Biotech Daily

Thursday June 29, 2023

Daily news on ASX-listed biotechnology companies

*** ASX FLAT, BIOTECH UP: NEXT SCIENCE UP 21%; ANTISENSE DOWN 5%**

*** HAEMALOGIX: KAPPAMAB COMBO BEATS MULTIPLE MYELOMA S-O-C**

*** IMPEDIMED: 80% OF MICHIGAN INSURED COVERED FOR SOZO LYMPHOEDEMA**

*** NEXT SCIENCE EXPECTS $6.6m Q2 SALES**

*** BIONICS INSTITUTE: PROF MAX ORTIZ CATALAN FOR NEURAL PROSTHETICS**

*** NSW UNI: 'AEROMONAS 2nd MOST PREVALENT GUT BUG'**

*** RESONANCE: FDA OKAYS HEPAFATSMART**

*** RECCE EXPANDS PHASE I/II R327 URINARY INFECTION TRIAL**

*** EMVISION OPENS ROYAL MELBOURNE TRIAL SITE**

*** ADALTA: UP-TO 16 PATIENT AD-214 PHASE I EXTENSION TRIAL**

*** IMUGENE: PD1-VAXX US PATENT EXTENDED TO 2040**

*** EMYRIA REQUESTS 'PSYCHEDELIC ACQUISITION' HALT**

*** KEFFORD TAKES 9.8% OF VECTUS**

*** DR BENJAMIN JANSEN REDUCES TO 22% OF VITURA**

*** DR PETER SMITH TO REPLACE RACE DIRECTOR DANIEL SHARP**

*** AUSCANN APPOINTS EX-MGC CHAIR BRETT MITCHELL DIRECTOR**

*** PRIYAMVADA RASAL REPLACES TISSUE REPAIR CO SEC MICHAEL AUSTIN**

MARKET REPORT

The Australian stock market slipped 0.02 percent on Thursday June 29, 2023, with the ASX200 down 1.6 points to 7,194.9 points. Twenty-four of the Biotech Daily Top 40 stocks were up, 11 fell, four traded unchanged and one was untraded.

Next Science was the best, up 10 cents or 20.8 percent to 58 cents, with 372,392 shares traded. Avita climbed 8.3 percent; Immutep improved seven percent; Mesoblast was up 5.1 percent; Atomo, Clinuvel, Cynata and Medical Developments were up four percent or more; Actinogen, Amplia, Impedimed, Polynovo and Universal Biosensors rose more than two percent; Alcidion, Nanosonics, Neuren, Opthea, Orthocell, Paradigm, Prescient and Pro Medicus were up more than one percent; with 4D Medical, Cochlear, Resmed, Telix and Volpara up by less than one percent.

Antisense led the falls, down 0.3 cents or 4.6 percent to 6.2 cents, with 888,873 shares traded. Cyclopharm, Micro-X and Pharmaxis fell more than four percent; Proteomics lost 3.4 percent; Imugene, Kazia and Resonance shed more than two percent; Emvision, and Nova Eye were down more than one percent; with CSL and Genetic Signatures down by less than one percent.

HAEMALOGIX

Haemalogix says its phase IIb trial of Kappamab with standard-of-care for multiple myeloma showed “significant efficacy … and a significant overall survival advantage”.
Haemalogix said that the trial at Melbourne’s Alfred Hospital enrolled 59 patients including 19 with who had relapsed or had stopped responding to standard-of-care, and in which the disease was progressing.
The company said the trial investigated Kappamab in combination with lenalidomide (Revlimid) and dexamethasone, compared to lenalidomide and dexamethasone, alone.
Haemalogix said that compared to the control group, the combination with Kappamab showed significant efficacy, with an overall response rate of 82.5 percent and a significant overall survival advantage of 46 percent reduction in the risk of death.
The company said that 59 patients were enrolled with 19 patients in the Kappamab alone stage and 40 in the Kappamab, lenalidomide and dexamethasone stage.
Haemalogix said that the combination of overall response rate of 82.5 percent “was significantly better than the contemporaneous and matched control group receiving Revlimid and dexamethasone [of] 45.1 percent.
The company said that when compared to the controls the Kappamab, lenalidomide and dexametasone cohort also showed a significant overall survival advantage with a 46 percent reduction in the risk of death compared to the matched control group.
Haemalogix said that having completed pre-clinical studies and phase I and phase IIa trials which showed “excellent safety and significant efficacy” it would progress Kappamab to a dose-escalation study as well as pairing Kappamab with pomalidomide and dexamethasone, another standard-of-care combination for multiple myeloma.
The company said that “despite advances in therapy, multiple myeloma … remains an incurable disease for most patients”.
“Kappamab is a novel immunotherapy that targets a receptor found only on the surface of myeloma cells, not healthy immune cells, making it highly specific, unlike most treatments for myeloma that form standard-of-care,” Haemalogix said.
The company said it had completed pre-clinical studies in chimeric antigen receptor T-cells (Car-T) with the Peter MacCallum Cancer Centre for multiple myeloma that targeted the same receptor, with a human clinical trial planned for 2024.
Haemalogix is a public unlisted company.

IMPEDIMED

Impedimed says 80 percent of Michigan’s insured population has reimbursement cover for its Sozo test for lymphoedema in breast cancer, a “critical mass” coverage.
In May, Impedimed said the Grand Rapids, Michigan-based Priority Health had published the first medical policy covering its Sozo test for lymphoedema following breast cancer treatment (BD: May 25, 2023).
Today, Impedimed chief executive officer Richard Valencia said that “within only three months of bio-impedance spectroscopy inclusion into the [National Comprehensive Cancer Network] guidelines for survivorship we have reached critical mass for reimbursement coverage in our first target state”.
“Furthermore, prior authorization is not required for Sozo measurements, which streamlines workflows and simplifies the reimbursement process,” Mr Valencia said.
“Our customers already believe in the clinical value of our technology, and now, with a strengthened return on investment model, the decision to adopt Sozo is even easier,” Mr Valencia said.
Impedimed was up half a cent or 2.8 percent to 18.5 cents with 3.4 million shares traded.

NEXT SCIENCE

Next Science says it expects unaudited sales for the three months to June 30, 2023 to be more than $US5.6 million ($A6.6 million), compared to the first quarter $US4.4 million.
Next Science said its product sales for the six months to June 2023 were on track to exceed previous half year periods, including $US5.2 million for the six months to June 30, 2022 and $US6.1 million for the six months to December 31, 2022.
The company said monthly sales of its wound care business surpassed $1 million in April 2023,
Next Science said that operating momentum had continued with sales traction in the commercial wound care market.
Next Science was up 10 cents or 20.8 percent to 58 cents.

BIONICS INSTITUTE

Melbourne's Bionics Institute says it has appointed Prof Max Ortiz Catalan as its head of neural prosthetic research to further develop bionic limb technology.
The Bionics Institute said that Prof Ortiz Catalan was a professor of bionics at the Gothenburg, Sweden-based Chalmers University of Technology where he had been working on joining prosthetic limbs to the patient's body.
"The prosthetic limbs currently available don't provide the wearer with sensory feedback, so patients can't tell if they're touching something or holding an object," Prof Ortiz Catalan said. "My team and I are using surgical and engineering techniques to connect a patient's prosthesis directly to their bones, nerves and muscles; creating a neuro-musculo-skeletal human-machine interface."
The Bionics Institute said that the interface supported brain signals to travel through the nerves and muscles safely and reliably to the bionic limb, giving the patient movement control and sensory awareness.
The Institute said that a "strong and comfortable mechanical connection to the prosthesis is created using a technique called osseo-integration, where a titanium implant is inserted into the patient's bone".
The Bionics Institute said that bone cells would grow around the implant so that the bionic limb could be directly attached to the skeleton.
The Institute said that in addition to skeletal attachment, Prof Ortiz Catalan had been re-engineering osseo-integrated implants to allow for bi-directional communication between the human nervous system and the prosthetic limb, a port to the human body.
Prof Ortiz Catalan said the "revolutionary approach to integrating a bionic limb with the body means that a patient can reliably move the bionic limb using their thoughts".
"For example, a patient can control a robotic hand as they would move their own biological hand [and] every finger on it," Prof Ortiz Catalan said.
The Bionics Institute said that sensors in the robotic hand made for "a more intuitive experience, enabling the patient to detect contact with the prosthesis, know what position the hand is in, and the amount of force applied to objects during grasping".
Bionics Institute chief executive officer Robert Klupacs said Prof Ortiz Catalan's appointment at the Bionics Institute "marks a new chapter in Australian medical technology] innovation and has the potential to improve healthcare outcomes worldwide".
"His cutting-edge research has the power to redefine the possibilities of bionic technologies, providing solutions that restore function and independence for those who have lost a limb through amputation or congenital limb malformation," Mr Klupacs said.

UNIVERSITY OF NEW SOUTH WALES

The University of New South Wales says that the Gram-negative bacteria Aeromonas is "the second most common cause of bacterial gastroenteritis".

The University said that a study of 341,330 patient samples by Prof Li Zhang and her team on the types of intestinal bacteria showed that Aeromonas was the second most prevalent bacterial pathogen found in patients with gastro-enteritis after Campylobacter infection, with Aeromonas testing not routine as for Campylobacter and Salmonella.

"Our results have found that Aeromonas are the second most prevalent enteric bacterial pathogens across all age groups, and are in fact the most common enteric bacterial pathogens in children under 18 months," Prof Zhang said.

The University said that the research, titled 'Enteric Aeromonas Infection: a Common Enteric Bacterial Infection with a Novel Infection Pattern Detected in an Australian Population with Gastroenteritis' was published in Microbiology Spectrum, with the full article available at: https://journals.asm.org/doi/10.1128/spectrum.00286-23.

The University of New South Wales said the results "could have an impact on the diagnostic process for gastroenteritis and ultimately lead to more targeted treatment".

"Once we're able to figure out the source of infection, we may eventually be equipped with the knowledge of how best to prevent Aeromonas infection," Prof Zhang said.

"Historically, Aeromonas species have been largely overlooked and understudied, but they are increasingly recognized as emerging enteric pathogens," Prof Zhang said.

The University said Aeromonas enteric infections were predominately observed in young children and individuals over 50 years old "suggesting a higher susceptibility to these infections during stages where the immune system tends to be weaker".

"The high rate of Aeromonas infection discovered in our study, and significantly, how they are impacting different patient age groups, suggest that Aeromonas species should be included on the common enteric bacterial pathogen examination list," Prof Zhang said.

The University said the next step for Prof Zhang's team was to identify Aeromonas pathogens at greater detail and identify their source, with research showing the majority of Aeromonas enteric infections were locally acquired, with no history of overseas travel.

RESONANCE HEALTH

Resonance says the US Food and Drug Administration will allow it to market its Hepafatsmart artificial intelligence magnetic resonance imaging-based liver fat scan.

Resonance said Hepafatsmart would replace its Hepafat-AI (artificial intelligence) system, which received FDA clearance in 2020 (BD: Dec 9, 2020).

The company said Hepafatsmart analyzed magnetic resonance imaging (MRI) images to assess a patient's liver fat, providing clinicians with three liver fat biomarkers, including volumetric liver fat fraction, proton density fat fraction and a steatosis grade.

Resonance managing-director Mitchell Wells said that "Hepafatsmart is our first software-as-a-medical device to receive US FDA regulatory clearance, developed entirely in-house by Resonance Health's AI development project team".

"The team worked closely with the company's experienced technical analysts to develop a new and materially improved approach to training Hepafatsmart that more closely emulates the Hepafat-Scan manual analysis methodology, achieving a sensitivity and specificity of 98 to 100 percent, versus Hepafat-Scan," Mr Wells said.

"This is one of several initiatives completed in recent months that collectively serve to significantly de-risk and improve the business into the future while ensuring we have control of our corporate destiny," Mr Wells said.

Resonance fell 0.1 cents or 2.4 percent to 4.1 cents.

RECCE PHARMACEUTICALS

Recce says it has ethics approval for the expansion of its phase I/II trial for the “faster infusion” of R327 for urinary tract infections.

Recce said the trial was assessing R327 at faster administration rates, potentially applicable for use at first presentation within a general practitioner or acute patient setting.

The company said R327 would be administered in about 16 patients as an anti-infective, with a phase II trial for urinary tract infection (UTIs) patients expected by the end of 2023.

Recce said the expanded trial would take place at Sydney-based Scientia Clinical Research, located in a research precinct with the Prince of Wales Hospital, Royal Hospital for Women, University of New South Wales and the Lowy Cancer Research Centre.

Recce chief executive officer James Graham said the company was “pleased to expand our phase I/II UTI studies with Scientia Clinical Research joining present dosing at [Adelaide’s] Cmax”.

“This now multi-state study expects to expedite our clinical trial progress and address the global health threats posed by UTIs and Urosepsis,” Mr Graham said.

Recce was up half a cent or 0.8 percent to 62 cents.

EMVISION MEDICAL DEVICES

Emvision says it has begun recruitment for the second stage of its portable brain scanner trial at the Royal Melbourne Hospital.

In May, Emvision said it had begun its up-to 150-patient, stage two, multi-site trial of its portable brain scanner for stroke and stroke mimic patients in emergency departments, at Sydney’s Liverpool Hospital, the Royal Melbourne Hospital and Brisbane’s Princess Alexandra Hospital (BD: May 29, 2023).

Today, the company said enrolment at Liverpool Hospital exceeded expectations and the Princess Alexandra Hospital was expected to start recruiting “in the coming weeks”.

Emvision fell 1.5 cents or 1.3 percent to $1.17.

ADALTA

Adalta says it has ethics approval for an up-to 16 patient, phase I, extension trial of AD-214 for lung and chronic kidney disease.

In May, Adalta said it had raised $3.15 million through a rights offer, with the proceeds to be used for the phase I extension study (BD: May 25, 2023).

Today, the company said the up-to 16-patient phase I extension study, titled ‘Safety, Tolerability, PK and PD Study of AD-214 Administered to Healthy Volunteers and Patients with Interstitial Lung Disease or Chronic Kidney Disease’ would extend prior phase I findings, help find partners and reduce phase II time and cost.

Adalta said up-to eight healthy volunteers and up-to eight patients with interstitial lung or chronic kidney disease or would receive four doses of 10mg/kg AD-214.

The company said the first part of the trial would be conducted in Adelaide with dosing anticipated to begin August 2023.

Adalta director of clinical and regulatory operations Darryn Bampton said the study aimed to “confirm safety and pharmaco-kinetic and pharmaco-dynamic trends of multiple doses of AD-214 using higher doses than in the previous study”.

Adalta chief executive officer Tim Oldham said meetings with potential partners had confirmed that the extension study would “enhance our ongoing partnering discussions”.

Adalta was unchanged at 2.4 cents with 1.3 million shares traded.

IMUGENE

Imugene says the US Patent and Trademark Office has allowed the extension of its PD1-Vaxx patent until February 11, 2040, compared to its previous March 28, 2038 expiry.
Imugene said the patent, titled 'Human PD1 Peptide Vaccines and Uses Thereof' protected its PD1-Vaxx composition of matter and method of treatment in cancer for the generation of antibodies against the PD1 checkpoint target.
Imugene chief executive officer Leslie Chong said that "with the US being the largest healthcare market in the world, this is a particularly important patent extension to protect our PD1-Vaxx technology as we continue its development."
Imugene fell 0.2 cents or 2.2 percent to 8.9 cents with 48.2 million shares traded.

EMYRIA

Emyria says it has requested a trading halt pending an announcement "regarding a strategic acquisition related to Emyria's psychedelic-assisted therapy program".
Trading will resume July 3, 2023 or on an earlier announcement.
Emyria last traded at 12.5 cents.

VECTUS BIOSYSTEMS

Kefford Holdings Pty Ltd says it has increased its substantial shareholding in Vectus from 4,650,000 shares (8.83%) to 5,178,668 shares (9.83%).
Brisbane's Kefford said it bought shares between June 9 and 27, 2023, with the single-largest purchase 300,000 shares for $135,000 or 45.0 cents a share on June 9, 2023.
Vectus was unchanged at 44 cents.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Dr Benjamin David Ngahuia Jansen says he has reduced his shareholding in Vitura from 129,890,570 shares (23.68%) to 124,290,842 shares (22.33%).
The Cannabis Doctors Australia co-founder Dr Jansen said that between December 19, 2022 and June 28, 2023, he sold shares at prices from 30.02 cents to 61 cents a share.
Vitura fell two cents or 3.7 percent to 52 cents.

RACE ONCOLOGY

Race says Dr Peter Smith will replace non-executive director Daniel Sharp, who has resigned to concentrate on "other personal and professional interests".
Race said Dr Smith was currently Myrio Therapeutics chief executive officer, and was previously the chief executive officer of Alchemia and Amrad, as well as the co-founder and chief financial officer of Onycax.
The company said that Dr Smith held a Bachelor of Arts and a Doctor of Philosophy from the University of Cambridge.
The company said that Dr Smith would be issued 182,792 options exercisable at $2.03 each within five years, subject to shareholder approval.
Race fell 11.5 cents or 8.5 percent to $1.24.

AUSCANN

Auscann says it has appointed former MGC Pharma chair Brett Mitchell as an independent, non-executive director.

Earlier this month, MGC said that Auscann chief executive officer Layton Mills would replace Brett Mitchell as director.

This week, Auscann said Mr Mitchell was a founder and director of Chieftain Securities and director of Uvre Limited and held a Bachelor of Economics from the University of Western Australia.

Auscann said that, as a result of Mr Mitchell's appointment, executive director Chris Mews would step down while remaining the company's chief financial officer.

Auscann was in a suspension and last traded at four cents.

TISSUE REPAIR

Tissue Repair says Priyamvada Rasal will replace Michael Austin as company secretary, effective from June 28, 2023.

Tissue Repair said Ms Rasal had managed company portfolios for more 12 years, and worked for Automic Group.

According to her Linkedin page, Ms Rasal held a Bachelor of Commerce from the Maharashtra, India-based Marathwada University and a Bachelor of Laws from India's Savitribai Phule Pune University.

Tissue Repair fell two cents or 7.4 percent to 25 cents.