its Fevertel organization platform and prepare its Medihale safety and tolerability studies.

The company said Sanlam Private Wealth was the lead manager of the placement and would be paid a fee equal to six percent of funds raised, or \$18,000.

Lifespot fell 0.3 cents or 8.6 percent to 3.2 cents.

TELIX PHARMACEUTICALS

Telix says it has recommenced its Zircon phase III trial of TLX250-CDx for kidney cancer in Europe, after a pause due to the Covid-19 pandemic.

Telix said the zirconium imaging in renal cancer oncology (Zircon) trial was being conducted across 33 sites in Europe, Australia, Turkey, Canada and the US.

The company said the trial would study about 250 renal cancer patients undergoing kidney surgery, to determine the sensitivity and specificity of TLX250-CDx positron emission tomography (PET) imaging to detect clear cell renal cell cancer, compared to the detection of cells in samples from surgical resection.

Telix said that clinical trial sites in France had restarted patient recruitment, with two patients dosed this week at the Nantes University Hospital Centre.

The company said clinical sites in Belgium and the Netherlands had reactivated the trial and patient recruitment was "expected to resume in the next two weeks".

Telix said it expected clinical trial sites in Australia, Canada, Turkey and the US to restart the Zircon trial "between now and September, subject to conditions remaining stable".

Telix chief executive officer Dr Christian Behrenbruch said the company was "relieved to be restarting patient recruitment into the Zircon study and gratefully acknowledge the patience and dedication of our investigators and their clinical staff".

"Although we had stopped patient enrolment, we had not paused recruitment and we see an encouraging patient backlog to regain momentum," Dr Behrenbruch said. Telix fell 1.5 cents or 1.1 percent to \$1.30.

ACRUX

Acrux says it has an agreement with the Berwyn, Pennsylvania-based Amring Pharmaceuticals Inc to develop and commercialize an unnamed generic product. Acrux said the product under development had generated more than \$400 million in US sales in the 12 months to March 31, 2020.

The company said it would continue to conduct "scientific and bioequivalence activities necessary to develop the generic product" and Amring would be responsible for obtaining US Food and Drug Administration regulatory approval.

Acrux said Amring would commercialize the product in the US, subject to approval and both parties would share development costs and profits generated from sales.

Acrux chief executive officer Michael Kotsanis said that agreement was "a significant opportunity for both Acrux and Amring and we look forward to developing a long-lasting relationship with Amring".

"The development of a generic of this product will benefit patients and provide a platform for continued long term growth," Mr Kotsanis said.

Acrux was up half a cent or 3.1 percent to 16.5 cents.

RESAPP HEALTH

Resapp says it has a memorandum of understanding with Reckitt Benckiser Group Plc to develop a smartphone application for respiratory condition identification

Resapp said the smartphone application would use its cough-based algorithm to identify conditions and "provide recommended next steps" to patients.

The company said the Slough, England-based Reckitt Benckiser owned brands including Durex condoms, Dettol, Nurofen, Clearasil and Mortein insecticide.

Resapp said both parties would work together "to build and test a prototype [software application] for consumers to self-assess, or assess with the assistance of a pharmacist, their respiratory symptoms".

Resapp last traded at 19 cents.

DIMERIX

Dimerix has requested a trading halt "for the purposes of considering, planning and executing a capital raising".

Trading will resume on June 22, 2020 or on an earlier announcement.

Dimerix last traded at 44 cents.

PATRYS

Patrys has requested a trading halt "pending an announcement ... in relation to a capital raising".

Trading will resume on June 22, 2020 or on an earlier announcement.

Patrys last traded at 1.4 cents.

OPYL

Opyl has requested a trading halt pending an announcement regarding "a proposed equity raising ... by way of a share placement".

Trading will resume on June 22, 2020 or on an earlier announcement.

Opyl last traded at 13 cents.

EMERALD CLINICS

Emerald Clinics has requested a trading halt pending "announcement regarding its [real world evidence] platform.

In May, Emerald said it would be paid \$100,000 to act as program manager and use its platform for a national clinical data analytics platform for Covid-19, saying the platform could capture, analyze and provide insights into "real-world" issues (BD: May 11, 2020). Trading will resume on June 22, 2020 or on an earlier announcement.

Emerald last traded at 5.6 cents.

PROBIOTEC

Pie Funds Management says it has become a substantial shareholder in Probiotec with 3,751,032 shares or 5.02 percent of the company.

The Auckland, New Zealand-based Pie Funds said it bought shares between March 31, 2019 and June 15, 2020 at prices ranging from \$1.41 to \$2.45 a share.

Probiotec was up 3.5 cents or 1.9 percent to \$1.91.

CELLMID

Cellmid director Dennis Eck says he has increased his substantial shareholding in Cellmid from 8,178,970 shares (8.47%) to 12,497,152 shares (9.98%).

The Las Vegas-based Mr Eck said his holding was diluted in the April placement and May share plan and he acquired 4,318,182 shares in the placement, following approval. In April, Cellmid said it had raised \$6 million in placement at 22 cents, with a further \$1 million to be raised in a share plan (BD: Apr 7, 2020).

Cellmid was up half a cent or 4.55 percent to 11.5 cents with 1.6 million shares traded.

NOXOPHARM

Noxopharm executive chair Dr Graham Kelly says he has increased and been diluted from 31,540,756 shares (20.71%) to 37,002,294 shares (17.36%).

Dr Kelly said the shares were held directly and by Phytose Corp for Boundary One Super Fund, Milligene Pty Ltd for the GE and PR Kelly Family Trust, and Bende Holdings. Dr Kelly said that on June 18, 2020, he acquired 5,461,538 shares in the pro-rata rights offer at 13 cents a share, which raised \$7,918,876 (BD: Jun 15, 2020). Noxopharm was unchanged at 19 cents.

NOXOPHARM

Eleanore Goodridge says she has increased her holding in Noxopharm from 10,628,590 shares (6.99%) to 17,705,340 shares (8.30%).

The Sydney-based Ms Goodridge said that between May 5 and May 20, 2020 she sold shares at prices ranging between 20 cents a 26.77 cents a share, and on June 18, 2020, she bought shares at 13 cents each as a subscriber and underwriter of the rights issue.

ESENSE-LAB

Esense says it has a joint-venture agreement with Sassey Ptd Ltd owner of Wise Wine, to produce liquid ethanol sanitizers infused with its marijuana-based terpenes.

Esense said it would launch a joint-venture company with the Eagle Bay, Western Australia-based wine maker and distiller Sassey which would order 2,000,000 terpenes units from Esense worth \$US600,000 (\$A872,970), with \$A150,000 to \$200,000 paid upfront and the remainder paid from sanitizer sales proceeds.

The company said it would contribute \$200,000 for operational expenses and Sassey would provide \$200,000 of ingredients and well as manufacture and brand the product. Esense said the joint-venture would be owned in equal proportions.

Esense was up 0.1 cents or 7.1 percent to 1.5 cents with 2.3 million shares traded.

MGC PHARMACEUTICALS

MGC says it will sell subsidiary MGC Nutraceuticals to the New York-based Onassis Holdings Corp for \$US6 million (\$A8.7 million) worth of Onassis shares.

MGC said the it had an agreement with Onassis to supply cannabidiol, raw materials and intellectual property for the future production and manufacturing of food additive products, conditional to continuing to product products in Europe.

The company said it had the right to appoint one director to the Onassis board and the transaction would be settled within 150 days of signing the agreement.

MGC was unchanged at 2.3 cents with 3.2 million shares traded.

PHARMAUST, WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Pharmaust says the Walter and Eliza Hall Institute has confirmed that monepantel and monepantel sulfone reduces Sars-Cov-2 infectivity in-vitro "by up-to ... 95 percent". 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).

Today, the company said repeat experiments at Melbourne's Walter and Eliza Hall Institute showed that the infectivity of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) virus particles "can be suppressed by up-to approximately 95 percent in cell cultures" by either monepantel or monepantel sulfone.

Earlier this month, Pharmaust said monepantel and monepantel sulfone reduced Sars-Cov-2 replication and infectivity in tissue culture by 50 percent to 95 percent, with the lowest inhibition value from the tissue culture infectious dose (TCID50) assay measured at about 50 percent and the highest value at about 95 percent (BD: Jun 4, 2020).

Today, the company said that the confirmation tests repeated the TCID50 method. Pharmaust said it was in discussions with the Institute on the next steps to explore the significance of the work, including comparisons with other mammalian target of rapamycin (mTOR) inhibitors and current anti-viral drugs used to emergency treatment of Covid-19. WEHI researcher Prof Marc Pellegrini said the "repeat results validate the results of the initial test and form strong grounds for progressing the drug to the next step ... [and] demonstrating twice that infectivity of Sars-Cov-2 virus particles can be suppressed by upto approximately 95 percent in cell cultures is a remarkable outcome".

Pharmaust was up 2.5 cents or 22.7 percent to 13.5 cents with 13.6 million shares traded.

RESPIRI

Respiri says it has reached a legal settlement with former chief executive officer and director Mario Gattino and will pay him "an immaterial cash payment".

Last year, Respiri said Marjan Mikel would replace Mr Gattino as chief executive officer, after announcing that Mr Gattino would "leave the company" (BD: Oct 9, Nov 25, 2019). In February, Mr Gattino said he would take Respiri to court for breeching his employment contract and told Biotech Daily he was owed 20,000,000 bonus options and \$225,000 in unpaid bonusses, along with damages and penalties (BD: Feb 27, 2020).

Today, Respiri said the settlement was confidential but confirmed that a cash payment would be paid in consideration of Mr Gattino agreeing to forfeit his entitlement to potential short-term incentive payments and dropping any legal claims.

The company said Mr Gattino would finalize and pay for 1,125,000 million Respiri shares at eight cents and 10 cents each.

Respiri fell 0.4 cents or 4.8 percent to eight cents.