Biotech Daily

Thursday September 29, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: ACTINOGEN UP 12%; MESOBLAST DOWN 5%**

*** CENTENARY, SYDNEY UNI $19m US TB VACCINE CONTRACT**

*** FEDERAL $1m FOR MONASH UNIVERSITY HEART-LUNG MACHINE**

*** BRANDON CO-LEADS $105m RAISE FOR LONDON'S PHEON**

*** ORTHOCELL: 'ORTHO-ATI REDUCES ROTATOR CUFF PAIN AT 6 MONTHS'**

*** CYBAN PAYS HYDRIX $1.3m FOR BRAIN OXYGEN MONITOR**

*** CARDIEX 'OVERSUBSCRIBED' PLAN RAISES $1.6m, TOTAL $5.9m**

*** ARGENICA ARG-007 'REDUCES BRAIN TISSUE DEATH 86%, IN RATS'**

*** GENETIC SIGS EASYSCREEN 'ACCURATE FOR ANTIBIOTIC RESISTANCE'**

*** GENETIC TECHNOLOGIES: 'GENETYPE SUPERIOR FOR BREAST CANCER'**

*** REGAL FUNDS TAKES 9.15% OF ADHERIUM**

*** WATERCREST, STUART CAMERON, KARANTZIAS TAKE 9% OF EPSILON**

*** DIRECTOR JAMES CORBETT REPLACES AVITA CEO DR MIKE PERRY**

MARKET REPORT

The Australian stock market climbed 1.44 percent on Thursday September 29, 2022, with the ASX200 up 93.0 points to 6,555.0 points. Twenty-six Biotech Daily Top 40 companies were up, seven fell, six traded unchanged and one was untraded. All three Big Caps rose.

Actinogen was the best, up 0.9 cents or 12.0 percent to 8.4 cents, with 3.1 million shares traded. Universal Biosensors climbed 10.2 percent; Amplia and Medical Developments were up more than nine percent; Orthocell rose 6.2 percent; Emvision, Neuren, Paradigm and Prescient improved five percent or more; Alcidion, Avita and Next Science were up four percent or more; Clinuvel, Cyclopharm, Pharmaxis and Volpara were up more than three percent; Cochlear, Impedimed, Imugene, Oncosil, Pro Medicus and Telix rose two percent or more; Atomo, CSL, Nanosonics, Proteomics, Resmed and Resonance were up more than one percent; with Opthea up by 0.9 percent.

Mesoblast led the falls, down four cents or 4.8 percent to 79 cents, with 1.5 million shares traded. Nova Eye and Polynovo fell four percent or more; Dimerix lost 3.3 percent; Antisense and Starpharma shed more than one percent; with Genetic Signatures down 0.6 percent.

CENTENARY INSTITUTE, UNIVERSITY OF SYDNEY

The Centenary Institute and the University of Sydney says they have a $19 million contract from the US National Institutes of Health to develop tuberculosis vaccines.
Sydney's Centenary Institute said the NIH National Institute of Allergy and Infectious Diseases would fund the research and development of new tuberculosis vaccines and test them in clinical trials, over five years.
Centenary said that the contract was titled 'Advancing Vaccine Adjuvant Research for TB (AVAR-T)' and as part of its research it would conduct a head-to-head comparison of critical components, such as antigens and adjuvants, which were necessary to create a successful tuberculosis vaccine.
Centenary head of tuberculosis research program and lead investigator Prof Warwick Britton said that a more effective tuberculosis vaccine was "urgently needed", with the only licenced vaccine, Bacille Calmette-Guérin (BCG), more than 100 years old.
"BCG is effective in reducing the risk of disease for infants but performs poorly in preventing infection in older children and adults," Prof Britton said.
"A new and improved tuberculosis vaccine with increased efficacy rates is required to help decrease the global tuberculosis burden and to save lives around the world," Prof Britton said.
The University of Sydney's principal investigator for the project Prof Jamie Triccas said the researchers would work with centres in Copenhagen, Oregon and New Orleans.
"The successful development of a new vaccine could be an absolute game-changer in terms of reducing the spread of tuberculosis and reducing deaths globally," Prof Triccas said.

MONASH UNIVERSITY, FEDERAL GOVERNMENT

Monash University says it has a $999,779 Federal Government grant for research relating to its heart and lung machine for organ failure.
Melbourne's Monash University said that the Minister For Health And Aged Care Mark Butler announced the Medical Research Future Fund Cardiovascular Health Mission grant at the Alfred's Intensive Care Unit in Melbourne on National Heart Day.
The University said that the researched involved the extra-corporeal membrane oxygenation machine (ECMO), which simulated a heart-lung bypass after acute cardiac and respiratory failure and cardiac arrest, replacing a non-function heart or lung for weeks.
Monash said that ECMO was used in adults, children and newborns when all other forms of life support had failed, and that it increased survival in those patients by about 60 percent.
Monash said it would conduct a 236-patient, cardiogenic shock evaluation study, led by Dr Aidan Burrell, in collaboration with Alfred Health, St Vincent's Hospital Sydney, the University of Sydney and the University of Queensland's Critical Care Research Group.
The University said the prospective, multi-centre study would investigate whether biomarkers could better identify patients who would derive the best long-term benefit from the extra-corporeal membrane oxygenation machine.
Monash said it would embed the study in the national ECMO registry, which covered more than 95 percent of ECMO patients nationally.
Monash dean of faculty of medicine, nursing and health sciences Prof Christina Mitchell said the funding would "allow us to investigate whether biomarkers can better identify which patients will derive the best long-term benefit from ECMO, potentially leading to more targeted ECMO support and improved patient care".

BRANDON CAPITAL

Brandon Capital says it has co-led a $US68 million ($A105 million) series A foreign capital raise for the antibody drug conjugate company Pheon Therapeutics.

The Melbourne-based Brandon said that the investment was its largest into a European-based company and would allow the London-based Pheon to advance its lead antibody drug conjugate program for hard-to-treat cancers to clinical proof-of-concept and to develop novel conjugates.

The company said that partner Jonathan Tobin was head of its offices in London which opened in Kings Cross a year ago, and would chair Pheon.

Brandon said it had backed about “60 innovative life sciences companies over the past 15 years” including Myricx Pharma and Pathios Therapeutics.

Brandon Capital is a private company.

ORTHOCELL

Orthocell says its 30-patient rotator cuff tendon study showed that Ortho-ATI reduced almost all pain six months after treatment, performing better than cortico-steroids.

Orthocell said the randomized, multi-centre, open-label study assessed autologous tenocyte implantation (Ortho-ATI) in comparison to cortico-steroids, as an emerging treatment for patients with rotator cuff tendinopathy with intra-substance tendon tear.

The company said that the 30 patients were verified by magnetic resonance imaging with symptom duration of more than six months and who had previously received physiotherapy and one or more cortico-steroid injections, with 19 patients in the Ortho-ATI group and 11 patients in the cortico-steroid group.

Last year, Orthocell said the 30-patient study showed that Ortho-ATI was “significantly more effective than steroid injection” for rotator cuff tendinopathy (BD: Dec 8, 2021).

Today, Orthocell said that nine of 11 patients who received cortico-steroid treatment in the trial requested subsequent crossover treatment with Ortho-ATI due to “a lack of improvement in their shoulder pain and/or function”, which on average, resulted in the group experiencing an “almost complete resolution of pain by month six following treatment with Ortho-ATI”.

The company said the average visual analogue scale pain score was reduced by 3.2 points, from 4.7 pre-treatment to a 1.5 at 12 months post-treatment, and that at six months post-treatment, 67 percent of participants reported a score of three or less, with an 89 percent improvement at 12 months post-treatment, demonstrating a “successful outcome”.

Orthocell said that the average American shoulder and elbow surgeons shoulder assessment (ASES) score improved by 26.8 points from 66.2 pre-treatment to 93.0 at 12 months post-treatment, with “clinically meaningful” mean improvements in ASES scores pre-treatment to six months post-treatment was 21.4 and to 12 months was 26.8.

The company said seven of nine patients (78%) reported an ASES score of 78.6 or better at six months post-treatment, improving to 100 percent at 12 months post-treatment.

Orthocell managing-director Paul Anderson said the company was “delighted with the cross-over patient study results clearly demonstrating that Ortho-ATI is more effective than steroid injection for treatment of rotator cuff tendinopathy with intrasubstance tendon tear”.

“This is an important validation for Ortho-ATI… [and] we are now in a very strong position to progress our US commercialization strategy to deliver the first injectable cell therapy in orthopaedics that truly addresses the cause of degeneration and returns patients to full use of their chronically damaged tendons,” Mr Anderson said.

Orthocell was up 2.5 cents or 6.2 percent to 43 cents.

HYDRIX

Hydrix says the Melbourne-based Cyban Pty Ltd will pay it $1.3 million to develop Cyban's next generation brain oxygen monitor.
Hydrix said the program followed concept generation and commercial device system architecture stages and was the start of the detailed development of the system.
The company said that Cyban was a technology company focused on developing a novel, non-invasive continuous brain oxygen monitor, in which it owned 5.85 percent, and the contract was expected to be completed by July 2023.
Hydrix Services general manager Michael Trieu said the company was "pleased to be Cyban's preferred product development partner and an investor via Hydrix Ventures".
"This development and investment structure provides Hydrix multiple ways to participate in the potentially significant market opportunity to create a new gold standard of care in brain trauma injury management," Mr Trieu said.
Hydrix was unchanged at 5.9 cents.

CARDIEX

Cardiex says it has raised $1.593 million in an over-subscribed share plan at 30 cents a share, taking the total raised to $5.923 million.
In August, Cardiex said it had "commitments" for $4.33 million in a placement at 30 cents a share and would offer a share plan to raise $1 million (BD: Aug 22, 2022).
Cardiex fell half a cent or 1.6 percent to 30 cents.

ARGENICA THERAPEUTICS

Argenica says ARG-007 reduced brain tissue death 86 percent in a rat model of paediatric hypoxic-ischaemic encephalopathy (HIE).
Argenica said ARG-007 "significantly reduced the volume of brain tissue death … at 48 hours post injury", in a rat equivalent to 37 to 40 weeks gestation in humans.
The company said hypoxic-ischaemic encephalopathy occurred when the brain did not receive enough oxygen or blood and was most common among infants as the result of an oxygen-depriving event during or around the time of birth, resulting in life-long disabilities.
Argenica said the trial at Perth's Perron Institute for Neurological and Translational Science by Dr Adam Edards and its chief scientific officer Prof Bruno Meloni examined the neuro-protective properties of ARG-007 administered immediately following hypoxia-ischaemia encephalopathy in a rats, at different doses and compared to a saline control.
Argenica said the reduction in brain death was "dose dependent with higher doses showing greater infarct reduction", with a 86 percent reduction ($p = 0.01$) at the 300 nanomole per kilogram (nmol/kg) dose level and a 62 percent reduction ($p = 0.05$) at 100nmol/kg, when compared to the control group.
Argenica said it would look to engage a specialist paediatric clinical research facility to develop ARG-007 for human infants with hypoxia-ischaemia encephalopathy.
Argenica chief executive officer Dr Liz Dallimore said the data "further expands our pre-clinical data package for ARG-007 as a potential treatment for this devastating condition".
"Confirming ARG-007 works in a term animal model of HIE strengthens our position to potentially be able to successfully move ARG-007 into clinical trials in human infants who have been exposed to an ischaemic injury prior to, during or immediately after birth," Dr Dallimore said. "Assuming the company's upcoming phase I trial for ARG-007 is successful, we look forward to progressing ARG-007 into infants for HIE."
Argenica was up two cents or 4.35 percent to 48 cents.

GENETIC SIGNATURES

Genetic Signatures says an in-vitro trial shows its Easyscreen detection kit has “excellent sensitivity and specificity” for detection of antibiotic resistance.

Genetic Signatures said that the study, titled ‘Evaluation of the Easyscreen ESBL/CPO Detection Kit for the Detection of Beta-Lactam Resistance Genes’, was published in Diagnostics and available at: https://www.mdpi.com/2075-4418/12/9/2223.

The company said that the study evaluated the ability of Easyscreen extended-spectrum beta-lactamase/carbapenemase producing organisms (ESPL/CPO) detection kit to detect 15 different beta-lactamase genes in different gram-negative bacteria, and the colistin-resistance gene mcr-1 from 341 bacterial isolates.

Genetic Signatures said that beta-lactam antibiotics included penicillin, cephalosporin and carbapenem and were among the most frequently prescribed antibiotics used to treat bacterial infections but that their utility was at threat from the proliferation of an enzyme called beta-lactamase in multi-drug-resistant strains of gram-negative bacteria able to inactivate these antibiotics.

Genetic Signatures said that the study showed that irrespective of the host bacteria, the Easyscreen ESBL/CPO detection kit showed “excellent biological performance, sensitivity and specificity, for the five most common carbapenemases … [and was] “effective at identifying other anti-microbial resistance genes that are not well detected by most other molecular assays”.

The company said that the kit had a “short turnaround time and simplicity” which made it suitable for routine use in most clinical microbiology laboratories.

Genetic Signatures said that its Easyscreen detection kit was registered for sale in Australia and had a Conformité Européenne (CE) in-vitro diagnostic marking.

Genetic Signatures chief executive officer John Melki said the data reinforced results from a previous published, independent study “which reported that our Easyscreen ESBL/CPO Detection Kit provided the highest positive predictive value, with 100 percent sensitivity, of the four commercially available kits tested”.

“Antimicrobial resistance has been declared one of the top 10 global public health threats facing humanity by the World Health Organisation,” Mr Melki said.

Genetic Signatures fell half a cent or 0.6 percent to 82 cents.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype Risk Test outperformed traditional risk assessments for breast cancer.

Genetic Technologies said that a research article, authored by its science team and titled. ‘Integrating Personalised Medicine into Preventative Care through Risk Stratification’ was published in the Journal of Precision Medicine and was at: https://bit.ly/3foP9jA.

The company said that a side-by-side comparison of clinical risk assessment models showed that the Genetype Risk Assessment for breast cancer showed a nine-fold improvement (22.4%) in identifying at-risk women when compared with traditional gold-standard methods (2.5%).

Genetic Technologies said that the article showed that a simple risk report enabled a clinician to “communicate risk in a standard format, within the confines of clinically actionable thresholds resulting in improved patient outcomes”.

Lead author Dr Erika Spaeth said “continued improvement in risk prediction using tests such as Genetype strengthens the ability of clinicians to stratify their at-risk patients enabling earlier intervention and better outcomes for patients”.

Genetic Technologies fell 0.05 cents or 14.3 percent to 0.3 cents.

ADHERIUM

Regal Funds Management Pty Ltd says it has become substantial in Adherium with 234,359,947 shares or 9.15 percent.
The Sydney-based Regal said on September 26, 2022 it bought the shares for $1,171,800 or 0.5 cents a share.
Earlier this month, Adherium said it had commitments for a $13.5 million placement at 0.5 cents a share, including “cornerstone investments” from the London, Ontario-based Trudell Medical, Melbourne’s Bioscience Managers Translation Fund 1, and another unnamed “significant institutional investor” (BD: Sep 16, 2022).
Adherium was unchanged at 0.55 cents.

EPSILON HEALTHCARE

Watercrest Asset Management, Stuart Cameron and Karantzias Superfund say they have become substantial in Epsilon with 26,639,516 shares or 8.98 percent.
The Sydney-based Watercrest, Stuart Cameron, and Karantzias said they bought the shares between September 21 and 23, 2022, with the largest purchase on September 21 of 17,647,059 shares for $750,000 or 4.25 cents a share.
Epsilon fell 0.1 cents or 4.35 percent to 2.2 cents.

AVITA MEDICAL

Avita says it has appointed non-executive director James Corbett as chief executive officer, replacing five-year chief executive officer Dr Mike Perry, effective immediately.
Avita said Mr Corbett had about 40 years of experience in life sciences and had worked for Microtherapeutics Inc, Ev3 Inc, Alphatec Spine, Home Diagnostics Inc, Vertos Medical Inc and Cathworks Ltd as chief executive officer, as well as Baxter Japan, Scimed Life Systems as an executive.
According to his Linkedin page, Mr Corbett held a Bachelor of Science in Business Administration from the Lawrence-based University of Kansas.
The company did not disclose Mr Corbett’s yearly salary or incentives.
Avita said Dr Perry was appointed chief executive officer in 2017 and chair Lou Panaccio said the company was “grateful to Dr Perry for his many contributions to Avita Medical”.
“We thank him for his commitment to Avita Medical, its customers, employees, shareholders and the patients we serve,” Mr Panaccio said.
Avita was up 7.5 cents or 4.45 percent to $1.76.