Biotech Daily

Thursday September 10, 2020

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH UP: RESONANCE UP 11.5%; ANTISENSE DOWN 4%**

*** CMRI CHALLENGES AAV2 AS LIVER GENE THERAPY VECTOR**

*** MORNINGSIDE FUNDS HUDSON OVARIAN CANCER THERAPY**

*** CLINUVEL TRIALS SCENESSE FOR XP SKIN DNA REGENERATION**

*** RHYTHM ADDS NEWCASTLE HOSPITAL TO COLOSTAT TRIAL**

*** RESONANCE LICENCES CYSTIC FIBROSIS DATA FOR AI ANALYSIS**

*** ANTEOTECH WINS ISO 13485 QUALITY CERTIFICATION**

*** RECCE APPOINTS CMAX FOR RECCE-327 TRIAL**

*** CELLMID HIRES C14, PHARMAVENTURES FOR LYRAMID MIDKINE SALE**

*** MGC: UP TO $15m MERCER EQUITY-DRAWDOWN FACILITY**

*** DIMERIX REQUESTS 'DMX-200 KIDNEY TRIAL RESULTS' TRADING HALT**

*** AUSTRALIAN ETHICAL TAKES 14% OF NOVA EYE**

*** SANDON CAPITAL TAKES 9% OF IDT**

*** BONVOYOLO DILUTED BELOW 5% OF NEUROTECH**

*** OPTHEA APPOINTS DANIEL SPIEGELMAN DIRECTOR**

*** HELEN WISEMAN REPLACES ELIXINOL CHAIR PAUL BENHAIM**

*** AUSBIOTECH, J&J AWARDS FOR BEST COVID-19 RESPONSES**

MARKET REPORT

The Australian stock market was up 0.51 percent on Thursday September 10, 2020, with the ASX200 up 29.9 points to 5,908.5 points. Twenty-two Biotech Daily Top 40 stocks were up, 14 fell, three traded unchanged and one was untraded. All three Big Caps rose.

Resonance was the best, up 1.5 cents or 11.5 percent to 14.5 cents, with 962,372 shares traded. Clinuvel climbed 9.2 percent; both Osprey and Patrys were up 8.3 percent; LBT was up 7.7 percent; Pharmaxis improved 5.2 percent; Actinogen, Kazia and Oncosil were up more than three percent; Next Science, Universal Biosensors and Uscom rose two percent or more; Nova and Pro Medicus were up more than one percent, with Avita, Cochlear, CSL, Cyclopharm, Medical Developments, Nanosonics, Paradigm, Polynovo, Resmed, Starpharma and Telix up by less than one percent.

Antisense led the falls, down 0.4 cents or 4.3 percent to 8.9 cents, with 48,764 shares traded. Alterity, Immutep, Neuren and Optiscan lost two percent or more; Impedimed, Orthocell, Prescient, Proteomics and were down more than one percent; with Compumedics, Cynata, Mesoblast and Opthea down by less than one percent.

CHILDREN'S MEDICAL RESEARCH INSTITUTE

Sydney's Children's Medical Research Institute says it understands why the widely-used adeno-associated virus 2 (AAV2) is not good for delivering gene therapy to the liver.

The Institute said that trials targeting liver diseases "had an unexpectedly low success rate" because AAV2 bound too tightly to its attachment receptor, heparan sulfate proteoglycans (HSPGs), and because HSPGs were found in many places in the body, the vector was trapped before it reached its intended destination.

The CMRI said that a research paper, titled 'Restoring the natural tropism of AAV2 vectors for human liver', was published in Science Translational Medicine, and is available at: https://stm.sciencemag.org/content/12/560/eaba3312.

The Institute said that adeno-associated virus 2 (AAV2) was a viral vector used to deliver gene therapy to the liver, but clinical trials targeting liver diseases "had an unexpectedly low success rate using this vector and now the researchers from CMRI appear to have discovered the reason".

CMRI's Dr Leszek Lisowski told Biotech Daily that while AAV2 was no longer used to target the liver it continued to be used for eye and central nervous system therapies.

The Institute said the researchers found that the original AAV2, which was commonly used in pre-clinical and clinical studies, bound too tightly to its attachment receptor, heparan sulfate proteoglycans (HSPGs) and because HSPGs were found in many places in the body, not just on liver cells, the vector was trapped before it reached its intended destination and "very few vectors manage to deliver their therapeutic cargo to the liver, which greatly diminishes the therapeutic efficacy".

CMRI said its staff studied naturally occurring adeno-associated viruses which they found were much more successful at delivering the therapy into the liver.

The Institute said that these viruses used another receptor that was "yet to be discovered" but were able to make vectors in the laboratory that use this better receptor, instead of HSPGs, potentially making the next generation of gene therapy targeting the liver vastly more successful.

In a media release, Dr Lisowski said the research "really challenges a basic concept in our field that binding strongly to HSPG was essential for AAV's entry into human cells and suggests that vectors targeting the other receptor used by natural AAVs, of human liver origin, are likely to be more effective for clinical gene therapy applications".

"The prototypical AAV2, discovered over 50 years ago, is the serotype on which the entire field of AAV vectorology and gene therapy is based," Dr Lisowski said.

"Our discovery will shake the foundations of the field of AAV-based gene therapeutics and will mark the beginning of a new era not only for biomedical research, but most importantly, for millions of patients affected by genetic disorders," Dr Lisowski said.

"It sheds new light and challenges our previous understanding and corrects misconceptions about how the vector binds to the cells," Dr Lisowski said.

The publication's lead author Dr Marti Cabanes-Creus said researchers could improve the use of vectors to help children with liver conditions.

"By having a better vector, we can increase the safety and improve the efficiency," Dr Cabanes-Creus said.

"Because a lower dose will be needed to achieve therapeutic efficacy, the cost of those therapies will be decreased, which is an additional benefit to the patients, their families and the healthcare system," Dr Cabanes-Creus said. "The lessons learnt can potentially be extended to other tissues, beyond the liver, making this a very impactful study which will change the trajectory of AAV-based gene therapies."

CMRI said it was working with teams from Sydney Children's Hospitals Network; the CSIRO, the Centenary Institute, the University of Florida and University College London.

HUDSON INSTITUTE OF MEDICAL RESEARCH

Melbourne's Hudson Institute says that funds from the Boston-based Morningside Ventures will support development of a potential therapeutic for ovarian cancer.

The Hudson Institute, based at Monash University's Clayton campus, was formerly Prince Henry's Institute of Medical Research and the Monash Institute of Medical Research.

The Institute said that its staff found that the presence of the cytokine, interferon epsilon, in the female reproductive tract activated the body's immune response to infections and had a similar immune response to cancer.

The Hudson Institute said that the amount of funding from Morningside was undisclosed, as was the nature of the treatment.

The Institute said that the investment would "allow progress from the laboratory through safety testing and into clinical trials".

The Hudson said that Epsila Bio Inc had been spun-out to develop and commercialize the treatment.

Hudson chief commercialization officer Rob Merriel said there was "a huge unmet need for a breakthrough ovarian cancer treatment".

"This is a silent disease which is often asymptomatic and therefore discovered too late when it has already spread extensively," Mr Merriel said.

"Current disease management is ultimately limited by the development of chemotherapy resistance," Mr Merriel said.

The Institute said that Morningside was founded in 1986 by the Hong Kong-based Chan family.

CLINUVEL

Clinuvel says it will trial its Scenesse for xeroderma pigmentosum patients to test whether the drug can regenerate the DNA of ultraviolet-damaged skin.

Previously, Clinuvel said it had US Food and Drug Administration approval of Scenesse, or afamelanotide 16mg, for erythropoietic protoporphyria (EPP) and had applied for FDA approval of Scenesse for vitiligo (BD: Oct 9, 2019; May 1, 2020).

Today, the company said that patients with the rare genetic disorder xeroderma pigmentosum, most common in people with fair-skinned complexions, had "extreme deficiencies in their skin DNA repair processes, leading to a 10,000-fold increase in their risk of skin cancer".

Clinuvel said that skin incurred DNA damage following ultraviolet (UV) light exposure, or when non-ionising light penetrated the nucleus of skin cells, causing chemical changes to the DNA helix, which could replicate as mutations leading to irreversible damage or skin cancer, including melanoma.

Clinuvel chief scientific officer Dr Dennis Wright said Scenesse had a "hormone acting on various organs and receptors, but most of all known to protect human DNA".

"Our task is to confirm how DNA regeneration occurs within genetically affected patients and healthy subjects," Dr Wright said.

"[Xeroderma pigmentosum] provides an extreme model of what happens to our skin if UV-induced damage is left unrepaired," Dr Wright said. "From a young age, [xeroderma pigmentosum] patients are incapable of responding to DNA damage caused by UV exposure and experience disfiguring and aggressive skin cancers," Dr Wright said.

"We will facilitate treatment for the first patient in the next few weeks," Dr Wright said.

Clinuvel said the first clinical results from the DNA repair program are expected to be reported in 2021.

Clinuvel was up $1.82 or 9.2 percent to $21.51 with 216,911 shares traded.

RHYTHM BIOSCIENCES

Rhythm says Newcastle's John Hunter Hospital has joined its 1,000-patient Colostat clinical trial for colorectal cancer, with patient recruitment underway across all trial sites.
Rhythm chief executive officer Glenn Gilbert told Biotech Daily that Melbourne's Alfred Hospital, Monash Health and Royal Melbourne Hospital, along with Adelaide's Lyell McEwin Hospital had all recruited patients for the trial.
Last year, the company said the study was a prospective, cross-sectional, multi-centre study with the primary endpoint of evaluating the diagnostic performance of the Colostat in-vitro diagnostic relative to colonoscopy (BD: Feb 20, 2019).
Today, Rhythm said the New South Wales John Hunter Hospital was the fifth site in the trial and had appointed Dr Alkesh Zala as the site's principle investigator.
The company said it expected to sign further hospitals for the trial "in the coming months".
Rhythm was up one cent or eight percent to 13.5 cents with 2.0 million shares traded.

RESONANCE HEALTH

Resonance says it will licence computed tomography (CT) cystic fibrosis data sets from Perth's Telethon Kids institute and the Rotterdam's Erasmus University Medical Centre.
Resonance said the five-year licencing agreement with the Telethon and Erasmus would allow the company to potentially develop an artificial intelligence algorithm for the assessment of lung disease progression in patients with cystic fibrosis, a genetic disease which causes irreversible lung damage.
The company said that Telethon and Erasmus had developed the Pragma-CF method that analyzed CT scans to detect and quantify lung disease in children with cystic fibrosis, allowing clinicians to better monitor progression and tailor treatment.
Resonance chief executive officer Alison Laws said that condition assessments and treatment for cystic fibrosis patients were time-consuming and lengthy, and standardization and full automation of the CT component of the suite of assessments might increase efficiency in reporting and provide high quality information for clinicians.
Resonance said it would issue Telethon 297,620 shares on receipt of all of the datasets, and a further 297,620 shares on the submission of a resulting artificial intelligence medical device to a regulatory body.
The company said it would pay 10 percent of net royalties from sales of the resulting analysis device to Telethon.
Resonance was up 1.5 cents or 11.5 percent to 14.5 cents.

ANTEOTECH

Anteotech says it has International Organization for Standardization (ISO) 13485 certification for the development and manufacture of its lateral flow assays.
Anteotech said the ISO certification allowed the company to participate in the point-of-care market as a legal manufacturer of medical devices.
The company said the certification approved the development of its "high sensitivity multiplex rapid test" for the differentiation of severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) from influenza A and B (BD: Jul 16, Sep 9, 2020).
Anteotech chief executive officer Derek Thomson said that ISO 13485 certification was "the final element completing Anteotech's progression to a position that will allow us to launch our own assays into the market and we are delighted to have achieved this key milestone".
Anteotech was up 0.4 cents or 7.1 percent to six cents with 18.0 million shares traded.

RECCE PHARMACEUTICALS

Recce says it has appointed Adelaide's CMax Clinical Research facility to conduct its 48-patient phase I trial of Recce-327 for blood infection and sepsis.
Recce said Recce-327 was a broad-spectrum synthetic antibiotic formulated using synthetic polymer technology to treat blood infections and sepsis derived from Escherichia coli, and Staphylococcus aureus, or golden staph.
The company said the trial would be a randomized, double blind, placebo-controlled single-ascending dose study of healthy adult subjects to evaluate the safety, tolerability, pharmacokinetics and pharmacodynamic profile of Recce 327 following intravenous administration.
Recce said formal subject recruitment would begin "shortly" with the first subjects expected to be screened by the end of the year.
Recce was up 3.5 cents or 2.2 percent to $1.625 with 633,118 shares traded.

CELLMID

Cellmid says it has agreements with C14 Consulting and Pharmaventures to advise and facilitate the sale of its subsidiary Lyramid's midkine asset portfolio.
Cellmid said its wholly-owned subsidiary Lyramid developed treatment for inflammatory diseases and cancer targeting midkine, an embryonic growth factor implicated in a number of disease indications.
The company said that it had two separate agreements with the Malvern, Pennsylvania-based C14 and the San Francisco-based Pharmaventures, and the only fee payable by Cellmid to either of the consultants would be a success fee on completion of the sale or partnering of the midkine asset portfolio.
Cellmid fell 0.4 cents or four percent to 9.6 cents.

MGC PHARMACEUTICALS

MGC says it has an up to $15 million drawdown facility with the New York-based Mercer Street Global Opportunity Fund LLC, with $2.25 million to be received upfront.
MGC said it would use the fund for the phase II trial of the artemisinin and curcumin-based Artemic for Covid-19 patients, the phase IIb trial of its marijuana-based Cannepil for epilepsy and its glioblastoma brain cancer research.
The company said the first $2.25 million tranche would "be provided shortly … upon satisfaction of the closing conditions … through the issue of 2,475,000 convertible notes with a face value of $1.00 each to Mercer".
MGC said first tranche notes would convert at 2.4 cents a share within two months of the issue and afterwards, the price would be the lower of 2.0 cents or 92 percent of the lowest daily 10-day volume weighted average price, with a minimum 1.8 cents.
The company said that within 18 months of the agreement, it could request additional drawdowns of a further $12.75 million through the issue of 14,025,000 convertible notes to Mercer at a face value of $1.00 each.
MGC said the convertible notes from subsequent drawdowns would have the conversion price of the lower of 3.5 cents or 92 percent of 10-day volume weighted average price, with the minimum price of 1.8 cents.
The company said that Mercer could convert the notes to shares at its discretion within 12 months from the date of issue.
MGC said it would issue Mercer 9,375,000 commencement shares
MGC fell 0.1 cents or 4.2 percent to 2.3 cents with 10.0 million shares traded.

DIMERIX

Dimerix has requested a trading halt “in relation to the results of the company’s phase II clinical study of DMX-200 in patients with diabetic kidney disease”.
Trading will resume on September 14, 2020 or on an earlier announcement.
Dimerix last traded at 74 cents.

NOVA EYE MEDICAL (FORMERLY ELLEX MEDICAL LASERS)

Australian Ethical Investment says it has increased its substantial shareholding in Nova Eye from 19,029,175 shares (13.25%) to 20,522,701 shares (14.29%).
The Sydney-based Australian Ethical said that between August 19 and September 8, 2020 it bought 1,493,526 shares for $463,382 or an average of 31.0 cents a share.
Nova Eye was up half a cent or 1.6 percent to 31.5 cents.

IDT AUSTRALIA

Sandon Capital says it has increased its shareholding in IDT from 18,395,015 shares (7.8%) to 21,085,119 shares (8.8%).
The Sydney-based Sandon said that between October 25, 2019 and September 8, 2020, it bought 2,690,104 shares for $434,667 or an average price of 16.15 cents a share.
IDT was unchanged at 18 cents.

NEUROTECH

Bonvoylo Pty Ltd says its 12,596,786 shares substantial holding in Neurotech has been diluted below five percent following a $500,000 placement (BD: Jul 3, 2020).
The Perth-based Bonvoylo said that on September 7, 2020 its shares were diluted from 5.85 percent to below five percent (BD: Jul 15, 2020).
The substantial shareholder noticed was signed by Bonvoylo director Erlyn Dale, Neurotech’s company secretary.
According to its most recent Appendix 2A, Neurotech had 388,564,756 shares on issue, and Biotech Daily calculates that Bonvoylo’s 12,596,786 shares amount to 3.24 percent of the company after the dilution.
Neurotech was unchanged at 1.3 cents.

OPTHEA

Opthea says it has appointed Daniel Spiegelman as a non-executive director, effective from September 10, 2020.
Opthea said Mr Spiegelman was currently the interim chief executive officer of Recardia Therapeutics and a director at Myriad Genetics, Tizona Therapeutics and Spruce Biosciences and previously worked for Genentech.
The company said Mr Spiegelman held a Bachelor of Arts from the California-based Stanford University and a Master of Business Administration from the Stanford Graduate School of Business.
Opthea fell two cents or 0.7 percent to $2.75 with 430,825 shares traded.

ELIXINOL GLOBAL

Elixinol says it has appointed Helen Wiseman to replace Paul Benhaim as chair, with Mr Benhaim to move into a non-executive director role.
Elixinol said Ms Wiseman joined the company in April as a non-executive director and was previously the chair of Bid Corp and Bidvest international food service (BD: Apr 21, 2020).
Elixinol fell half a cent or 2.9 percent to 16.5 cents with 2.9 million shares traded.

AUSBIOTECH, JOHNSON & JOHNSON

Ausbiotech says its Innovation Industry Excellence Awards will go to life science leaders who have been critical in Australia's response to the Covid-19 pandemic.
Ausbiotech said that the awards, presented in collaboration with Johnson & Johnson would be in four Covid-19 related categories including the innovation award, the collaboration award, the communication leaders award and the industry's choice award.
In previous years, the industry organization awards included the industry leader award, the company of the year award, the emerging company of the year award.
Ausbiotech said nominations for the 2020 awards were open with nomination submissions available at: https://bit.ly/3m8jemo.
The industry organization said the award winners would be announced on October 29, 2020 during Ausbiotech and Invest 2020.
Ausbiotech and Invest 2020 will run online between October 28 and 30, 2020.