Biotech Daily

Wednesday November 2, 2022

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ALCIDION UP 7%; ACTINOGEN DOWN 11%**

*** CSL $312m UPFRONT FOR ARCTURUS mRNA TECHNOLOGY**

*** CYNATA: LEIDEN UNI TO FUND CYMERUS RENAL TRANSPLANT TRIAL**

*** VIETNAM APPROVES TRUSCREEN FOR 2 HOSPITALS; SYMPOSIUM**

*** CLARITY SAR-BOMBESIN PROSTATE CANCER TRIAL '50% IMAGED'**

*** IMPEDIMED PERFORMS 500k SOZO PATIENT TESTS**

*** ADALTA PRIORITIZES AD-214 FOR LUNG, RENAL, EYE FIBROSIS**

*** ARGENICA STARTS 2nd ARG-007 COHORT**

*** CHIMERIC, CASE WESTERN UNI WORK ON PRE-CLINICAL NK CELLS**

*** NUHEARA WINS 2 US O-T-C HEARING AID PATENTS**

*** ALTHEA TAKES 'CAPITAL RAISE' TRADING HALT TO SUSPENSION**

*** LIFE BIOSCIENCES BELOW 5% IN ALTERITY**

*** ALCIDION LOSES CO-FOUNDER DR MALCOLM PRADHAN**

MARKET REPORT

The Australian stock market was up 0.14 percent on Wednesday November 2, with the ASX200 up 9.8 points to 6,986.7 points. Fifteen of the Biotech Daily Top 40 stocks were up, 15 fell, eight traded unchanged and two were untraded.

Alcidion was the best, up one cent or 6.9 percent to 15.5 cents, with 5.4 million shares traded. Emvision and Pharmaxis climbed more than six percent; Imugene improved 5.1 percent; Genetic Signatures and Resonance rose more than four percent; Dimerix, Immutep and Prescient were up more than three percent; Uscom was up two percent; Atomo, Next Science and Polynovo were up one percent or more; with Cochlear, Medical Developments, Neuren and Resmed up by less than one percent.

Actinogen led the falls, down 1.5 cents or 11.1 percent to 12 cents, with two million shares traded. Kazia lost 7.4 percent; Cyclopharm and Paradigm fell more than five percent; Cynata was down 3.3 percent; Nanosonics, Oncosil, Patrys, Pro Medicus and Proteomics shed two percent or more; Impedimed, Orthocell and Starpharma were down more than one percent; with Clinuvel, CSL and Opthea down by less than one percent.

CSL

CSL says it will pay $US200 million ($A311.5 million) to the San Diego California-based Arcturus Therapeutics to licence its self-amplifying mRNA vaccine technology.

CSL said that under the agreement, through its Seqirus subsidiary, it would pay Arcturus the upfront fee and "further payments dependent upon the achievement of certain development and commercial milestones along with royalties [and] profit sharing on future product sales".

The company said it would have an exclusive licence to Arcturus' late-stage mRNA technology for influenza, Covid-19 and other respiratory viral diseases, and a non-exclusive licence for multi-pathogen pandemic preparedness, with an option to turn the licence exclusive.

CSL said Arcturus was currently developing "next generation mRNA vaccines, including a Covid-19 vaccine candidate that recently reported results from a large phase III vaccine efficacy study, meeting its primary and secondary endpoints of prevention of infection and severe disease with a favorable safety and tolerability profile".

CSL chief operating officer Paul McKenzie said the collaboration was "an exciting opportunity to complement CSL's own next generation mRNA program with a partner who developed a platform to deliver late-stage clinical supplies at scale".

"These combined capabilities will accelerate our journey in mRNA," Mr McKenzie said.

CSL Seqirus general manager Steve Marlow said the licence was "another step towards our long-term aim to advance public health by developing and commercializing enhanced vaccines for influenza and multi-pathogen pandemic preparedness".

"The collaboration also provides a pathway to offer a Covid-19 booster, providing another differentiated option to healthcare providers and governments around the world," Mr Marlow said.

CSL fell 55 cents or 0.2 percent to $282.71 with 600,770 shares traded.

CYNATA THERAPEUTICS

Cynata says Leiden University Medical Centre will fund a 10-patient trial of its Cymerus mesenchymal stem cells in renal transplant patients, starting in 2023.

Cynata said that it would provide its induced pluripotent stem cell-derived Cymerus mesenchymal stem cells to Leiden University, with all commercial rights derived from the study returning to Cynata.

The company said that about 130,000 kidney transplants were performed each year and could be life-saving in patients with chronic renal failure, freeing the patient from the need for dialysis.

The company said that currently, lifelong immune suppressive therapy was required in renal transplant patients to reduce the risk of rejection, which could lead to increased risk of infections and cancer, with the main anti-rejection drugs directly toxic to the kidneys.

Cynata said stem cells had shown potential to enable the early withdrawal of anti-rejection drugs in transplant recipients without increased rejection and with preserved renal function.

Cynata chief executive officer Dr Ross Macdonald said the collaboration followed "very promising clinical trial data with [mesenchymal stem cells] published by Prof Rabelink and our own published pre-clinical data in organ transplant rejection".

"The potential to enhance survival of transplanted donor organs while at the same time reducing or eliminating the need for damaging anti-rejection drugs would be a substantial breakthrough in transplantation medicine," Dr Macdonald said.

Cynata fell one cent or 3.3 percent to 29 cents.

TRUSCREEN

Truscreen says the Vietnam Ministry of Health has approved its Truscreen Ultra device for cervical cancer screening in two major hospitals in Southern Vietnam.

Truscreen said four Truscreen Ultra devices, which “detect pre-cancerous and cancerous cervical changes in real-time via optical and electrical measurements” and circumvent the need for cytology, would be installed in Ho Chi Minh City’s Tu Du Hospital, as well as Hau Giang province’s Hau Giang Hospital.

The company said it expected the Ministry’s decision would accelerate approvals for a further four hospitals under consideration.

Truscreen chief executive officer Dr Beata Edling said that Vietnam would be “a significant market for Truscreen, and we are now seeing good acceptance of our technology, post-Covid”.

“We will work closely with our distributor, on supporting our key opinion leaders with all clinical data to optimize Truscreen Ultra uptake in Vietnam,” Dr Edling said.

Truscreen said it had also completed a virtual medical symposium with opinion leaders from China, Mexico, Russia, Poland, Vietnam, Zimbabwe and Saudi Arabia, presenting data from trials of Truscreen in cervical cancer screening programs.

The company said the largest study was a 15,000-subject trial reported by Prof Fei Chen which compared Truscreen Ultra to liquid-based cytology and high-risk human papillomavirus testing in China.

Truscreen said the study found that for detection of pre-cancerous Cin2+ cells, Ultra’s sensitivity was 87.5 percent compared to 66.5 percent for liquid cytology ($p < 0.001$), and that its specificity was 88.4 percent compared to 86.3 percent for liquid-based cytology, and 78.3 percent for high-risk human papillomavirus testing ($p < 0.001$).

Truscreen was up 0.2 cents or 5.1 percent to 4.1 cents.

CLARITY PHARMACEUTICALS

Clarity says it has recruited 15 of 30 subjects in its 64-copper sarcophagine (SAR)-Bombesin prostate cancer imaging trial at Sydney’s St Vincent’s Hospital.

In August, Clarity said the trial would assess the safety of 64-copper SAR-Bombesin, as well the diagnostic potential for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA expression disease in patients with suspected biochemical recurrence of prostate cancer, and patients with metastatic castrate-resistant prostate cancer not eligible for PSMA therapy (BD: Aug 22, 2022).

Clarity fell half a cent or 0.7 percent to 69 cents.

IMPEDIMED

Impedimed says it has reached a milestone of 500,000 patient tests performed using its Sozo digital health platform.

Impedimed said Sozo used bioimpedance spectroscopy to measure body fluid, allowing the prevention of lymphoedema.

Impedimed interim chief executive officer Dave Anderson said “every time a patient is measured using Sozo, our bioimpedance spectroscopy technology delivers condition-specific metrics that inform medical decisions at the point-of-care”.

“Reaching 500,000 patient tests is an important milestone and positive indicator of the future health of our business,” Mr Anderson said. “Many lives have been dramatically improved by the reduction on lymphoedema as a result of this testing.”

Impedimed fell 0.1 cents or 1.1 percent to 9.1 cents with 1.5 million shares traded.

ADALTA

Adalta says it will prioritize clinical development of injectable AD-214 for lung kidney and eye fibrosis and partner for other applications of the drug.

Adalta said it expected pre-clinical data from AD-214 in eye and kidney fibrosis by July 2023, and that this would guide the indications it pursued to clinical trials.

The company said progress on manufacturing yield and formulation development would enable continuation of intravenous delivery for lung and kidney fibrosis and intravitreal development for eye fibrosis.

Adalta said that as it focused on injectable routes of administration, it would make inhaled delivery data available for potential lung fibrosis commercialization partners.

Adalta managing-director Dr Tim Oldham said that “in the interval between phase I and phase II trials of AD-214 we have made significant progress in expanding the value of this asset”.

“We now have compelling preclinical data supporting efficacy in kidney fibrosis and have established that AD-214 can be delivered to the lungs via inhalation with mode of action evidence supportive of potential efficacy,” Dr Oldham said. Importantly, we have also made progress identifying manufacturing and formulation improvements.”

“We have secured manufacturing and toxicology bookings to prepare us for the next clinical trial in 2024,” Dr Oldham said.

Adalta was up 0.4 cents or 8.3 percent to 5.2 cents.

ARGENICA THERAPEUTICS

Argenica says it will progress to the second cohort of its 32-subject, phase I trial of ARG-007 following independent review of first cohort safety data.

Last month, Argenica said the first cohort of eight healthy subjects had been dosed, indicating “good safety and tolerability” (BD: Oct 26, 2022).

Today, the company said one participant had non-serious adverse events, including headache and dizziness, that were possibly related to the drug administration.

Argenica noted that these symptoms resolved quickly and are recognized as common symptoms in trial participants, even when placebo was administered.

Argenica was up 6.5 cents or 12.15 percent to 60 cents.

CHIMERIC THERAPEUTICS

Chimeric says it will sponsor about two years of pre-clinical trials of several of its natural killer cells at the Cleveland, Ohio-based Case Western University.

Chimeric said that it would have an exclusive option to licence the intellectual property collected as part of the sponsored research.

The company said its central asset, CHM-0201 was invented and developed by the same team at Case Western, led by Dr David Wald and his team would study CHM-0301, CHM 1301, CHM 2301, and CHM 3301.

Chimeric managing-director Jennifer Chow said that “with the encouraging clinical data” seen with the core natural killer cell platform the company was “very excited to be enhancing our collaboration with Dr Wald and his team at Case Western”.

“By building upon Dr Wald’s [natural killer] cell scientific experience and expertise we believe we will be able to advance [natural killer] cell therapies to benefit patients in multiple disease areas in the future,” Ms Chow said.

Chimeric fell 0.4 cents or five percent to 7.6 cents.

NUHEARA

Nuheara says the US Patent and Trademark Office has granted two patents protecting its self-fitting over-the-counter hearing aid.
In August, Nuheara said it welcomed the US Food and Drug Administration's decision to allow over- the-counter hearing aids (BD: Aug 17, 2022).
Today, the company said the patents were titled 'System for configuring a hearing device' which would protect its self-fitting system intellectual property until May 18, 2038, and 'Audio Accessory' which would protect its audio transmission until January 2, 2040.
Nuheara was up three cents or 10.9 percent to 30.5 cents with 4.6 million shares traded.

ALTHEA GROUP HOLDINGS

Althea says it has requested a voluntary suspension to follow its October 31, 2022 trading halt "pending an announcement by the company of a capital raise" (BD: Oct 31, 2022).
Today, the company said it expected the suspension to last until November 3, 2022 or the release of an announcement.
Althea was untraded at 8.3 cents.

ALTERITY THERAPEUTICS (FORMERLY PRANA BIOTECHNOLOGY)

Boston's Life Biosciences says it has reduced its substantial holding in Alterity from 146,300,493 shares (6.1%) to 114,560,553 shares (4.7%).
In 2018, the then-Prana Biotechnology said that Life Biosciences had agreed to invest up to $US29.4 million ($A41.8 million) and that it expected to raise a further $US2 million ($A2.8 million) (BD: Jan 20, 2019).
In 2019, Prana said shareholders approved Life Biosciences investing up to $41.8 million for 63 percent of the company and a change of name to Alterity (BD: Mar 6, 2019).
Today, Biosciences said that between August 26 and October 31, 2022, it sold American depository shares at prices from 40.04 US cents to 60.06 US cents, equivalent to about 1.04 cents to 1.56 cents per Australian share, with 60 Australian shares to one ADS.
Alterity fell 0.1 cents or 8.3 percent to 1.1 cents with 1.8 million shares traded.

ALCIDION

Alcidion says company co-founder, executive director, and chief medical officer Dr Malcolm Pradhan will retire at its November 30, 2022 annual general meeting.
Alcidion said Dr Pradhan's retirement was part of "a natural evolution and a well-established succession plan adopted by the board several years ago".
Alcidion chair Rebecca Wilson said Dr Pradhan "made a tremendous contribution to Alcidion".
"His vision to deliver decision support for clinicians was born two decades ago and he has continued to play an important role in making this vision a reality and providing the strong foundations for our success today and in the future," Ms Wilson said.
Ms Wilson thanked Dr Pradhan for his "commitment and contributions".
Alcidion was up one cent or 6.9 percent to 15.5 cents with 5.4 million shares traded.