

Biotech Daily

Wednesday May 19, 2021

Daily news on ASX-listed biotechnology companies

* ASX DOWN, BIOTECH UP: IMMUTEP UP 11%; ACTINOGEN DOWN 6%

* VICTORIA \$245m FOR INSTITUTE OF INFECTIOUS DISEASE

- * PARADIGM CLAIMS 1st 'MODEST' PPS (ZILOSUL) REVENUE
- * BARD1: 'EXO-NET HIGH-YIELD PURE EXOSOMES FOR TESTS, THERAPIES'
- * JAPAN PATENT FOR ADALTA
- * US PATENT FOR ISLAND ISLA-101 PROGRAM
- * RECCE: R327 'EFFECTIVE, NOT HIGHLY TOXIC FOR SARS-COV-2, IN-VITRO'
- * NEUROSCIENTIFIC LOSES CHAIR BRIAN LEEDMAN

MARKET REPORT

The Australian stock market fell 1.9 percent on Wednesday May 19, 2021, with the ASX200 down 134.3 points to 6,931.7 points.

Twenty of the Biotech Daily Top 40 stocks were up, 12 fell and eight traded unchanged. All three Big Caps fell.

Immutep was the best, up five cents or 11.0 percent to 50.5 cents, with 8.4 million shares traded. Imugene improved 10.6 percent; Genetic Signatures and Paradigm climbed more than four percent; Telix and Uscom were up more than three percent; Amplia, Clinuvel, Pharmaxis, Proteomics and Resonance rose two percent or more; Compumedics, LBT, Optiscan and Universal Biosensors were up more than one percent; with Avita, Cynata, Mesoblast, Neuren and Starpharma up by less than one percent.

Actinogen led the falls, down 0.4 cents or 5.9 percent to 6.4 cents, with 5.8 million shares traded. Impedimed fell four percent; Alterity was down 3.85 percent; Antisense and Nanosonics shed more than two percent; Cochlear, CSL, Medical Developments, Opthea, Orthocell, Resmed and Volpara were down one percent or more; with Clinuvel, Polynovo and Pro Medicus down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says it will provide a further \$245 million to the Australian Institute of Infectious Disease "to lead the fight against future pandemics".

The State Government said the funding was further to the \$155 million announced last year and the additional \$245 million would "get the project off the ground and build the Institute in the heart of the Parkville biomedical precinct".

Last year, the Victoria Government said it would invest \$155 million for a \$550 million Institute of Infectious Disease in Parkville, incorporating the Burnet Institute, with \$150 million from the University of Melbourne and its partners, and the remaining capital to be sought from the Federal Government (BD: Nov 13, 2020).

A Burnet spokesperson said at that time the move would take "at least four years". Today, the State Government said that the \$650 million project would be supported with \$250 million from the University of Melbourne and its partners.

A Victoria Government media release said that the Covid-19 pandemic "highlighted the importance of backing science and research in getting ahead of outbreaks and keeping people safe, with the Institute designed to deliver everything researchers need to detect, analyze, manage and treat infectious diseases".

"The Institute will be the largest centre of expertise in the Southern Hemisphere region ... [and would] accelerate research into the prevention of future pandemics and rapidly developing treatments," the media release said.

The Government said that the Institute would be the new home of the Burnet Institute, located next to the Peter Doherty Institute for Infection and Immunity, and would allow the Doherty to expand its research operations.

The media release said the Institute would bring together the Walter and Eliza Hall Institute, the University of Melbourne, the Murdoch Children's Research Institute, Monash University and CSL.

The Government said the Institute would include laboratories, containment facilities and a robotic bio-bank facility to ensure specimen storage in large-scale clinical trials.

The media release said the funding would deliver 350 jobs during construction, 850 ongoing Institute jobs and the potential for up to 5,000 jobs in the biomedical sector.

The Government said the investment added to the \$50 million previously announced to build an mRNA vaccine manufacturing capability (BD: Apr 21, 2021).

The Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said that the facility would "enable us to protect Victoria and the country against future pandemics - that's why we're delivering the funding needed to get it off the ground."

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has its first revenue from pentosan polysulfate sodium (Zilosul) through the Australian Therapeutic Goods Administration special access scheme.

Paradigm said that injectable pentosan polysulfate sodium (PPS) was not available for general sale but was available to patients who qualify for a sponsored trial or via a treating physician applying for its use in patients via the [special access scheme]".

The company said it previously provided Zilosul at no cost to prescribing physicians but requested doctors collect safety and efficacy data from patients.

Paradigm said the cost would be at a premium to the previously disclosed price of \$2,500 for a course of bi-weekly injections for six weeks.

The company said that it had received five Zilosul prescriptions and the patients would begin treatment in the coming week, and modest revenues were expected.

Paradigm was up 10 cents or 4.8 percent to \$2.20 with 501,637 shares traded.

BARD1 LIFE SCIENCES

Bard1 says its Exo-Net technology is a novel approach for the rapid, pure and high yield capture of exosomes from complex samples, including body fluids.

Bard1 said that the poster, titled 'A Novel, Rapid, Scalable Exosome Isolation Technology' explained its technology and would be presented at the International Society for Extracellular Vesicles meeting on May 18 to 21, 2021.

The company said that Exo-Net could capture exosomes from plasma, urine and saliva and provided "superior exosome-specific nucleic acid and protein yield and purity compared to market leading products and methods".

The poster was authored by Exo-Net inventor and Bard1 US head of research Dr Emily, Stein, chief scientific officer Dr Peter French and research scientist Luke Morton.

The presentation said that Exo-Net captured exosomes in 15 minutes, was easy-to-use and compatible with small volume, high through-put sample analysis, "allowing ready integration of Exo-Net into multiple downstream research applications".

Dr French said that showcasing "the superior performance, flexibility and ease of use of Exo-Net ... [provided] a great opportunity to embed Exo-Net into a range of research projects that are isolating and characterizing exosomes for potential diagnostic and therapeutic applications".

Bard1 chief executive officer Dr Leearne Hinch told Biotech Daily that exosomes "contain important bio-molecules, such as DNA, RNA, proteins and lipids, that can be used in the diagnosis and treatment of multiple diseases, including cancer, inflammation, cardio-vascular disease and neuro-degenerative diseases".

In a media release to the ASX Dr Hinch said that Exo-Net had "the potential to become the exosome isolation product of choice for researchers globally".

The presentation said that Exo-Net consisted of "a covalently linked, multi-layered threedimensional matrix comprising several exosome-specific antibodies and spacer and linker molecules that interact to confer a characteristic topology to maximize specific binding and capture of exosomes from complex biofluids, in a reproducible manner".

"Exo-Net has demonstrated compatibility with multiple downstream chemistries for analysis of lipid, protein and nucleic acids," the presentation said.

The research presentation concluded that "recovered exosome content is not contaminated with Golgi, extraneous serum proteins, or free lipids ... [provided] superior exosome-specific nucleic acid and protein marker results compared to market leading products and methods ... and was a cost-effective tool for rapid isolation of highly pure exosomes for downstream analysis".

Bard1 was up 11 cents or 4.5 percent to \$2.57.

<u>ADALTA</u>

Adalta says the Japan Patent Office has granted a patent relating to AD-214 for fibrosis. Adalta said that the patent, titled 'CXCR4 binding molecules and methods of use thereof' would provide intellectual property protection until January 8, 2036.

The company said that the patent included the composition of AD-214 and its use in therapeutic and diagnostic applications, including idiopathic pulmonary fibrosis, the lead indication for which AD-214 was being developed.

Adalta said the international patent application was filed in January 2016 with a priority date of January 9 2015 and the Japan approval was the third patent granted under the application, with the Australian patent was granted in 2017 and the US version in 2020. The company said that the claims were being pursued in the European Union and China. Adalta fell half a cent or 3.6 percent to 13.5 cents.

ISLAND PHARMACEUTICALS

Island says it has been granted a US patent relating to its ISLA-101 lead program for dengue fever and other mosquito-borne viruses.

Island said the patent, titled 'Method of viral inhibition' would provide coverage until April 16, 2034, and was granted to Monash University, from whom it had licenced the program. Island executive chair Dr Paul MacLeman said the grant was "a significant development for Island Pharmaceuticals".

"Having an allowed patent that protects Island's lead program in this large market provides protection for the development of ISLA-101 and further underpins our ability to advance the program in the US, a key target market," Dr MacLeman said.

Island was unchanged at 34 cents with 1.5 million shares traded.

RECCE PHARMACEUTICALS

Recce says further testing of R237 shows it is "effective and not highly toxic at a small window of concentrations" with further in-vitro testing to conducted by the CSIRO. Recce said its synthetic anti-infective R327 was part of a fee-for-service severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) screening program by the Commonwealth Scientific and Industrial Research Organisation and Doherty Institute. In February, Recce said that R327 showed a 99.9 percent reduction of Sars-Cov-2, in-vitro (BD: Feb 12, 2021).

Today the company said that high concentrations of R327 of 13,333ppm and 40,000ppm, "showed a 4-log reduction in Sars-Cov-2 viral genome numbers ... but severe cellular toxicity was observed in vero cells at these concentrations".

Recce said that at 4,444ppm, R327 "showed some toxicity" and it was "shown to be effective and not highly toxic at a small window of concentrations in the preliminary in-vitro testing in vero cells" and received a qualified recommendation to proceed to stage 2 of the program for testing in human bronchial epithelial cells, with results expected this year. "Further testing must be completed in order to determine whether R327 will show an inhibitory effect against the Sars-Cov-2 virus without associated toxicity," Recce said. Recce chair Dr John Prendergast said the "encouraging results continue to reinforce our confidence in the potential of R327 against Sars-Cov-2 as another line of defence in the arsenal against Covid-19".

Recce was unchanged at \$1.13.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says that non-executive chair Brian Leedman has resigned from the company, effective from May 18 2021.

Neuroscientific managing-director Matthew Liddelow said that Mr Leedman was "instrumental" to the company's progress since the initial public offer in 2018.

The company said that until a replacement chair was appointed Dr Anton Uvarov would be the interim chair.

Yesterday, Resapp said it had re-appointed co-founder Brian Leedman as executive director of corporate affairs starting on \$187,000 a year (BD: May 18, 2021). Neuroscientific was unchanged at 23 cents.