Biotech Daily

Tuesday July 19, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 8%; ALCIDION DOWN 11%**

*** HARRY PERKINS 5-HOUR 'EFFECTIVE' ANTIBIOTIC TEST**

*** MESOBLAST MPCs 'IMPROVE EJECTION FRACTION, REDUCE HEART EVENTS'**

*** ZELIRA TELLS ASX AWARE QUERY 'INFORMAL EMAIL CONFIDENTIAL'**

*** MEDADVISOR RECEIPTS UP 101% TO $76m**

*** VISIONEERING H1 RECEIPTS UP 17% TO $5.5m**

*** NEUREN: ACADIA FILES TROFINETIDE RETT NDA TO FDA**

*** ONCOSIL: 2nd PANCREATIC CANCER PATIENT RESECTED**

*** RHYTHM EXPANDS COLOSTAT TEST BIOMARKER**

*** HERAMED FOETAL TELE-MONITOR STUDY 'SATISFACTION'**

*** JIMMY THOMAS, IVY PONNIAH SELL ALL LIVING CELL SHARES**

*** ANTEO APPOINTS DAVID RADFORD M-D, ON $450k**

*** ISLAND APPOINTS DR AMY PATICK ADVISER**

*** MGC APPOINTS ROBERT CLEMENTS CCO**

*** CONTROL BIONICS APPOINTS DOMINIK KUCERA INTERIM CFO**

MARKET REPORT

The Australian stock market fell 0.56 percent on Tuesday July 19, 2022, with the ASX200 down 37.5 points to 6,649.6 points. Eight of the Biotech Daily Top 40 stocks were up, 19 fell, 10 traded unchanged and three were untraded. All three Big Caps fell.

Mesoblast was the best, up 6.5 cents or 7.6 percent to 92 cents, with 2.85 million shares traded. Medical Developments and Neuren climbed more than five percent; Oncosil and Opthea were up more than three percent; Compumedics rose 2.6 percent; Proteomics was up 1.7 percent; with Pro Medicus up by 0.6 percent.

Alcidion led the falls, down 1.5 cents or 10.7 percent to 12.5 cents, with 4.55 million shares traded. Actinogen and Kazia lost more than seven percent; Micro-X shed 6.7 percent; Cochlear, Resmed and Telix fell more than four percent; Cyclopharm, Dimerix, Paradigm and Polynovo were down more than three percent; Amplia, Avita, Clinuvel, CSL, Next Science, Prescient and Starpharma shed two percent or more; Atomo Cynata and Universal Biosensors lost more than one percent; with Volpara down by 0.9 percent.

HARRY PERKINS INSTITUTE OF MEDICAL RESEARCH

The Harry Perkins Institute says its staff have developed a method to confirm infections and treat them with effective antibiotics in five hours, rather than days.

Perth's Harry Perkins Institute said a research team, with the University of Western Australia, Pathwest Laboratory Medicine, Dr Aron Chakera, and Dr Kieran Mulroney published the research article, titled 'Same-day confirmation of infection and antimicrobial susceptibility profiling using flow cytometry' in E-Bio-Medicine at: https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(22)00326-7/fulltext.

University of Western Australia fellow Dr Mulroney said the test could confirm whether the cause of the patient's serious illness was a bacterial infection.

"This test takes 30 minutes, rather than one to two days," Dr Mulroney said.

"Once a patient has a confirmed bacterial infection, we then expose the bacteria to different types of antibiotics in the laboratory… using a device that measures hundreds of thousands of individual bacteria in just a few seconds, the research team can detect the damage antibiotics cause to bacteria, and then use this information to confirm which antibiotic will be an effective treatment," Dr Mulroney said.

"We can predict which antibiotics will be effective to treat that infection with 96.9 percent accuracy," Dr Mulroney said.

"The established method involves growing bacteria from a patient sample then applying different antibiotics to see which are effective," Dr Mulroney said. "Patients with serious infections cannot wait the several days it can take to return antibiotic test results."

"Consequently, the patient's doctor has to rely on a best guess, 'one-size-fits-all', antibiotic choice to treat patients," Dr Mulroney said.

"The biggest problem with prescribing broad-spectrum antibiotics is that it encourages some bacteria to become resistant to the antibiotics," Dr Mulroney said.

"This is a growing and serious problem world-wide, because antibiotic resistant bacteria can spread from person to person and reduce treatment options," Dr Mulroney said.

"The overuse of broad-spectrum antibiotics is one of the key drivers in the spread of resistance to antibiotics," Dr Mulroney said.

The Institute said that quicker and more accurate tests meant that treatments could be targeted to each infection, so that antibiotics were not too strong or ineffective.

Sir Charles Gairdner Hospital renal physician Dr Chakera said the test would be "potentially lifesaving" for patients with chronic illnesses.

"I treat patients with end-stage kidney disease who need to be in hospitals or clinics for several hours a week connected to dialysis machines," Dr Chakera said. "Many could manage their own dialysis using a surgically implanted catheter, which actually has better outcomes, is far less costly and is more satisfying for patients, but the ever-present fear of infection from the catheter deters many from choosing it."

Western Australia Country Health Service Translation Fellow Dr Tim Inglis said "the time and effort it takes to produce accurate antibiotic test results make this technique very attractive to busy clinical laboratories".

"When the Covid pandemic finally tails off, the challenge of antibiotic resistance will still be there, demanding urgent attention from the clinical lab," Dr Inglis said.

"Even in the most advanced health systems, hospital patients risk bacterial infection through trauma wounds, surgery sites, breathing machines and indwelling catheters… [which] can lead to pneumonia, urinary tract, abdominal and bloodstream infections," Dr Inglis said.

"Applying the research team's new technology to these infections is expected to transform how quickly and effectively we treat patients in Western Australia and further afield," Dr Inglis said.

MESOBLAST

Mesoblast says that a single dose of rexlemestrocel-L improves left ventricular ejection fraction and reduces major adverse events in class II and III cardiac patients.

Last year, Mesoblast said that a single dose of its mesenchymal precursor cell (MPC) product, rexlemestrocel-L, previously known as Revascor and MPC-150-IM, with standard-of-care showed greater benefit for class II and III cardiac patients than originally released and "reduced the incidence of heart attacks or strokes by 65 percent across all 537 [New York Heart Association] class II or class III treated patients compared with standard of care alone (p = 0.001)" (BD: Nov 15, 2021).

In 2020, the company said its 537-patient phase III trial of its stem cells for chronic heart failure reduced cardiac events, but did not meet its primary endpoint (BD: Dec 15, 2020).

Today, Mesoblast said that treatment of class II/III chronic heart failure with reduced ejection fraction patients with rexlemestrocel-L "resulted in greater improvement in the pre-specified analysis of left ventricular ejection fraction at 12 months relative to controls".

The company said improvement in left ventricular ejection fraction "was most pronounced in the setting of inflammation and preceded long-term reduction in the three-point [major adverse cardiovascular events] of cardiovascular death, non-fatal heart attack or stroke".

Mesoblast said that rexlemestrocel-L was an immune-modulatory therapy "developed to target the high degree of inflammation and resultant endothelial dysfunction" present across the spectrum of heart failure with reduced ejection fraction from NYHA class II through to end-stage chronic heart failure on left ventricular assist devices.

The company said the mechanism of action was "postulated to improve systolic function and left ventricular ejection fraction and reduce the high rate of major cardiovascular events and complications".

Mesoblast said "the results from two large placebo-controlled randomized studies … provide support for a common [mechanism of action] for rexlemestrocel-L across the spectrum of heart failure with reduced ejection fraction" and cited the Dream-HF trial and the 159-patient trial of end-stage heart failure patients implanted with a left ventricular assist device, as well as a 30-patient trial in left ventricular assist device patients.

Mesoblast said that "among the 537 patients who were randomized … a single injection of rexlemestrocel-L resulted in a 52 percent greater increase in [left ventricular ejection fraction] from baseline to 12 months compared with controls".

The company said that both groups had similar left ventricular ejection fraction at baseline (28.7% and 28.6%), but at 12 months the "least squared mean change from baseline was 5.0 for the rexlemestrocel-L group and 3.3 for controls (p = 0.021)".

Mesoblast said that at 30 months, there was 65 percent reduction in non-fatal heart attacks or strokes compared to controls (p = 0.001), a 33 percent reduction in the three-point major cardiac adverse events (p = 0.021), and a 68 percent reduction in the rate of recurrent hospitalizations from non-fatal heart attacks or strokes (p = 0.0002).

The company said that "outcomes were even more pronounced in the pre-specified subgroup of 301 class II/III patients with detectable circulating evidence of inflammation with a single injection of rexlemestrocel-L resulted in 86 percent greater increase in left ventricular ejection fraction from baseline to 12 months compared with controls (p = 0.005) and a 79 percent reduction in the two-point major adverse cardiac events compared to controls (p = 0.004) at 30 months.

The company said it intended to meet with FDA under the regenerative medicine advanced therapy (RMAT) framework to discuss the totality of the data and the evidence of a common rexlemestrocel-L mechanism of action across the broader heart failure with reduced ejection fraction spectrum.

Mesoblast was up 6.5 cents or 7.6 percent to 92 cents with 2.85 million shares traded.

ZELIRA (FORMERLY ZELDA) THERAPEUTICS

Zelira says it was aware of German regulatory approval by way of an “informal email” and received formal approval for Zenivol for insomnia, on July 11 at 8pm (AWST).

Last week Zelira told an ASX price query share price rise of 94.1 percent, “was most likely driven by an increase in small volume buyers being met by a reduction in small volume sellers”, as investors began “to identify the unique investment opportunity Zelira’s multiple shots on goal strategy presents” (BD: Jul 13, 14, 2022).

Today, in an ‘Aware’ query, the ASX said Zelira’s shares rose 94.1 percent from $1.02 on July 6 to $1.98 on July 12, 2022, which was prior to the pause in trading and subsequent trading halt, and prior to announcing German regulatory approval for its marijuana-based Zenivol for insomnia.

The ASX asked Zelira when it first become aware of the information and, if it was prior to the release of the German regulatory approval announcement Zelira made on July 13, then why was the information not released to the market at an earlier time?

Zelira said that on receiving an “informal email” detailing German approval, it began to prepare an announcement but “sought to ensure that it’s understanding of the information was accurate and certain as to ensure the company did not incorrectly announce the receipt of regulatory approval”, but did not state the date it received the “informal email”.

The company said that it considered that until official approval was received, it would not expect the information to be disclosed, and that “due to time zone restrictions [it] was unable to obtain approval from its commercialization partner on July 12, 2022”.

Zelira said that throughout the day on July 12, it “took steps to ensure that the information remained confidential and sought and received confirmation from its employees that the information remained confidential”.

The company said that its share price increased from $1.02 to $1.54 “prior to the company receiving formal approval”, and that trades on July 12 were “sporadic, relatively small in value and consistent with trading prior to the company becoming aware of the approval”.

Zelira said that it considered it was obliged to cease trading of its securities on forming the view that the information ceased to be confidential, which it did on July 12.

Zelira said it was in compliance with ASX listing rule 3.1, regarding confidentiality exceptions for the requirement to disclose information.

Zelira fell 59 cents or 17.9 percent to $2.70.

MEDADVISOR

Medadvisor says that receipts from customers for the year to June 30, 2022, were up 100.75 percent to $75,923,000 compared to the previous corresponding period.

Medadvisor that revenue from its prescription reminder software for the three months to June 30 was up 34.1 percent to $17.8 million, it had a cash burn rate of $3,618,000, with cash and cash equivalents of $7,679,000 and 2.6 quarters of funding available.

Medadvisor was up half a cent or 3.6 percent to 14.5 cents.

VISIONEERING TECHNOLOGIES

Visioneering says customer receipts for the six months to June 30, 2022 were up 17.1 percent to $US3,740,000 ($A5,474,477) compared to the prior corresponding period.

Visioneering said customer receipts from the sales of its Naturalvue multifocal contact lenses for the three months to June 30 was up 18.7 percent to $US1,939,000, its cash burn was $US1,860,000 with cash and equivalents of $US6,856,000.

Visioneering was untraded at 30.25 cents.

NEUREN PHARMACEUTICALS

Neuren says Acadia has submitted a new drug application to the US Food and Drug Administration for trofinetide for Rett syndrome in adults and paediatric patients.

Last year, Neuren said a 187-patient, 12-week, doubled-blind, randomized, placebo-controlled, phase III trial of trofinetide showed statistically significant benefit for Rett syndrome compared to placebo, for both co-primary endpoints (BD: Dec 7, 2021).

The company said the San Diego-based Acadia Pharmaceuticals reported "statistically significant improvement over placebo in the Rett syndrome behavior questionnaire ($p = 0.0175$) and the clinical global impression of improvement ($p = 0.0030$)".

Today, Neuren said Acadia had exclusive rights to develop and commercialize trofinetide in North America, and that it was eligible to receive potential milestone payments of up to $US455 million ($A666 million) plus double-digit percentage royalties on net sales of trofinetide in North America, plus one third of the market value of a rare pediatric disease Priority Review Voucher if awarded by the FDA on approval of an NDA for trofinetide.

The company said that if its new drug application was accepted by the FDA, it expected revenue over 2022 and 2023 for Rett syndrome in the US of $118 million, as well as double-digit percentage royalties on net sales.

The company said that following acceptance by the FDA of the application, it expected a $US10 million milestone payment in 2022, a $US40 million milestone payment in 2023, and payments of up to $US350 million on achievement of a "series of four thresholds of total annual net sales for all indications".

Neuren said it also expected to receive $US33 million in 2023, as part of its one third share of the estimated market value of a priority review voucher.

Neuren said it retained all rights to trofinetide for all countries outside the US and had a fully paid-up, irrevocable licence for use in those countries to all data generated by Acadia.

Acadia chief executive officer Steve Davis said "this is an important step forward for members of the Rett community who face a devastating disease with no approved therapies".

"We look forward to working with the FDA as it evaluates the [new drug application]," Mr Davis said.

Neuren was up 23 cents or 5.9 percent to $4.14 with 590,448 shares traded.

ONCOSIL MEDICAL

Oncosil says the second patient treated with its Oncosil device in Madrid has undergone a successful resection of the locally advanced pancreatic cancer tumor.

In April, the company said it would receive EUR374,000 ($A553,000) from Hospital Universitario de Fuenlabrada for the expanded use of its Oncosil device, and that it had completed the first commercial use of the device in Europe (BD: Apr 13; Apr 29, 2022).

Oncosil managing-director Nigel Lange said "we look forward to working with additional institutions in Spain and throughout Europe, in order to accelerate the use of the Oncosil device for the benefit of patients suffering from [locally advanced pancreatic cancer]".

"In addition, we continue to investigate all relevant means to broaden the approved labelling for use," Mr Lange said.

Hospital Universitario de Fuenlabrada head of surgery Prof Fernando Pereira said he was "pleased that treatment with the Oncosil device has led to this excellent outcome for my patient and I look forward to further treating patients with the Oncosil device to improve both their quality of life and overall clinical outcomes".

Oncosil was up 0.2 cents or 3.45 percent to six cents with 9.3 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says the lead biomarker in its Colostat bowel cancer test will be used to expand its diagnostic platform to breast, lung, cervical, pancreatic and gastric cancers.
Last year, Rhythm said it would invest $750,000 to assess whether its test had promise for breast, cervical, lung, gastric and pancreatic cancers (BD: Dec 14, 2021).
Today, the company said that some of the biomarkers identified appeared to be common between cancer types.
Rhythm said it would focus on the next stage of feasibility, testing and validation of the biomarkers of interest, and it had hired Adelaide's Agilex Biolabs to assess and develop one initial cancer target, allowing it to continue developing Colostat.
Rhythm managing-director Glenn Gilbert said "the completion of the initial program of biomarker identification directly supports our platform expansion program and is a significant step forward".
"The potential here is exciting across the five additional cancer targets that have unmet screening needs and globally addressable markets," Mr Gilbert.
"The company is working diligently to consider how best to leverage the outstanding cancer detection technology already built for Colostat," Mr Gilbert said.
Rhythm fell 6.5 cents or 4.4 percent to $1.415.

HERAMED

Heramed says a 10 women study of its Herabeat remote foetal cardiac monitor shows that the device is feasible and "results in high patient satisfaction"
Heramed said the study of 10 low risk full term pregnant women at Sheba Medical Centre in Tel Aviv measured the length of visit and reported a six question patient satisfaction survey.
The study, titled 'Novel Remote Fetal Wellbeing Assessment: Feasible, Time-saving and Associated With High Patient Satisfaction - A Prospective Pilot Study' was published by the Foetal Medicine Foundation, with an abstract available at: https://fetalmedicine.org/abstracts/2022/var/pdf/abstracts/2022/04211.pdf.
The company said the study found that remote telemedical monitoring deliver high-quality, reliable and accurate vital signs measurements of both the expectant mother and foetus.
Heramed said that there was a 60 percent reduction on average on the 'telemedicine encounter length' from 247.2 minutes to 93.1 minutes, which had the potential to save more than two and a half hours for both the patients and medical staff, and that based on a questionnaire, patients had "high satisfaction with the remote care assessment".
Heramed was unchanged at 12 cents.

LIVING CELL TECHNOLOGIES

Jimmy Thomas and Ivy Ruth Ponniah say they have ceased their holdings in Living Cell after selling all 48,573,386 shares for $354,418 or 0.73 cents a share.
Last year Mr Thomas and Ms Ponniah said they had increased their substantial holding in Living Cell to 48,573,386 shares (8.5%) after they bought 5,000,000 shares for $115,032 or 2.3 cents a share (BD: Feb 17, 2021).
Living Cell was up 0.05 cents or 6.25 percent to 0.85 cents with 1.2 million shares traded.

ANTEOTECH

Anteo says it has appointed David Radford as managing-director and chief executive officer, on a base salary of $450,000, effective from October 4, 2022.
Anteo said Mr Radford most recently worked for Allvascular as chief executive officer and was previously an executive with Recall Asia, General Electric and Nanosonics.
Mr Radford was the previously the chief executive officer for the then The Hydroponics Company (THC), now Epsilon Healthcare and the then Hunter Immunology, now Bioxyne, and Nanosonics (BD: May 16, 2011; Dec 14, 2021; Mar 15, 2018).
Anteo said Mr Radford held a Bachelor of Science from Bristol Polytechnic and a Master of Business Administration from Sydney's Australian Graduate School of Management.
The company said the Mr Radford would be paid a base salary of $450,000 a year, superannuation contributions of $25,292, as well as 30,000,000 options, exercisable at 7.5 cents or the 5-day volume-weighted average price to today, whichever was higher, vesting in three equal tranches, from his commencement date, pending share price hurdles.
Anteo was up 0.2 cents or 2.7 percent to 7.5 cents with 2.4 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has appointed Dr Amy Patick to its scientific advisory board, effective immediately.
Island said that Dr Patick had more than 30 years of research and development experience in biotechnology and pharmaceutical companies, and had previously worked for Bristol-Myers Squibb and Agouron Pharmaceuticals, which became Pfizer Global R&D, as well as Genelabs Technologies, Adamas Pharmaceuticals and Idekos.
The company said Dr Patick held a Doctor of Philosophy from the University of Wisconsin in Madison, and had co-authored more than 80 scientific publications, more than 100 abstracts, and was named on more than 10 patents.
Island was unchanged at 15.5 cents.

MGC PHARMA

MGC says it has appointed Robert Clements as chief commercial officer.
MGC said Mr Clements had more than 30 years of experience in the pharmaceutical sector, most recently working as head of business development for Sciensus Rare.
MGC co-founder and managing-director Roby Zomer said that Mr Clements appointment followed that of Angela-Marie Graham as the London-based chief financial officer "and completes the restructure of MGC Pharma executive team".
MGC fell 0.1 cents or five percent to 1.9 cents with 1.5 million shares traded.

CONTROL BIONICS

Control Bionics says it has appointed Dominik Kucera as interim chief financial officer as it continues its search for a permanent appointment.
Control Bionics said that Pitcher Partners continued to provide accounting services.
Control Bionics was up four cents or 21.05 percent to 23 cents.