Biotech Daily

Monday October 7, 2024

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: MICRO-X UP 12%; RESONANCE DOWN 3%**

*** PRO MEDICUS $98m MERCY HEALTH VISAGE RENEWAL**

*** IMMURON: 'COW COLOSTRUM 10% EFFECTIVE FOR DIARRHOEA'**

*** FEDERAL $18m FOR QUEENSLAND UNI SPIDER VENOM HEART DRUG**

*** CANN RIGHTS OFFER FOR $6.25m**

*** ORTHOCELL 2nd RECORD QUARTER, Q1 REVENUE UP 15% TO $2m; HALT**

*** SOMNOMED: FDA OKAYS REST ASSURE, NOT INTERNET MONITORING**

*** CHIMERIC 1 COMPLETE AML RESPONSE IN CHM0201 TRIAL**

*** MONASH UNI: 'PSILOCYBIN MAY AID DEPRESSION, IN RATS'**

*** RHYTHM '2nd GEN COLOSTAT CANCER TEST BEATS 1st GEN'**

*** NEUREN, FDA DISCUSS PHASE III NNZ-2591 PHELAN-MCDERMID TRIAL**

*** ENLITIC SIGNS DMC, JAPAN NCC, ULTRARAD DEALS**

*** ONCOSIL: AL ZAHRAWI TO SELL DEVICE IN UAE, QATAR, OMAN, BAHRAIN**

*** ECHO IQ 12m CEO, DIRECTORS RIGHTS AGM; 'FDA CLEARANCE, US CEO' HALT**

*** ALLEGRA DIRECTOR DR NICHOLAS HARTNELL TAKES 90.8%**

*** IMMUTEP LOSES DIRECTOR ANNE ANDERSON**

*** ARGENICA APPOINTS DR STUART GRIBBLE PRODUCT DEVELOPMENT HEAD**

MARKET REPORT

The Australian stock market was up 0.68 percent on Monday October 7, 2024, with the ASX200 up 55.4 points to 8,205.4 points. Twenty-three of the Biotech Daily Top 40 stocks were up, four fell, 12 traded unchanged and one was untraded. All three Big Caps fell.

Micro-X was the best, up 0.7 cents or 11.7 percent to 6.7 cents, with 851,585 shares traded. Prescient climbed 6.8 percent; Opthea was up 5.3 percent; Nanosonics, Orthocell, Polynovo and Syntara were up more than four percent; Aroa, Compumedics, Curvebeam and Universal Biosensors climbed more than three percent; Clarity and Imugene improved more than two percent; Avita, Emvision, Mesoblast, Neuren, Nova Eye, Pro Medicus, Proteomics and Starpharma were up by more than one percent; with Clinuvel and Telix up by less than one percent.

Resonance led the falls, down 0.2 cents or 3.3 percent to 5.8 cents, with 166,979 shares traded. Cyclopharm fell 2.9 percent; Alcidion and Medadvisor were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

PRO MEDICUS

Pro Medicus says its wholly-owned US subsidiary Visage Imaging has a $98 million, eight-year renewal of its contract with the St Louis, Missouri-based Mercy Health.

In 2016, Pro Medicus said Visage Imaging had signed a $21 million, seven-year contract with Mercy Health System "the seventh largest Catholic health care system in the US" and the contract included its Visage 7 imaging technology installed at Mercy's 46 acute care and specialty hospitals, in Missouri, Arkansas, Oklahoma and Kansas (BD: Apr 4, 2016).

Pro Medicus said Visage 7 would be a key component of Mercy's image viewing platform and would be used for primary diagnoses, clinical distribution and access to radiology images through Mercy's electronic health record system.

Today, the company said the deal covered both its Visage 7 viewer and Visage 7 open archive, and was "transaction-based" with the company negotiating for a higher per transaction cost.

Pro Medicus managing-director Dr Sam Hupert said the contract renewal for a longer term and at an increased price showed "confidence in our offering and reinforces our belief that the Visage solution delivers unparalleled value in terms of both financial and clinical [return on investment]".

Pro Medicus was up $3.29 or 1.8 percent to $182.31 with 149,741 shares traded.

IMMURON

Immuron says interim results from the 27-participant trial of its Campetec, cow colostrum-based prophylactic for diarrhoea shows 10.4 percent protective efficacy.

In 2016, Immuron said it had a collaboration with the US Naval Medical Research Center (NMRC) to test Travelan in Campylobacter and entero-toxigenic Escherichia coli (Etec), both of which were major causes of travellers' diarrhoea (BD: Aug 30, 2016).

At the time, the company said the testing of its cow colostrum-based products, including Campetec, by the US Army and the US Navy could lead to the development of a vaccine-based, hyper-immune colostrum product that contained all three sets of antibodies, providing a broad-spectrum prescription product for military and civilian use.

Last year, Immuron said it had enrolled the first of up-to 30 healthy volunteers in a phase I trial with the NMRC studying the efficacy of Campetec to prevent infectious diarrhoea caused by Campylobacter (BD: Dec 5, 2023).

Today, the company said the NMRC reported that the randomized, placebo-controlled trial compared Campetec to placebo, with the safety and protective efficacy of the product tested "focusing on the ability of the hyperimmune product to protect volunteers against moderate to severe campylobacteriosis".

Immuron said interim results showed a "10.4 percent protective efficacy against moderate to severe campylobacteriosis following challenge with Campylobacter compared to the placebo group".

The company said data analysis by the NRMC continued "including secondary and exploratory endpoints, which may provide insights as to why protective efficacy for Campetec was lower than that achieved in similar studies with Travelan".

Immuron said it was "not privy to any further details of the study at this time".

The company said principal investigator Dr Frédéric Poly would present the findings at the International Workshop on Campylobacter, Helicobacter & Related Organisms which began in Perth, Australia today.

Immuron said the trial results were unrelated to Travelan and did not impact its planned meeting with the US Food and Drug Administration to conduct a phase III Travelan trial.

Immuron fell 1.5 cents or 15.0 percent to 8.5 cents with 2.9 million shares traded.

FEDERAL GOVERNMENT, UNIVERSITY OF QUEENSLAND

The Federal Government says it has granted $17.86 million to the University of Queensland to use spider venom to protect the heart during cardiac arrest.
A media release from the Federal Minister for Health and Aged Care Mark Butler said the Medical Research Future Fund grant would fund the project for five years.
The Government said the research would use Hi1a, a peptide "inspired" by a molecule discovered in Australian funnel-web spider venom, for cardiac arrest treatment and improvement of donor heart viability.
The media release said the project would include clinical trials with a miniaturized version of Hi1a to develop "the first ever drugs for heart attack and heart transplantation".
The Federal Government said that researchers hoped to complete the new treatment within 10 years.
A University of Queensland media release said that its Institute for Molecular Biosciences' Prof Gleen King would conduct a four-year trial to assess the potential of Hi1a for preventing heart damage during a heart attack or donor heart procurement.
The University said the trial followed pre-clinical studies led by Prof Nathan Palpant showing the efficacy of Hi1a in cardiac disease models.
The University of Queensland said the research, titled 'Acid-sensing ion channel 1a blockade reduces myocardial injury in rodent models of myocardial infarction', was published in the European Heart Journal, and available at: https://bit.ly/47VagBa.
The University said that the project would involve Brisbane's Infensa Bioscience, whose chief scientific officer was Prof King and head of biology was Dr Palpant.
Prof King said the study showed that "Hi1a protects the heart from damage sustained due to lack of oxygen during a heart attack or during donor heart retrieval".
Prof King said the funding would enable clinical trials to test a miniaturized version of Hi1a as a drug "to treat heart attack and protect donor hearts during the retrieval process".
"If successful it will improve patient survival and quality of life, dramatically expand the pool of donor hearts available for transplantation and significantly reduce healthcare costs," Prof King said.
The Federal Minister for Health and Aged Care Mr Butler said the research was "a world-first and could only have come from our world-class Australian researchers".
"Based on a molecule in the venom of an Australian funnel-web spider, this could save thousands of lives," Mr Butler said.
"These world-first trials will give hope to thousands of Australians who suffer from a heart attack and heart failure," Mr Butler said.

CANN GROUP

Cann Group says it hopes to raise about $6.25 million through a one-for-three rights offer at 4.0 cents with one attaching option for every three shares issued.
Cann said the issue price was a 53.3 percent discount to its five-day volume weighted average price with the options exercisable at 8.0 cents each within two years.
Cann said the funds would be used for production of its dry marijuana flower as well as broadening its Botanitech range to include several additional products by June 30, 2025, supporting its curated and vape products and working capital.
The company said the rights offer had a record date of October 10, would open on October 15 and close on October 24, 2024.
Cann said Alpine Capital was the lead manager to the offer, and that its directors who were eligible shareholders had indicated their intention to take up their entitlements.
Cann Group fell 0.9 cents or 13.0 percent to six cents with 3.55 million shares traded.

ORTHOCELL

Orthocell says revenue for the three months to September 30, 2024 was up 15.3 percent to $2.03 million, its second consecutive quarter of record revenue.
Orthocell said the revenue from its Striate+ and Remplir products, for dental bone regeneration and peripheral nerve repair, respectively, for the three months was up 8.0 percent on the previous quarter's $1.88 million, and up 15.3 percent on the prior period.
Orthocell managing-director Paul Anderson said the company was "delighted with the continued growth in demand and record quarterly revenue for … Striate+ and Remplir".
"These sales results demonstrate increasing market traction, which is driven by the consistent and predictable outcomes surgeons can achieve using our products," Mr Anderson said.
Separately, Orthocell requested a trading halt "pending an announcement by the company in relation to a new Replir regulatory approval".
Trading will resume on October 9, 2024, or on an earlier announcement.
Orthocell last traded up two cents or 4.35 percent at 48 cents.

SOMNOMED

Somnomed says it has US Food and Drug Administration approval for Rest Assure as an oral device, but not the device's internet cloud-based monitoring system.
Somnomed said its Rest Assure device for sleep apnoea included sensors, software and an internet cloud-based computing system, with the FDA not clearing its monitoring of efficacy via an apnoea hypopnea index (AHI) measurement within its cloud-based system.
The company said it was "encouraged by the FDA's decision" and was currently reviewing the requirements of a subsequent submission for the efficacy algorithm and the commercialization pathway of the product over the medium term.
Somnomed said its strategy for Rest Assure "was predicated on both compliance and efficacy to enable clinical validation of the therapy and align with data currently available from most [continuous positive airway pressure] therapies".
Somnomed co-chief executive officers Karen Borg and Amrita Blickstead said that the clearance was "a significant achievement for Somnomed".
Somnomed fell 1.5 cents or 3.9 percent to 37 cents.

CHIMERIC THERAPEUTICS

Chimeric says one patient has had a complete response in its 12-patient, phase Ib trial of CHM0201 with standard-of-care vactosertib for acute myeloid leukaemia (AML).
Chimeric said the trial at Cleveland Ohio-based Case Comprehensive Cancer Center was separate from the Houston's University of MD Texas Anderson Cancer Center 20-patient trial of CHM0201 with standard-of-care azacitidine with venetoclax for patients ineligible for intensive chemotherapy or allogeneic stem cell transplant (BD: Sep 13, 2023).
Today, Chimeric said the complete response was "the first and currently only patient treated in the blood cancer arm of the phase Ib trial" with three more patients enrolled.
Chimeric said a complete response was the "absence of cancer through standard laboratory testing" following intravenous administration of the combination therapy on day one, with the patient to continue on study and be monitored for up-to 15 years.
Chimeric chief operating officer Dr Rebecca McQualter said as the study continued to enroll subjects with advanced cancer the company was "pleased to see the clinical combination can be delivered safely".
Chimeric was in a suspension and last traded at 1.4 cents.

MONASH UNIVERSITY

Monash University says it has shown psilocybin may be helpful for addressing depression symptoms and increase optimistic behavior, in rats.

Monash University said researchers used computational modelling to show that rats given psilocybin, the psychedelic compound found in “magic mushrooms” displayed long-lasting, increased optimistic behavior to perform reward-based tasks.

The University said the findings suggested psilocybin could be “helpful for addressing the core symptoms of major depression and other conditions characterized by reduced engagement and withdrawal”.

Monash University said doctoral candidate Elizabeth Fisher lead the study with Prof Jakob Hohwy and Dr Claire Foldi, and that the study should “motivate confirmation of these effects in human studies”.

The University said the study, titled ‘Psilocybin increases optimistic engagement over time: computational modelling of behavior in rats’ was published in Translational Psychiatry, with the full article available at: https://bit.ly/3NgPaUA.

Ms Fisher said “insights into the mechanisms of psilocybin allow us to unpack who may benefit from psychedelic therapies” as well as who might not benefit from psilocybin.

“With many people around the world affected by depression, our ultimate goal is to help build understanding of how psilocybin might be used to treat core symptoms people experience, such as diminished optimism, apathy and withdrawal from the world around them,” Ms Fisher said.

Prof Hohwy said the results were a “promising step toward explaining the mechanisms of how psychedelics may work to change the brain and increase engagement after treatment”.

“Our team found that rats given psilocybin were more motivated to explore their environment and perform reward-based tasks,” Prof Hohwy said.

“These exciting results show the mechanisms of how psilocybin may work to increase optimism in an animal model, which we hope may translate to humans as well,” Prof Hohwy said.

RHYTHM BIOSCIENCES

Rhythm says its second-generation Colostat colorectal cancer test shows “a more than 70 probability of superior performance” compared to the first-generation.

Rhythm said tests on previously collected patient samples, from 100 cancer patients and 100 controls, showed performance measured by the area under the curve to be 0.805 for the second version of the kit compared to 0.784 for the previous version ($p < 0.0001$).

The company said it would work with its contract manufacturing organization Quansys to generate the second version of the assay to start developing the commercial version of the algorithm and further verification and validation.

Rhythm chief executive officer Dr David Atkins said the second-generation Colostat kits combined “five separate antibody-based assays that previously constituted the original Colostat assay into a single reaction for each patient blood sample”.

“It is well known that combining multiple antibodies into a single reaction vessel could generate unexpected results and the evaluation of the Alpha kit has always been an important milestone for the company to achieve,” Dr Atkins said.

“The goal was to successfully re-engineer the assay to increase quality and make the assay easier to use and more reproducible while maintaining at least the performance of our first generation Colostat assay,” Dr Atkins said.

Rhythm was up 3.4 cents or 44.7 percent to 11 cents with 7.95 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has agreed with the US Food and Drug Administration on several of the protocols for its pediatric, phase III trial of NNZ-2591 for Phelan-McDermid syndrome.
Last year, Neuren said an 18-child, phase II trial of NNZ-2591 for Phelan-McDermid syndrome showed a statistically significant improvement (BD: Dec 18, 2023).
In July, the company said the FDA had granted NNZ-2591 rare paediatric disease designation for Phelan-McDermid syndrome (BD: Jul 19, 2024).
At the time, Neuren said it was preparing for an end-of-phase II meeting with the FDA, which it expected before October, to discuss “the development program for NNZ-2591 in Phelan-McDermid syndrome”.
Today, the company said it had a “constructive end of phase II meeting” with the FDA and had “aligned” with the FDA on key aspects of its phase III trial.
Neuren said the trial would be single-randomized, double-blind, and placebo-controlled and treat children aged three-to-12 years of age for 13 weeks, but did not disclose the number of children expected to be enrolled.
The company said it would compare one active treatment group to a placebo group, with a dosage of 12mg/kg, equal to its previous phase II trial, with patients able to continue in an open-label extension study until commercial launch.
Neuren said that, based on the safety data from the phase II trial, it had proposed a “less burdensome” safety monitoring plan for the phase III and open-label extension trials, which was considered reasonable by the FDA, subject to review of the final protocol.
The company said it would submit further information to the FDA to confirm endpoints for the primary efficacy assessment.
Neuren said it was “well advanced in the selection of service providers for the phase III program and [had] commenced identification of potential trial sites” and manufacturing the required supplies of NNZ-2591 was on schedule.
Neuren managing-director Jon Pilcher said the company was “pleased with the outcomes of a very collaborative meeting with the FDA”.
Neuren was up 15 cents or 1.1 percent to $14.20 with 543,306 million shares traded.

ENLITIC

Enlitic says it has deals for its Endex medical data and radiology software with DMC Healthcare and Japan’s National Cancer Center, with Ultrarad as a reseller.
Enlitic said its distribution partner Biotronics 3D had signed a three-year deal with London’s DMC Healthcare, which provided dermatology, radiology reporting and endoscopy services at more than 30 National Health Service organizations, to use Endex for “[artificial intelligence] orchestration and radiology workflow improvement”.
The company said its distribution partner Clairvo Technologies had signed a five-year deal for Japan’s largest cancer research center, the Tokyo-based National Cancer Center, to use Endex for radiology workflows.
Enlitic said it had signed a three-year licencing agreement allowing the Philadelphia, Pennsylvania-based Ultrarad Corp, a healthcare software and internet cloud-based services provider, to distribute Endex in the US.
The company said that “while each of these new agreements are not considered material in respect of their terms and conditions or in respect of their financial impact for Enlitic, they evidence the progress that the company is making in respect of its business model”.
Enlitic managing-director Michael Sistenich said the company continued “to make good commercial progress”.
Enlitic was untraded at seven cents.

ONCOSIL MEDICAL

Oncosil says the Dubai-based Al Zahrawi Medical Supplies LLC will sell its pancreatic cancer device in the United Arab Emirates, Qatar, Oman and Bahrain.

Oncosil managing-director Nigel Lange said the agreement marked “an important step in expanding access to our innovative Oncosil product in the Middle East, where there is a growing demand for effective treatments for pancreatic cancer”.

“Al Zahrawi’s expertise and established network will be invaluable in helping to bring our technology to patients in these key markets,” Mr Lange said.

Oncosil was unchanged at 1.4 cents with 1.6 million shares traded.

ECHO IQ

Echo IQ says shareholders will vote to issue 12,000,000 options to directors and chief executive officer and raise its directors fee pool 25 percent from $400,000 to $500,000.

Echo IQ said its annual general meeting would vote to issue executive chair Andrew Grover 6,500,000 performance rights, as well as 4,500,000 rights and 1,000,000 rights to non-executive directors Steve Formica and Stephen Picton, respectively.

The company said the performance rights were valued at 18.5 cents each, had an indicative value of 14.17 cents, would vest on the 30-day volume weighted average price of the company being at least 25 cents and would expire two years from issue.

Echo IQ said Mr Grover’s rights were in addition to his $240,000 a year pay, with Mr Formica being paid $73,590 annually and Mr Picton receiving $60,000 in fees.

The company said the meeting would vote to raise the total maximum aggregate directors pay from $400,000 to $500,000, re-elect Mr Picton, adopt the remuneration report, ratify placement shares issued and approve its 10 percent placement capacity.

The meeting will be held at Suite 2.144, 477 Pitt Street, Sydney on November 12, 2024 at 10am (AEDT).

Separately, Echo IQ requested a trading halt regarding “US [Food and Drug Administration] clearance and the appointment of a US-based chief executive officer”.

Trading will resume on October 9, 2024, or on an earlier announcement.

Echo IQ last traded at 24 cents.

ALLEGRA MEDICAL TECHNOLOGIES

Allegra director Dr Nicholas Hartnell says he has increased his substantial shareholding from 107,411,776 shares (89.80%) to 108,623,456 shares (90.81%).

In May, Allegra said Allegra Innovations, a related party of director Dr Hartnell, would pay 0.4 cents a share in a cash bid, valuing it at $478,444 (BD: May 27, 2024).

In August, the company said Allegra Innovations Pty Ltd held 80.6 percent of the company, with shareholders who had accepted the offer to be paid within 10 days of acceptance (BD: Aug 12, 2024).

Today, the Bowral, New South Wales-based Dr Hartnell said that with Robinwood and Allegra Innovations he acquired the shares “as a result of acceptances of takeover offers made by [Allegra Innovations] dated June 20, 2024”.

Allegra was in a suspension and last traded at 2.9 cents.

IMMUTEP

Immutep says non-executive director Anne Anderson has resigned and will not seek re-election at its upcoming annual meeting.

Immutep said its board would "review its requirements to support the company's next phase of growth" and that the role of non-executive director for the company currently demands sector knowledge".

Immutep chair Dr Russell Howard said Ms Anderson had "been a valued member of the board since her appointment in February 2024, contributing to the strength of our risk management and governance".

"On behalf of the board, I would like to thank her for her contribution to the success of Immutep and wish her every success with her next endeavors," Dr Howard said.

Immutep was unchanged at 31.5 cents with 1.25 million shares traded.

ARGENICA THERAPEUTICS

Argenica says it has appointed Dr Stuart Gribble as its head of product development, effective from today.

Argenica said Dr Gribble would lead "its product development activities, including new formulation development, manufacturing and preclinical and clinical development of indications outside of acute ischaemic stroke, whilst working with our existing clinical trial team to provide support on our stroke trial as required".

The company said Dr Gribble had more than 25 years of experience developing products from laboratory to commercialization and had been head of Telix's kidney cancer portfolio, including Caronic anhydrase IX, or CAIX, and had worked at CSL and Pfizer.

Argenica said Dr Gribble held a Bachelor of Science from Monash University and a Doctor of Philosophy from the University of Melbourne.

Argenica fell 1.5 cents or 2.1 percent to 70.5 cents.