Biotech Daily

Wednesday June 29, 2022

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: GENETIC SIGNATURES UP 13%**
- IMUGENE DOWN 14%

*** DEMENTIA AUSTRALIA $750k GRANTS FOR ALZHEIMER'S TOXINS**

*** UK APPROVES INVEX PRESENDIN PHASE III HYPERTENSION TRIAL**

*** BLUECHIIP RECEIVES $1.1m FEDERAL R&D TAX INCENTIVE**

*** CHIMERIC EXPANDS PENNSYLVANIA UNI VIRAL VECTOR LICENCE**

*** NYRADA NYX-PCSK9i PHASE I CHOLESTEROL TRIAL DELAY**

*** ACORN TAKES 6.5% OF MICRO-X**

*** PARADIGM TO RELEASE 638k ASX ESCROW SHARES**

*** CLARITY APPOINTS PROF LOUISE EMMETT ADVISER**

MARKET REPORT

The Australian stock market fell 0.94 percent on Wednesday June 29, 2022, with the ASX200 down 63.4 points to 6,700.2 points. Seven of the Biotech Daily Top 40 stocks were up, 28 fell and five traded unchanged.

Genetic Signatures was the best, up 15 cents or 13.0 percent to $1.30, with 54,700 shares traded. Uscom was up 10.2 percent; Compumedics climbed 6.25 percent; Resonance rose 3.5 percent; Orthocell improved 2.6 percent; Cyclopharm was up 1.4 percent; with Starpharma and Resmed were up by less than one percent.

Monday's 45.5 percent best, Imugene, led the falls for the second day in a row, down three cents or 13.95 percent to 18.5 cents, with 56.6 million shares traded.

Micro-X lost 11.5 percent; Amplia fell 9.5 percent; Emvision and Immutep shed more than seven percent; Pro Medicus was down 6.8 percent; Avita, Clinuvel, Medical Developments, Opthea and Paradigm were down more than five percent; Alcidion, Dimerix, Pharmaxis and Prescient fell four percent or more; Telix was down 3.6 percent; Actinogen, Antisense, Cochlear, Nanosonics, Next Science, Universal Biosensors and Volpara shed two percent or more; Atomo, CSL, Cynata, Impedimed and Neuren were down more than one percent; with Mesoblast and Polynovo down by less than one percent.

DEMENTIA AUSTRALIA

Dementia Australia says its Research Foundation has granted $750,000 for research on the reduction of toxins associated with development of Alzheimer's disease.
Dementia Australia said Monash University's Prof Clare Anderson and Melbourne's St Vincent's Institute of Medical Research's Prof Michael Parker were awarded Faye Williams Innovation Grants, worth $375,000 each.
The organization said that "in an Australian first" Prof Anderson's team at Monash's Turner Institute for Brain and Mental Health would use acoustic stimulation technology to elicit slow wave sleep in research participants, "providing a breakthrough in our understanding of the role of sleep in the development of Alzheimer's disease".
Prof Anderson said that "slow wave sleep, which is a very deep state of sleep, is thought to be very important for memory consolidation, as well as clearing out toxins in the brain that are associated with cognitive decline".
"Our facility enables us to take blood samples from participants without interrupting their sleep so we will be able to measure how much toxin is cleared from the brain during slow wave sleep," Prof Anderson said.
"We hope this study will inform future interventions for sleep and cognitive health that reduce the risk of developing Alzheimer's disease including public health messaging promoting the importance of sleep as we age and the development of slow wave enhancement sleep therapeutics," Prof Anderson said.
Dementia Australia said Prof Parker's team would test a drug that might help enhance the brain's ability to clear toxins associated with the development of Alzheimer's disease.
"The brain naturally has cells that act as garbage collectors by removing the toxins that are associated with Alzheimer's disease," Prof Parker said.
"We have some very promising preliminary results that indicate that the new drug we are developing can enhance this process without the negative consequences that have plagued drug trials," Prof Parker said.
He said the grant would enable the testing of the new drug in mouse models of Alzheimer's disease.
"If we can successfully enhance the brain's ability to clear these toxins, we delay, and even potentially reverse, some of the symptoms of Alzheimer's disease," Prof Parker said.
Dementia Australia Research Foundation chair Prof Graeme Samuel said the grants provided an opportunity for researchers to test new ideas and interventions for dementia.
"Without a medical breakthrough, the number of people living with dementia is expected to increase to almost 1.1 million by 2058," Prof Samuel said.

INVEX THERAPEUTICS

Invex says the UK Medicines and Healthcare Products Regulatory Agency has approved its 240-patient, phase III trial of Presendin for idiopathic intracranial hypertension.
Invex said the randomized, placebo-controlled, double-blind 'Evolve 'trial would test the safety and efficacy of Presendin, or exenatide, administered once weekly over 24 weeks.
The company said the trial's primary endpoint was the change in intracranial pressure from baseline, with secondary endpoints related to vision and headache outcomes.
Invex said that following the approval it intended to open a number of clinical sites in the UK and would progress contracts to facilitate the starts of patient recruitment.
The company said it was confident that all necessary approvals in Australia would be completed between July and September 2022.
Invex was up two cents or 4.5 percent to 46.5 cents.

BLUECHIIP

Bluechiip says it has received $1,093,275 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Bluechiip said the rebate related to research and development expenditure for the year to June 30, 2021.
Bluechiip was up 0.2 cents or eight percent to 2.7 cents.

CHIMERIC THERAPEUTICS

Chimeric says it has an expanded licence to the University of Pennsylvania's third-generation lentiviral vector plasmid system for its CHM2101 CDH17 Car-T-cell program.
Chimeric said that under the original license agreement in July 2021, Chimeric acquired the exclusive rights to develop and commercialize certain CDH17 Car-T-cell therapies licensed from the University (BD: Jul 28, 2021).
Today, the company said that the amended agreement, would enable it to manufacture clinical-grade lentiviral vector for use in its planned phase I study of CHM2101 for gastro-intestinal cancers.
The company said it would also allow it to cross-reference regulatory information on file with the US Food and Drug Administration to facilitate filing of an investigational new drug application for CHM2101.
Chimeric did not disclose the commercial terms of the amended license agreement, but said they were "not considered financially material … [and] the upfront licencing fee [was] expected to be funded from existing cash reserves".
Chimeric was up 0.2 cents or 2.2 percent to 9.4 cents with 1.65 million shares traded.

NYRADA

Nyrada says that Covid-related China manufacturing has delayed its 56-subject, phase I, oral cholesterol-lowering candidate NYX-PCSK9i trial, expected to begin by July 2023.
Nyrada said the manufacturing scale-up of the drug candidate was delayed due to Covid-19 lockdown measures in Shanghai, and the consequent "the inability of employees of the contract manufacturing organization … to access laboratory sites".
The company said "substantial efforts" had been made by its manufacturing partner to minimize the impact of pandemic-related lockdowns, including through the deployment of additional personnel and resources to recover lost time.
Nyrada said pre-clinical safety and toxicology studies would begin commence as anticipated by October 2022.
The company said the primary objective of the phase I study was to evaluate the drug candidate for safety and tolerability, with the secondary endpoint assessing blood cholesterol levels in cohorts treated for 14 days.
Nyrada chief executive officer James Bonnar said that the oral PCSK9 inhibitor "creates the potential for a next generation alternative to expensive and inconvenient PCSK9 injectable drugs and is attracting industry interest".
"We have already demonstrated in an in-vivo efficacy study that this class of compounds is able to reduce total cholesterol by 65 percent when given in combination with the statin Lipitor (atorvastatin, Pfizer) and 46 percent when dosed as a monotherapy," Mr Bonner said.
Nyrada said the European Patent Office had granted it a composition of matter patent for its PCSK9 inhibitor, protecting the technology to March 16, 2038.
Nyrada fell one cent or 6.7 percent to 14 cents.

MICRO-X

Melbourne's Acorn Capital says it has increased its substantial share-holding in Micro-X from 24,324,957 shares (5.29%) to 30,102,750 shares (6.52%).
Acorn said it bought shares between October 20, 2021 and June 28, 2022, with its most recent purchase 1,082,177 shares for $131,985 or 12.2 cents a share.
Micro-X fell 1.5 cents or 11.5 percent to 11.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says that 638,332 shares will be released from ASX escrow on July 10, 2022.
According to its most recent filing, Paradigm will have 228,234,127 shares available for trading, with a further 4,446,671 shares remaining in ASX escrow.
Paradigm fell five cents or 5.4 percent to 87.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has appointed Prof Louise Emmett to its scientific advisory board.
Clarity said Prof Emmett was currently Sydney's St Vincent's Hospital's director of "theranostics" (diagnostics and therapy) and nuclear medicine, a University of New South Wales professor of medicine, and a clinical research leader at the Garvan Institute of Medical Research.
The company said Prof Emmett held a Bachelor of Medicine, Bachelor of Surgery, and a Doctorate of Medicine from the University of Auckland.
Clarity was up 3.5 cents or 7.1 percent to 52.5 cents.