

Biotech Daily

Wednesday June 30, 2021

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: PRESCIENT UP 22.5%; ANTISENSE, OSPREY DOWN 7%
- * CYNATA READIES FOR DIABETIC FOOT ULCER STEM CELL TRIAL
- * PARADIGM RESPONDS TO FDA PPS OSTEO-ARTHRITIS QUESTIONS
- * AVITA IN US RUSSELL 3000 INDEX
- * UNIVERSAL BIOSENSORS 23% AGM DISSENT
- * NEUROSCIENTIFIC REQUESTS 'STUDY RESULTS' TRADING HALT
- * VANGUARD BELOW 5% OF COCHLEAR
- * APG ASSET TAKES 5.5% OF COCHLEAR
- * ADAM LEITZES, KARST PEAK TAKE 11% OF PHARMAXIS
- * AUSTRALIAN ETHICAL DILUTED TO 5.6% OF IMMUTEP
- * PERENNIAL TAKES 14% OF MEDADVISOR
- * NOXOPHARM DILUTED TO 24% OF NYRADA
- * NYRADA DIRECTOR DR IAN DIXON INCREASES, DILUTED TO 6.5%
- * ALCIDION LOSES CO-FOUNDER RAY BLIGHT

MARKET REPORT

The Australian stock market closed the financial year up 0.16 percent on Wednesday June 30, 2021, with the ASX200 up 11.8 points to 7,313.0 points. Nineteen of the Biotech Daily Top 40 stocks were up, 15 fell, five traded unchanged and one was untraded.

Prescient was the best, up 4.5 cents or 22.5 percent to 24.5 cents, with 15.2 million shares traded. Paradigm climbed 8.25 percent; Pharmaxis and Universal Biosensors were up more than seven percent; Clinuvel, Compumedics and Telix improved four percent or more; Alterity was up 3.7 percent; Amplia, Immutep, Imugene, Kazia and Opthea rose more than two percent; Cyclopharm, Nova Eye, Patrys, Pro Medicus, Resmed and Starpharma were up more than one percent; with Cochlear and Volpara up by less than one percent.

Antisense and Osprey led the falls, both down 7.1 percent to 19.5 cents and 1.3 cents, respectively, with 2.1 million and 9.2 million shares traded, respectively. Oncosil lost seven percent; Resonance retreated 6.1 percent; Mesoblast and Uscom were down three percent or more; Avita and Dimerix shed more than two percent; CSL, Cynata, Medical Developments, Next Science and Polynovo were down more than one percent; with Nanosonics, Neuren and Orthocell down by less than one percent.

CYNATA THERAPEUTICS

Cynata says it has ethics approval for a 30-patient, phase I trial of its Cymerus mesenchymal stem cells to treat patients with diabetic foot ulcers.

Cynata said the trial was expected to begin recruitment this year at the Royal Adelaide Hospital and Adelaide's Queen Elizabeth Hospital.

The company said the trial titled 'A Randomised, Controlled, Phase 1 Study to Investigate Safety, Tolerability and Efficacy of CYP-006TK in Adults with Diabetic Foot Ulcers' would randomly assign the 30 patients to receive either its CYP-006TK or standard of care treatment.

Cynata said the trial would be the first to use its CYP-006TK polymer-coated silicon dressing, licenced from Tekcyte.

In March, Cynata said it would trial its stem cells for diabetic foot ulcers with Tekcyte's polymer patch as a wound dressing seeded with stem cells (BD: Mar 1, 2021).

Today, the company said the treatment period would be four weeks and each patient would be evaluated for 24 weeks.

Cynata said the primary endpoint was safety, with secondary efficacy endpoints measured after 12 weeks and 24 weeks including the percentage of the ulcer area change, days taken to complete ulcer healing, days to 50 percent of ulcer healing, the percentage change in ulcer volume and ulcer pain.

Cynata said the trial would be led by University of Adelaide's Prof Robert Fitridge. Cynata fell one cent or 1.9 percent to 50.5 cents.

PARADIGM BIOPHARMACEUTICALS

Paradigm says it has responded to US Food and Drug Administration questions on its proposed trial of pentosan polysulfate sodium for osteo-arthritis.

Last month, Paradigm said the FDA had asked questions "principally in relation to recently completed non-clinical studies" regarding its investigational new drug application for pentosan polysulfate sodium for osteoarthritis (BD: May 25, 2021).

Today, the company said it had consulted with experts to review the document and ensure it had sufficient information "to be completely responsive" to the FDA questions. Paradigm said it believed the inputs from the experts, including a US pre-clinical

toxicologist and a former FDA physician, would increase the likelihood that its response would meet FDA's requirements to be considered complete and sufficient for proceeding. Paradigm chief medical officer Dr Donna Skerett said the company believed the responses were "sufficient to assure the agency the program is supported by non-clinical and clinical data and that the objectives, rationale, and study design will aim to demonstrate the safety and effectiveness of PPS for patients with painful osteo-arthritis of the knee".

Paradigm was up 16 cents or 8.25 percent to \$2.10 with 2.3 million shares traded.

AVITA MEDICAL

Avita says it has been included in the Russell 3000 Index as part of the annual reconstitution based on market capitalization, effective from June 28, 2021. Avita said the Russell Index captured the largest 4,000 US stocks in May of every year ranked by market capitalization.

Avita fell 11 cents or 2.1 percent to \$5.23 with 519,182 shares traded.

UNIVERSAL BIOSENSORS

Universal Biosensors says that 22.57 percent of annual general meeting votes opposed the "compensation of the company's named executive officers".

Universal Biosensors said that the executive pay vote was opposed by 19,758,375 votes (22.57%) votes, with 67,773,739 votes (77.43%) in favor.

The vote to elect Judith Smith a director was supported by 99.92 percent of the meeting. The company's most recent Appendix 2A said it had 177,542,700 Chess depository interests (CDIs) on issue, meaning that the votes against the compensation amounted to 11.13 percent of the company, sufficient to requisition extraordinary general meetings. Universal Biosensors was up six cents or 7.7 percent to 84 cents.

NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific has requested a trading halt "pending the release of the results of the company's pivotal safety and toxicity study".

Trading will resume on July 2, 2021 or on an earlier announcement.

Neuroscientific last traded at 33.5 cents.

COCHLEAR

The Malvern, Pennsylvania-based Vanguard Group says it has ceased its substantial shareholding in Cochlear with 217,347 shares or 4.913 percent of the company. Vanguard said between November 23, 2018 and June 24, 2021 it bought, sold and transferred shares, at prices ranging from \$140.00 a share to \$253.34 a share. Vanguard said there was "no sell-down activity associated with this change" but it ceased to be the investment manager for an unnamed institutional client. Cochlear was up 42 cents or 0.17 percent to \$251.67 with 143,394 shares traded.

COCHLEAR

APG Asset Management says it has become a substantial shareholder in Cochlear with 3,623,122 shares or 5.51 percent of the company.

Amsterdam's APG Asset Management said that between October 6, 2014 and June 28, 2021, it bought and sold shares at prices ranging from \$68.66 a share to \$248.78 a share.

PHARMAXIS

Adam Leitzes and Karst Peak Capital say they have increased their substantial holding in Pharmaxis from 40,214,643 shares (8.90%) to 50,966,207 shares (11.27%). Hong Kong's Karst Peak and Mr Leitzes said that between May 21 and June 25, 2021,

they bought 10,751,564 shares for \$790,159 or an average price of 7.35 cents a share. Pharmaxis was up 0.6 cents or 7.2 percent to 8.9 cents with 4.6 million shares traded.

IMMUTEP

The Sydney-based Australian Ethical Investment says its 41,583,333 shares in Immutep have been diluted from 6.75 percent to 5.56 percent due to a placement. Last week, Immutep said it raised \$60 million in a placement at 52 cents a share and hoped to raise up to \$5 million through a share plan (BD: Jun 21, 2021). Immutep was up 1.5 cents or 2.8 percent to 55 cents with 2.1 million shares traded.

MEDADVISOR

Perennial Value Management says it has increased its substantial shareholding in Medadvisor from 46,366,881 shares (12.29%) to 52,491,057 shares (13.91%). The Sydney-based Perennial said between June 23 and 25, 2021 it bought 6,124,176 shares for \$1,781,640 or an average price of 29.10 cents a share. Medadvisor fell half a cent or 1.6 percent to 30 cents.

NYRADA

Nyrada says Noxopharm's substantial share-holding of 33,373,245 Chess depository interests (CDIs) has been diluted from 24.09 percent to 21.39 percent. In March, Nyrada says it had firm commitments to raise \$11 million in a placement at 26 cents per Chess depository interest (CDI) (BD: Mar 22, 2021). Nyrada was unchanged at 32 cents.

NYRADA

Nyrada says that director Dr Ian Dixon has increased but been diluted from 9,921,725 Chess depository interests (CDIs) (7.16%) to 10,114,033 CDIs (6.48%). Ina separate Appendix 3Y directors interest statement Dr Dixon said he acquired 192,308 CDIs at 26 cents each (see above).

ALCIDION GROUP

Alcidion co-founder Ray Blight has resigned, effective from June 30, 2021. Alcidion said Mr Blight co-founded the company in 2000 with Dr Malcolm Pradhan and was its chief executive officer and executive chair until the acquisition of MKM Health and Patientrack in 2019.

The company said it was "well advanced in the identification of independent, non-executive director candidates to replace Mr. Blight and expects to announce a replacement in the near term".

Alcidion chair Rebecca Wilson thanked Mr Blight for his contribution to the company. "His ... knowledge of the health innovation industry has provided significant value over the last two decades," Ms Wilson said.

Alcidion fell 1.5 cents or 3.6 percent to 40 cents with 1.6 million shares traded.