



Biotech Daily

Monday August 21, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX DOWN, BIOTECH UP: PRESCIENT UP 25%; PARADIGM DOWN 14%**
- * **PM ANTHONY ALBANESE OPENS CSL HQ**
- * **ANTISENSE SHARE PLAN RAISES \$3.3m; TOTAL \$11.6m**
- * **FEDERAL RNA DISCUSSION PAPER**
- * **ECHO IQ EXPANDS ECHOSOLV TO 6 MORE INDICATIONS**
- * **AUSTCO \$2.6m TACERA NURSE CALL SYSTEM CONTRACT**
- * **NETHERLANDS OKAYS CYNATA CYP-001 KIDNEY TRANSPLANT TRIAL**
- * **INVEX CLOSES PRESENDIN III TRIAL CITING OZEMPIC, COSTS**
- * **RECCE: R327 'ANTIBIOTIC ACTIVITY' IN 4 BURN INFECTIONS, TRIAL CLOSED**
- * **UNIVERSAL BIOSENSORS RECEIVES \$4.5m FEDERAL R&D TAX INCENTIVE**
- * **CLARITY TO RELEASE 79m ASX ESCROW SHARES**
- * **DR MOHIT KAUSHAL REPLACES EMYRIA DIRECTOR MATTHEW CALLAHAN**
- * **IMUGENE APPOINTS DR BRADLEY GLOVER COO**

MARKET REPORT

The Australian stock market fell 0.46 percent on Monday August 21, 2023, with the ASX200 down 32.6 points to 7,115.5 points. Eighteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and two were untraded.

Prescient was the best on no news, up 1.5 cents or 25 percent to 7.5 cents, with 2.4 million shares traded. Atomo climbed 13.3 percent; Alcidion was up 9.1 percent; Universal Biosensors rose 8.3 percent; Proteomics was up 7.4 percent; Dimerix climbed 6.1 percent; Resonance and SDI improved more than five percent; Avita, Medical Developments, Mesoblast, Pharmaxis and Volpara rose more than two percent; Clinuvel, Cochlear, Neuren, Next Science and Pro Medicus were up one percent or more; with Nanosonics up by 0.4 percent.

Paradigm led the falls, down 11 cents or 13.75 percent to 69 cents, with 1.1 million shares traded. 4D Medical lost 7.35 percent; Opthea was down 6.5 percent; Impedimed, Imugene and Patrys fell five percent or more; Micro-X was down 4.55 percent; both Kazia and Starpharma were down 3.2 percent; Emvision shed 2.5 percent; CSL, Cyclopharm, Immutep, Orthocell and Polynovo were down one percent or more; with Resmed and Telix down by less than one percent.

CSL

CSL says that Australia's Prime Minister Anthony Albanese has opened its new Headquarters and Centre for Research and Development in Parkville.

Mr Albanese said that CSL was "one of Australia's most essential and successful biotech companies, and I am so pleased to be opening this world-class facility in Melbourne".

"This magnificent facility will help position CSL to compete in the global marketplace," Mr Albanese said.

Mr Albanese said the new research and development building was "world-class".

"It's a lab, a factory, a biotech start-up incubator, a multi-national business, and a piece of Australian history, all in one stunning, state-of-the-art building," Mr Albanese said. "This building and the people who work here are full of potential, as is this entire precinct."

Mr Albanese said that of the \$15 billion for the National Reconstruction Fund \$1.5 billion was targeted for medical manufacturing.

CSL said the "state-of-the-art facility strengthens Melbourne's world-class biomedical precinct".

The company said the move to the Haymarket district at the North end of Elizabeth Street, Melbourne was part of a \$2 billion infrastructure investment program in Australia over the past four years.

CSL said that the building would house more than 850 professionals CSL chair Dr Brian McNamee said the company developed and owned its own intellectual property and had collaborations with academia.

"We see our future completely integrated with the bio-medical precincts and recognize our long-term success is tied to Australia's excellence in bio-medical research and tertiary education," Dr McNamee said.

CSL said the new site, about 3km South-East of its previous Parkville headquarters would place it "in close proximity to its many valued partners, including the University of Melbourne, the Walter and Eliza Hall Institute, the Royal Melbourne Hospital, the Doherty Institute and the Murdoch [Childrens Research] Institute".

The company said the building had 18 floors "each designed with a specific purpose to drive innovation and progress" as well as two levels dedicated to the Jumar Bio-incubator, providing office and laboratory space for up to 40 Australian biotechnology start-ups to progress the commercialization of their research.

CSL managing-director Dr Paul McKenzie said the aim of the new building was "to catalyze even more research, more development and ultimately deliver more products that can help people in serious need all over the world".

The company said that the Green Building Council of Australia gave the building "a five-star rating" for its environmentally sustainable design features.

CSL fell \$3.71 or 1.4 percent to \$266.86 with 666,293 shares traded.

ANTISENSE THERAPEUTICS

Antisense says it raised \$3.26 million, \$1.76 million more than expected, through a share plan at five cents a share, taking the total raised to \$11.61 million.

In July, the company said it had raised \$8.35 million in a placement and hoped to raise about \$1.5 million through a share plan at five cents a share (BD: Jul 18, 20, 2023)

Today, Antisense chair Dr Charmaine Gittleston said "the funds raised in the recent institutional placement, combined with the proceeds of the share purchase plan, leave the company very well positioned to focus on its ongoing international phase IIb study of ATL1102 in Duchenne muscular dystrophy".

Antisense was unchanged at 5.1 cents.

FEDERAL GOVERNMENT

The Federal Government says it has released a discussion paper and survey to help it better understand and increase the opportunities of RNA technologies.

A media release from the Federal Minister for Industry and Science Ed Husic said the 'Understanding our RNA potential' discussion paper and survey would help gain a clearer understanding of the ribonucleic acid technologies under development in Australia.

The Federal Government said that the discussion paper outlined challenges Australia faces in developing an RNA industry.

"RNA technologies offer opportunities for Australia, from rebuilding onshore advanced manufacturing, boosting sovereign capability and creating highly skilled local jobs," Mr Husic said.

"Australia could be a global producer of new RNA vaccine treatments for conditions ranging from Covid-19 to cardiovascular disease and influenza in humans, as well as vaccines for animal illnesses," Mr Husic said.

"We're backing the development of RNA technology with billions of dollars of support for medical manufacturing and critical technologies through the National Reconstruction Fund," Mr Husic said. "We're also providing further support through the new \$392 million Industry Growth Program to help start-ups and small-to-medium businesses."

The Federal Government said that consultation was open until October 16, 2023, with the discussion paper available at: <https://consult.industry.gov.au/rnaplan>.

ECHO IQ

Echo IQ says it will expand its Echosolv artificial intelligence product for identifying patients with aortic stenosis through echo-cardiograms (ECG) to six further indications. Last month, Echo IQ said it had launched an Echosolv module to identify the progression of mitral regurgitation, the most common heart valve abnormality (BD: Jul 19, 2023).

Today, the company said it had plans for six further Echosolv modules to support cardiologists in accurately diagnosing and assessing diastolic dysfunction, heart failure, hypertension, left atrial volume, left ventricular mass and mitral stenosis.

Echosolv said it expected these modules to be rolled out between November 2023 and January 2024, with these additions advancing its Echosolv software towards "delivering a 'total heart solution' for eight cardiovascular diseases and diagnostic indicators".

Echosolv executive chair Andrew Grover said "with these new extensions to Echosolv, we are broadening the commercial application for this already impressive artificial intelligence-driven platform".

"Based principally on current industry diagnostic guidelines, these new modules fall outside the scope of [US Food and Drug Administration] regulation which allows us to fast-track their introduction to the market," Mr Grover said.

Echo IQ was unchanged at 15.5 cents.

AUSTCO HEALTHCARE

Austco says it has a \$2.6 million contract to supply its Tacera Nurse Call platform to the 345-bed Mount Elizabeth Hospital in Singapore.

Austco said the contract included its Tacera system with locating system-ready call points, pulse mobile and its clinical workflow product.

The company said the contract brought its total open sales orders, or unfulfilled and not revenue recognized sales, to a record \$36.1 million.

Austco was up half a cent or 2.9 percent to 18 cents.

CYNATA THERAPEUTICS

Cynata says the Netherlands has approved an up-to 16-patient, phase I trial of its CYP-001 for kidney transplant patients.

Cynata said the trial, titled 'Safety and Efficacy of MCA-derived Mesenchymal Stromal Cell Therapy in Renal Transplant Recipients: The Nereid Study' would be led by the Leiden University Medical Centre's Prof Ton Rabelink.

The company said it would supply CYP-001 for the trial which was funded and managed by Leiden University Medical Centre, but it would retain full commercial rights.

Cynata said the first six renal transplant patients would receive either one or two infusions of CYP-001 as well as standard treatment, and subject to a safety review a further 10 patients would receive two infusions of CYP-001.

The company said the primary endpoint was safety and efficacy in post-kidney transplant patients reducing tacrolimus, a calcineurin inhibitor sold as Prograf, which was an immune-suppressant drug used to prevent the rejection of transplanted organs.

Prof Rabelink said that the side effects from anti-rejection drugs in kidney transplant recipients were "a major problem".

"Risks include an increased incidence of serious infections and cancer, as well as potential damage to the transplanted kidney," Prof Rabelink said.

"We believe that [mesenchymal stem cells] therapy could help to facilitate dose reduction or even withdrawal of these drugs, which would be a huge step forward in the management of these patients," Prof Rabelink said.

Cynata managing-director Dr Kilian Kelly said the trial expanded "Cynata's reach in the field of transplant medicine, adding to our existing graft versus host disease program".

Cynata was unchanged at 13.5 cents.

INVEX THERAPEUTICS

Invex says it has closed its phase III trial of Presendin for idiopathic intracranial hypertension (IIH) due to limited market opportunity and operating costs.

Earlier this year, Invex said it had undertaken a strategic evaluation of its phase III study after slower than expected site activations and patient enrolments as well as the rapidly evolving uptake of GLP-1 receptor antagonists for obesity (BD: Jun 28, 2023).

Today, the company said an independent market analysis showed "major future impacts to IIH market opportunity for Presendin".

The company said the current price of GLP-1 receptor agonists made Presendin uneconomic in idiopathic intracranial hypertension and that achieving a reimbursement for the drug would be "challenging".

Invex said it would continue to explore strategic options to increase the value of its core intellectual property associated with raised intracranial pressure in neurological disorders.

Invex executive director Dr Tom Duthy said although the company was confident in Presendin's ability to lower intracranial pressure "the simple fact is that these patients are mostly obese, and weight loss is strongly correlated to improvement in IIH symptoms".

"It therefore stands to reason that the emerging, unfettered supply of affordable and/or reimbursed therapeutic agents with demonstrated long term clinical utility for weight loss such as Semaglutide, Ozempic, Wegovy and Rybelsus, along with other GLP-1 [receptor agonists] ... will become a preferred treatment option," Dr Duthy said.

"We have mitigated our substantial risks by taking decisive action to close the existing trial, materially reduce our future research and development costs and preserve our cash," Dr Duthy said.

Invex fell half a cent or 2.8 percent to 17.5 cents with 1.9 million shares traded.

RECCE PHARMACEUTICALS

Recce says its closed phase I/II trial of topical R327 for burn wound infections showed “visible reduction in bacterial infection within the first 24 hours” in four patients.

Recce said the drug showed broad spectrum antibiotic activity against Gram-positive and Gram-negative pathogens, listed on the World Health Organisation priority pathogen list of antibiotic-resistant bacteria and defined as multi-drug resistant and difficult to treat.

The company said all patients treated with R327 showed good indications of safety and tolerability, no adverse events were reported, and if doses were missed over a period, then the wound could deteriorate, a typical observation with interrupted wound treatments. Recce said of those who did not complete dosing one required systemic antibiotics for unrelated co-morbidities and the other’s post wound debridement surgery did not respond well to the gentle cold spray application of R327.

The company said that that investigators were preparing a new protocol for a stage 2 clinical trial which was expected to be a randomized, head-to-head study of patients with infected burn wounds where R327 Gel was compared to existing standard-of-care treatments.

Recce said that recruitment had concluded for stage 1 of the investigator-led trial due to the Perth-based Fiona Stanley Hospital Burns Unit experiencing difficulty recruiting appropriate patients said to be primarily due to implementation of Covid protocols resulting in preventative, systemic, antibiotic infection control practices.

Recce said the restrictions “led to patients not meeting protocol requirements - no prior antibiotic treatment prior to enrolment - thus limiting the recruitment of the study.

Recce fell half a cent or 0.7 percent to 71.5 cents.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has received \$4,495,137 from the Australian Taxation Office under the Federal Government Research and Development Tax Incentive program.

The company said the rebate related to expenditure for the year to December 31, 2022. Universal Biosensors was up two cents or 8.3 percent to 26 cents.

CLARITY PHARMACEUTICALS

Clarity says that it will release 78,742,707 shares from ASX escrow on August 25, 2023.

According to its most recent filing, following the release from escrow, Clarity will have 261,357,666 shares available for trading, with no further shares held in escrow.

Clarity fell two cents or 1.96 percent to \$1.00.

EMYRIA

Emyria says director Matthew Callahan has resigned and will transition to an advisory role, effective from today, and will be replaced by Dr Mohit Kaushal.

Emyria said Dr Kaushal previously worked for Humedica, Rxante, Citiustech, Wellframe and Change Healthcare, Elation Health, the Oncology Institute and Oak Street Health and was currently an adjunct professor at California’s Stanford University.

The company said Dr Kaushal held a Bachelor of Science, Bachelor of Medicine and Bachelor of Surgery from Imperial College London as well as a Master of Business Administration from Stanford University.

Emyria fell 0.1 cents or 1.1 percent to 9.2 cents.

IMUGENE

Imugene says it has appointed Dr Bradley Glover as its chief operating officer. Imugene said Dr Glover previously was the Celularity chief operating officer and Kite Pharma's head of corporate strategy and operations, and helped lead the integration of Genentech when it was acquired by Roche in 2009.

According to his LinkedIn page, Dr Glover held a Bachelor of Science and Master of Business Administration from the University of California San Diego and a Doctor of Philosophy from the University of Colorado.

Imugene fell 0.4 cents or 5.1 percent to 7.5 cents with 59.4 million shares traded.