

Biotech Daily

Tuesday June 7, 2022

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH DOWN: ANTISENSE UP 12%; IMMUTEP DOWN 11%
- * VICTORIA \$1m FOR MCRI, NOVO NORDISK STEM CELL COLLABORATION
- * GILEAD \$300k FELLOWSHIP GRANTS FOR 6 PROJECTS
- * AUDEARA RAISES \$1m IN BILL PENG PLACEMENT
- * ORTHOCELL: REMPLIR (CELGRO) 2-YEAR NERVE REGENERATION DATA
- * DIMERIX, ACADI TRIAL DMX-200 FOR DIABETIC KIDNEY DISEASE
- * PARADIGM RECEIVES \$8.2m FEDERAL R&D TAX INCENTIVE
- * TELIX RECEIVES \$17.25m FEDERAL R&D TAX INCENTIVE
- * NEUROSCIENTIFIC: ETHICS APPROVAL FOR EMTINB TRIAL
- * OVENTUS REQUESTS 'BOARD COMPOSITION' TRADING HALT
- * REGAL FUNDS REDUCES TO 19% OF OPTHEA
- * REGAL FUNDS DILUTED TO 19% IN VISIONEERING
- * REGAL FUNDS DILUTED TO 10.9% OF IDT
- * REGAL FUNDS TAKES 8.1% OF MEDADVISOR
- * REBECCA BRICE, JDB REDUCE TO 10.7% OF AUDEARA
- * AROVELLA LOSES CHAIR PAUL HOPPER, DR ELIZABETH STONER INTERIM

MARKET REPORT

The Australian stock market fell 1.53 percent on Tuesday June 7, 2022, with the ASX200 down 110.6 points to 7,095.7 points. Ten of the Biotech Daily Top 40 stocks were up, 27 fell and three traded unchanged. All three Big Caps fell.

Antisense was the best, up 1.2 cents or 12.2 percent to 11 cents, with 1.9 million shares traded. Prescient climbed 10 percent; Amplia and Proteomics rose four percent or more; Alcidion and Orthocell were up more than three percent; Medical Developments and Nova rose two percent or more; Neuren was up 1.3 percent; with Starpharma up 0.7 percent.

Immutep led the falls, down 4.5 cents or 11.1 percent to 36 cents, with four million shares traded. Clinuvel lost 6.7 percent; Impedimed and Volpara were down more than five percent; Cyclopharm fell 4.2 percent; Avita, Kazia, Mesoblast, Micro-X, Next Science, Oncosil, Resonance and Universal Biosensors were down more than three percent; Atomo, Cochlear, Genetic Signatures, Imugene, Nanosonics and Opthea shed more than two percent; Actinogen, Cynata, CSL, Emvision, Paradigm, Pharmaxis, Polynovo and Uscom were down more than one percent; with Pro Medicus, Resmed and Telix down by less than one percent.

VICTORIA GOVERNMENT, MURDOCH CHILDREN'S RESEARCH INSTITUTE

The Victoria Government says it has provided \$1 million for a stem cell research program at the Royal Children's Hospital in Flemington.

A media release from the Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford said the Novo Nordisk Foundation Centre for Stem Cell Medicine was "a new international centre of excellence" and partnership between the Hospital's Murdoch Children's Research Institute (MCRI), the University of Copenhagen and Leiden University Medical Center in the Netherlands.

The Victoria Government said that the Novo Nordisk Foundation Center for Stem Cell Medicine collaboration would be known as 'Renew'.

The media release said that the collaboration would "pave the way for future stem cell drugs and therapies for diseases including congenital heart disease, inherited kidney diseases, muscular dystrophies, inflammatory bowel disease and type 1 diabetes". Ms Pulford's media release said that MCRI researchers were "growing complex tissues from stem cells of patients, with the goal to increase understanding of childhood heart disease, find treatments and eventually to develop replacement organs".

The Victoria Government said that the team was "bio-engineering a heart patch - a patch of cardiac muscle made from patient stem cells - that could help improve heart function in children ... preventing their hearts from failing or requiring transplantation".

The Government said it had provided \$1 million to the Murdoch Children's Research Institute "to develop a business case to supercharge research for innovative stem cell therapies for conditions in children and to support its role in [the collaboration].

The Government said it had provided \$2.3 million to the Institute for a stem cell study to grow "miniature organs so researchers can look into the impacts of coronavirus on the heart, lungs, brain, kidneys and blood vessels".

Novo Nordisk Foundation Centre for Stem Cell Medicine chief executive officer Prof Melissa Little said the collaboration would "enable outcomes across the breadth of stem cell medicine [including] new drugs based on human stem cell models, cell and tissue therapies and new cell and gene therapies".

GILEAD SCIENCES AUSTRALIA NEW ZEALAND

Gilead says its 2022 Fellowship Research Grants Program has awarded \$300,000 to six research projects, on hepatitis, HIV, breast cancer and invasive fungal infections. The company said the recipients included Royal Adelaide Hospital Infectious Diseases Unit's Dr Erin McCartney to scale-up hepatitis C virus screening for people experiencing homelessness and the Illawarra Sexual Health Service's Dr Caroline Lade for improving HIV prevention in women.

Gilead said that Melbourne's St Vincent's Hospital's Dr Joan Flores would study the use of "big data to improve the diagnosis of liver cirrhosis; and Box Hill Hospital's Dr Sara Latham received funding for research on using bone turnover markers to guide the frequency of medication administration for patients with bone metastases from breast cancer.

The company said that the Peter MacCallum Cancer Centre and the University of Melbourne's Dr Zoe Neoh won a grant to develop and establish a streamlined database for systematic collection, analysis and management of non-Aspergillus mold infection data, and the Burnet Institute's Michael Traeger would be funded to research the acceptability and preference for new ways of delivery pre-exposure prophylaxis (Prep) amongst men who have sex with men.

Applications for the 2023 grants have opened at: <u>www.gileadfellowship.com.au</u>.

AUDEARA

Audeara says it has completed a \$1 million placement with Hsin-Chieh 'Bill' Peng, issuing him 10,000,000 shares at 10 cents a share.

Audeara said the issue price was an 11 percent premium to the closing price on June 6, 2022, and were issued to Mr Peng through BP Peng Pty Ltd as trustee for BP Peng Trust. The company said that funds would be used for working capital, an expanding sales team, stock ordering and logistics.

Audeara was up 0.7 cents or 7.8 percent to 9.7 cents.

ORTHOCELL

Orthocell says final data from its Remplir shows 23 of 27 (85%) nerve reconstructions resulted in functional recovery of target muscles closest to the reconstruction site. Orthocell said that the follow-up data at 24 months post treatment was available for 14 of 19 patients, involving 27 nerve reconstructions.

Last year, the company said that 12-month follow-up data for 16 of 19 patients, with 33 nerve repairs showed 25 of 33 (76%) nerve reconstructions resulted in functional recovery of muscles controlled by the reconstructed nerve (BD: Jun 21, 2021).

Today, the company said that more than half (17 of 33) of the nerve repairs with Remplir (formerly Celgro) were performed in five quadriplegic patients and resulted in "faster and better results in muscle function restoration", with 11 of 12 (92%) quadriplegic nerve transfers at 24 months post treatment, resulting in "best-case clinical outcome for target muscles", compared to 13 of 17 (76%) at 12 months post treatment.

Orthocell managing-director Paul Anderson said that "consistently returning function to paralyzed upper limbs was the primary goal in this study ... [and] I am delighted by the results showing early recovery and continued improvement in arm and hand function in these difficult to treat patients".

"This study has demonstrated higher quality outcomes, improved predictability, and consistency of return of muscle function following Remplir nerve reconstruction treatment," Mr Anderson said.

Orthocell was up 1.5 cents or 3.9 percent to 40 cents.

<u>DIMERIX</u>

Dimerix says that with the Australian Centre for Accelerating Diabetes Innovations (ACADI) it will conduct a longer-term trial of DMX-200 for diabetic kidney disease. Dimerix said that "encouraging data" in its phase II study suggested that "greater albuminuria reductions may be observed over a longer study treatment duration". In 2020, the company's share price fell on news that its 45-patient, phase II trial of DMX-200 for diabetic kidney disease did not meet its primary endpoint of the change in 24-hour albuminuria from baseline compared to a placebo (BD: Sep 14, 2020).

The company said at that time that "although a statistically significant difference in reduction of albuminuria for the primary endpoint was not seen ... analysis showed statistically and clinically significant variation in treatment response for patients with higher levels of albuminuria at study baseline".

Today, Dimerix did not disclose the number of patients but said the trial protocol was being finalized and it was expected to be a 12 month to 24-month study of the effect of DMX-200 on proteinuria and estimated glomerular filtration rate (kidney function) in patients with diabetic kidney disease, starting by the end of June 2022. Dimerix was unchanged at 16 cents.

PARADIGM BIOPHARMA

Paradigm says it has received \$8,212,492 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.

Paradigm said the rebate related to research and development expenditure for the year to June 30, 2021.

Paradigm fell two cents or 1.7 percent to \$1.14.

TELIX PHARMACEUTICALS

Telix says it has received \$17,250,000 from the Australia Tax Office under the Federal Government Research and Development Tax Incentive program.

Telix said the rebate related to research and development expenditure for the year ended December 31, 2021.

Telix fell two cents or 0.5 percent to \$4.13 with 712,842 shares traded.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says it has ethics approval for an early-phase, up-to 30-healthy volunteer trial of its drug candidate Emtinb for neurodegenerative conditions.

The company said the trial would assess biomarkers in blood samples that indicated proof of the mechanism-of-activity of Emtinb to guide efficacy outcomes in future trials, with trial activities expected to begin "immediately".

Neuroscientific managing-director Matt Liddelow said that the start of the clinical development program was "a significant milestone in progressing our lead drug candidate towards commercialization and is a historic accomplishment for the company, being the first clinical trial to be initiated by Neuroscientific".

"This clinical trial forms the initial part of our clinical development strategy for Emtinb as a potential disease-modifying treatment for neurodegenerative conditions, such as our lead indications Alzheimer's disease and Multiple sclerosis," Mr Liddelow said.

Neuroscientific was up 1.5 cents or 6.5 percent to 24.5 cents.

OVENTUS MEDICAL

Oventus has requested a trading halt pending "an announcement ... in relation to its board composition".

Trading will commence on June 9, 2022 or on an earlier announcement.

Oventus last traded down 0.2 cents or 9.1 percent to two cents with 1.05 million shares traded.

<u>OPTHEA</u>

Regal Funds Management says it has reduced its substantial share-holding in Opthea from the equivalent of 67,328,864 shares (19.13%) to 66,771,342 shares (18.96%). Sydney's Regal Funds said it held 43,701,022 (14.41%) Australian shares and 2,883,790 (6.55%) American depositary shares, each representing eight Australian shares. The company said it bought and sold shares between May 16 to June 1, 2022, with the single largest sale on May 20 of 521,587 Australian shares for \$719,790 or \$1.38 a share. Opthea fell 3.5 cents or 2.8 percent to \$1.215.

VISIONEERING TECHNOLOGIES

Regal Funds Management says it has been diluted in Visioneering, from 454,656,490 shares (19.82%) to 4,546,566 shares (18.92%).

Last year, Visioneering said it had completed a 100-to-one consolidation reducing the Chess depositary interests (CDIs) on issue from 2,264,679,811 CDIs to 22,647,141 CDIs (BD: Jun 28, 2021).

Today, the Sydney-based Regal said that on March 14, 2022 its holdings had been diluted following the issue of shares in March 2022.

Visioneering fell one cent or 3.2 percent to 30 cents.

IDT AUSTRALIA

Regal Funds Management says its 26,360,286 share-holding in IDT has been diluted from 11.01 percent to 10.94 percent.

The Sydney-based Regal said that on April 4, 2022 its holdings were diluted following the issue of shares.

IDT was up half a cent or 3.6 percent to 14.5 cents.

MEDADVISOR

Regal Funds Management says it has increased its substantial share-holding in Medadvisor from 29,187,739 shares (7.73%) to 30,787,747 shares (8.09%). The Sydney-based Regal said that on November 17, 2021 it bought 1,600,000 shares for \$576,000 or 36 cents a share.

Medadvisor was unchanged at 17.5 cents.

<u>AUDEARA</u>

JDB Services Pty Ltd says it has reduced its substantial share-holding in Audeara from 12,466,707 shares (11.87%) to 11,250,726 shares (10.71%).

In a substantial shareholder notice signed by director Rebecca Brice, the Brisbane-based JDB Services (RAC and JD Brice Investment account) said that between May 28, 2021 and June 6, 2022 it sold shares, with the single largest sale on January 20, 2022 of 252,231 shares for \$35,274 or 14 cents a share.

AROVELLA THERAPEUTICS

Arovella says non-executive chair Paul Hopper will resign from the company, effective from June 30, 2022, with Dr Elizabeth Stoner as interim chair.

Mr Hopper said he was executive chair of three other ASX listed companies and was "no longer able to commit the amount of time I would like to Arovella".

Arovella said Dr Stoner would be interim chair while it searched for a replacement. Arovella fell 0.3 cents or 9.1 percent to three cents with 1.2 million shares traded.