Biotech Daily

Tuesday September 21, 2021

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: PRESCIENT UP 11.5%; AMPLIA DOWN 12%**

*** CERTA TRIALS FT011 FOR DIFFUSE SYSTEMIC SCLERODERMA**

*** POLYNOVO: ENROLS 1st PATIENT IN US BARDA BURNS TRIAL**

*** NEUREN FILES NNZ-2591 PHELAN-MCDERMID SYNDROME FDA IND**

*** RESONANCE: 'AS3 SAFE, KNOCKS DOWN TARGET mRNA, IN MICE'**

*** AUSCANN APPOINTS CANNVALATE FOR CLINICAL REVIEW**

*** CLARITY RELEASES 6m ASX ESCROW SHARES**

*** BLACKROCK TAKES 11% OF IMRICOR**

*** PERENNIAL TAKES 10% OF LUMOS**

*** VICTORIA: PROF RICKY JOHNSTONE, DR MINNA-LIISA ÄNKÖ MRNA SAB**

MARKET REPORT

The Australian stock market recovered 0.35 percent on Tuesday September 21, 2021, with the ASX200 up 25.6 points to 7,273.8 points. Thirteen of the Biotech Daily Top 40 stocks were up, 18 fell and nine traded unchanged. All three Big Caps were up.

Prescient was the best, up three cents or 11.5 percent to 29 cents, with 8.8 million shares traded, followed by Osprey up 11.4 percent to 78 cents, with 37,667 shares traded. Uscom climbed 7.7 percent; Optiscan improved 4.35 percent; Mesoblast was up 3.1 percent; Oncosil, Paradigm, Patrys and Resmed rose more than two percent; CSL, Genetic Signatures, Polynovo and Universal Biosensors were up one percent or more; with Cochlear, Nanosonics and Pro Medicus up by less than one percent.

Amplia led the falls, down 2.5 cents or 11.9 percent to 18.5 cents, with 415,751 shares traded. Immutep lost 8.3 percent; Compumedics fell five percent; Volpara was down 4.2 percent; LBT and Proteomics was down more than three percent; Actinogen, Avita, Imugene, Opthea and Telix shed more than two percent; Clinuvel, Cynata, Neuren and Next Science were down more than one percent; with Kazia, Medical Developments and Starpharma down less than one percent.

CERTA THERAPEUTICS

Melbourne's Certa says it has begun a 30-patient, randomized, double-blind, placebo-controlled phase II trial of oral FT011 for diffuse systemic scleroderma.
Certa said the three-month trial at Melbourne's St Vincent's Hospital and the Royal Adelaide Hospital would enrol patients who had the disease for less than five years.
In 2018, media releases from the Federal Government and Brandon Capital Partners said that through Brandon's Medical Research Commercialisation Fund they would invest $22 million in Certa and Uniseed would invest a further $3 million in Certa for kidney disease (BD: Jun 5, 2018).
Brandon said at that time that Certa used genetic information to identify which patients would respond best to specific treatments, initially targeting kidney disease.
Brandon said that fibrosis, or scarring, of the kidney led to kidney failure and ultimately dialysis or kidney transplantation.
Brandon said that Certa's drugs blocked a receptor that was a key driver of fibrosis, with Certa using genetic analysis to identify which patients were most likely to benefit from the therapy, addressing a market worth about $US5 billion a year.
Today, Certa said that fibrosis was a natural healing process within the body, but excessive fibrosis in diffuse systemic scleroderma could cause "tight, hard skin … [and] heart and lung failure".
The company said that FT011 was designed to treat diffuse systemic scleroderma by blocking a receptor key to its excessive fibrotic activity.
Certa chief executive Prof Darren Kelly said "nearly half of all human disease involves fibrosis, so finding a drug … to stop the progression of fibrosis would be revolutionary".
Prof Kelly said that FT011 would be tested against targets for more common inflammatory and fibrotic conditions.
"Our initial focus on diffuse systemic scleroderma could be the first step towards a major anti-fibrotic breakthrough", Prof Kelly said.
Clinicaltrials.gov said that the primary outcome was FT011 levels in plasma with secondary outcomes including safety and efficacy measures.
Certa said trials in Europe would begin in August or September.
Certa is a private company.

POLYNOVO

Polynovo says it has enrolled the first of 150 patients in a BARDA-funded, pivotal trial of Novosorb biodegradable temporizing matrix (BTM) for full-thickness burns.
Polynovo said that the US Biomedical Advanced Research Development Authority (BARDA) would provide funding support of $US15 million ($A20.6 million) for the trial.
The company said the trial was being conducted over three years in 20 US and five Canadian burns centres and would compare Novosorb BTM against the existing standard-of-care for full thickness burn patients.
Polynovo said it would use the data generated to support an application to the US Food and Drug Administration for an on-label claim supporting the use of Novosorb BTM in full thickness burns.
Polynovo managing-director Paul Brennan said the start of the trial was "an exciting milestone".
"This will bring our US market in line with global markets where this claim is already established," Mr Brennan said.
Polynovo was up three cents or 1.6 percent to $1.94 with 2.9 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has filed a US investigational new drug application for an about 20-child, phase II trial of NNZ-2591 for Phelan-McDermid Syndrome.

Neuren chief executive John Pilcher said the filing of the application to the US Food and Drug Administration was “another important milestone achieved in our plan to develop NNZ-2591 for multiple serious neurological conditions”.

“We are eager to start the phase II trial in children with Phelan-McDermid syndrome, which we hope will demonstrate the potential for NNZ-2591 to provide an urgently needed treatment option,” Mr Pilcher said.

Neuren said there was no cure for Phelan-McDermid syndrome, and it was estimated that between one in 8,000 and one in 15,000 people suffered from the disease.

The company said that the most common characteristics of Phelan-McDermid syndrome were intellectual disability, delayed or absent speech, symptoms of autism, low muscle tone, motor delays and epilepsy.

Neuren said it had filed an investigational new drug application for NNZ-2591 to treat Angelman syndrome and was finalizing an application for NNZ-2591 for Pitt Hopkins syndrome.

In 2019, the company said that it had received orphan drug designation for NNZ-2591 for all three syndromes from the US Food and Drug Administration (BD: Oct 11,16, 2019).

In 2021, Neuren said that the European Medicines Agency had granted orphan drug status to NNZ-2591 for all three syndromes (BD: Jan 17, 2021).

Neuren fell three cents or 1.5 percent to $2.02.

RESONANCE HEALTH

Resonance says that its lead antisense oligo-nucleotide AS3 has “induced robust knockdown of the target mRNA” for liver disease at all three doses, in mice.

Resonance said that subcutaneous AS3 was trialled at 5mg/kg, 10mg/kg, and 25mg/kg for six days, with an average efficacy of 96 percent and the lowest dose achieving 98 percent efficacy.

In May, the company said it had filed a patent application for antisense oligo-nucleotides to target a “gene associated with viral inflammatory and malignant disease” and had selected AS3 as its lead compound which had shown “significant viral suppression” in a pre-clinical hepatitis B virus model (BD: May 17, 24, 2021).

Today, the project leader Dr Sherif Boulos said that “despite the relatively short six-day duration of the study, we observed inhibition of liver disease-related inflammatory and fibrotic disease markers, and a corresponding increase in the expression of an anti-fibrotic factor”.

“Importantly, AS3 was well-tolerated by all the mice, with no evidence of any toxicity,” Dr Boulos said.

“While we caution that our findings are preliminary, they support the continued development of AS3,” Dr Boulos said.

Resonance said that showing that AS3 was highly efficacious in a humanized-liver mouse model, it has achieved “a significant milestone”.

The company said it had begun discussions with an academic team to develop a collaborative study to evaluate AS3 in a humanized-liver mouse model of hepatitis B virus infection, expected to start in late 2021 or early 2022 for completion by July 2022.

Resonance was unchanged at 10 cents.

AUSCANN

Auscann says it has appointed Melbourne's Cannvalate Pty Ltd to review its animal data and research to develop drugs for human traumatic injury and neurological disorders.
Auscann said Cannvalate was a marijuana-focussed company with a contract research organisation arm, and would review Auscann's research to address US Food and Drug Administration "regulatory pathways, commercial feasibility, clinical trial mapping and the pathology and symptoms for target indications with a high likelihood of response to cannabinoid therapy".
The company said the market for human traumatic injury and neurological disorders was worth more than $US2 billion ($A2.75 billion) a year.
Auscann said Cannvalate would review its marijuana-based CPAT-01 "canine investigational formulation" and existing animal safety, toxicology, pharmacokinetic and biomarker data to accelerate FDA registration pathways for its human drug candidates.
Earlier this year, Auscann acquired Cannpal which was developing marijuana-based treatments for dog osteoarthritis in collaboration with the Commonwealth Scientific and Industrial Research Organisation (BD: Nov 16, 2020; Mar 18, 2021).
In April, Auscann said that a trial of 46 dogs with osteoarthritis showed that its liquid, oral formulation of tetrahydrocannabinol (THC) and cannabidiol (CBD) based CPAT-01 was safe, effective and improved lameness, pain and quality of life (BD: Apr 30, 2021).
Auscann fell 0.2 cents or 2.25 percent to 8.7 cents with 1.1 million shares traded.

CLARITY PHARMACEUTICALS

Clarity says that 6,265,585 shares will be released from mandatory ASX escrow on September 29, 2021.
Clarity executive chair Dr Alan Taylor told Biotech Daily that following the release from escrow, there would be 171,717,166 shares on issue on the ASX, of which 65,796,554 shares are subject to voluntary escrow arrangements, with a further 84,415,380 shares in ASX escrow.
Clarity fell 3.5 cents or 2.6 percent to $1.305.

IMRICOR MEDICAL SYSTEMS

Imricor says that New York's Blackrock Investment Management has increased its substantial holding from 7,851,367 shares (6.98%) to 15,448,252 shares (10.86%).
Imricor did not disclose the prices paid for the shares.
Imricor fell eight cents or 6.7 percent to $1.12.

LUMOS DIAGNOSTICS

Perennial Value Management says it has increased its substantial holding in Lumos from 13,722,761 shares (9.14%) to 15,337,608 shares (10.21%).
The Sydney-based Perennial said it bought 2,735,391 between August 18 and September 16, 2021, with the largest purchase on September 13 of 440,000 shares for $496,089 or $1.127 a share.
Lumos was unchanged at $1.085.

VICTORIA GOVERNMENT

The Victoria Government says it has appointed Prof Ricky Johnstone and Dr Minna-Liisa Änkö to the mRNA Victoria's scientific advisory group.

A media release from Victoria's Minister for Innovation and Medical Research Jaala Pulford said that Prof Johnstone was the Peter MacCallum Cancer Centre's head of the gene regulation laboratory.

The media release said that Dr Änkö is the head of the functional RNAomics laboratory at the Hudson Institute of Medical Research.

The State Government said that Prof Johnstone and Dr Änkö joined the advisory group was chaired by Victoria's lead scientist, Dr Amanda Caples and included the US National Institutes of Health Vaccine Research Center deputy director Dr Barney Graham, the Doherty Institute director Prof Sharon Lewin and the Burnet Institute director Prof Brendan Crabb (BD: Jun 17, 2021).

Ms Pulford said Victoria was "proud to be the home of Australia's biotech community, drawing from an unmatched pool of experts and researchers that are best placed to advise us on how to accelerate onshore mRNA manufacturing".