



Biotech Daily

Thursday October 21, 2021

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH DOWN: AMPLIA UP 5%; PROTEOMICS DOWN 7%**
- * **FEDERAL \$25m FOR STEM CELL RESEARCH**
- * **HEMIDEINA RAISES \$10m FOR COCHLEAR IMPLANTS**
- * **CANN GROUP PLAN RAISES \$8.7m, TOTAL \$18.7m**
- * **DIMERIX: '1st PHASE III DMX-200 APPROVAL FOR FSGS'**
- * **NEUREN: 2nd FDA 'HOLD' ON NNZ-2591, FOR PHELAN-MCDERMID**
- * **SUDA: CHILE APPROVES TEVA ZOLPIMIST APPLICATION**
- * **AVECHO, LAMBERT TRIAL TPM-MARIJUANA FOR ARTHRITIS PAIN**
- * **PHARMAUST MANUFACTURES TRIAL BATCHES OF MONEPANTEL**
- * **CANNIM HIRES EPSILON FOR HUMMINGBUD MARIJUANA**
- * **RHYTHM 5.3m DIRECTOR OPTIONS AGM**
- * **NOVA EYE: 2.25m DIRECTOR OPTIONS AGM**
- * **TELIX RELEASES 21m VOLUNTARY ESCROW SHARES**

MARKET REPORT

The Australian stock market edged up 0.02 percent on Thursday October 21, 2021, with the ASX200 up 1.7 points to 7,415.4 points. Ten of the Biotech Daily Top 40 stocks were up, 20 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Amplia was the best, up one cent or 5.1 percent to 20.5 cents, with 5,058 shares traded. Prescient rose 2.2 percent; Avita, Cyclopharm, Dimerix, Imugene, Medical Developments, Mesoblast and Orthocell improved more than one percent; with Cynata up 0.8 percent.

Proteomics led the falls, down 6.5 cents or 6.9 percent to 87.5 cents, with 65,528 shares traded, followed by Pharmaxis down 6.4 percent to 11 cents, with two million shares traded. Osprey lost 5.3 percent; Optiscan fell 4.4 percent; Antisense, Neuren, Next Science, Oncosil and Uscom were down more than three percent; Clinuvel, Impedimed, Paradigm, Patrys and Volpara shed more than two percent; Compumedics, CSL, Nanosonics, Starpharma and Telix were down one percent or more; with Cochlear, Kazia, Pro Medicus and Resmed down by less than one percent.

FEDERAL GOVERNMENT

The Federal Government says it will provide \$25 million for stem cell research in two grant streams under the Stem Cell Therapies Mission over five years from 2021-'22.

A media release from the Minister for Health Greg Hunt said the first stream would allocate up to \$15 million to support the development of stem-cell based treatments by disease-focused, large-scale, multi-disciplinary teams.

The Government said that \$10 million in grants would “support large-scale projects that will focus on pre-clinical evaluation and screening of new treatments using human tissues made from stem cells involving large-scale multi-disciplinary teams”.

The Federal Government said the grant was part of the \$150 million Stem Cell Therapies Mission, under the \$20 billion Medical Research Future Fund.

The Government said that to be considered for a grant, the projects must have been working towards a final product or therapy, had a feasible pathway to market, and had considered the ethical, legal, and social issues associated with the treatment.

Mr Hunt said previous projects funded by the Mission were “already starting to show promising results”.

“These early, yet promising findings, show that our Mission is on track to develop and deliver safe and effective stem cell medicines and treatments that will benefit all Australians who need them,” Mr Hunt said.

The media release said applications for the grant were open and more information go to: www.grants.gov.au and on the MRFF website at www.health.gov.au/mrff.

HEMIDEINA

Hemideina says it has closed its \$10 million series A capital raise “fully subscribed” to fund staff expansion and its cochlear implant technology development program.

Hemideina said the funds would help achieve “the technical milestones needed to bring the Hera Wireless Implant System to those with severe-to-profound hearing loss”.

The company said it intended to test a benchtop prototype of the Hera Wireless Implant System for performance and safety against known industry and regulatory standards and begin pre-clinical testing of the system’s stimulation strategy, that is, the pattern of electrical impulses stimulating nerves within the cochlear to present sound, for improved audiological response, a precursor to human clinical trials.

Hemideina chief executive officer Dr Liz Williams said that Melbourne’s Henslow Capital managed the capital raise.

Last year, the company said it had won a \$660,000 Biomedtech Horizons grant for its Hera miniature wireless power and data transfer system for implantable hearing devices (BD: Jul 30, 2020).

Hemideina is a private company.

CANN GROUP

Cann Group says its share plan at 27.5 cents a share has raised \$8.69 million taking the total raised to \$18.69 million.

In July, Cann Group said it raised \$10 million in a placement at 27.5 cents and hoped to raise another \$10 million in a share plan (BD: Jul 26, 2021).

Today, the company said the funds would be used to further integrate its supply chain and expand production through its manufacturing plant near Mildura, “strengthen [its] in-house extraction, laboratory and manufacturing capabilities and expand subsidiary Satipharm.

Cann Group fell half a cent or 1.5 percent to 32.5 cents.

[DIMERIX](#)

Dimerix says it has its first approval to begin its up to 250-patient, phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) kidney disease.

In August, Dimerix said it had filed for ethics approval for the trial (BD: Aug 25, 2021).

Today, the company said that the first part of the trial would assess 70 patients to confirm efficacy and study powering for statistical measures, based on the estimated patient recruitment rate, expected by the end of 2022.

Dimerix said that if recommended to continue to part two the study, it would enrol a further 180 patients.

Today, Dimerix managing-director Dr Nina Webster told Biotech Daily that full results were expected by the end of 2023.

Dimerix was up half a cent or 1.85 percent to 27.5 cents with 3.3 million shares traded.

[NEUREN PHARMACEUTICALS](#)

Neuren says the US Food and Drug Administration has placed a “clinical hold” on its application for a trial of NNZ-2591 in children with Phelan-McDermid syndrome.

Earlier this month, Neuren said the FDA placed a clinical hold on its investigational new drug application for NNZ- 2591 for Angelman syndrome (BD: Oct 1, 2021).

The company said at that time that the FDA “specified additional clinical assessments to be added to the phase II trial protocol to enhance safety monitoring during this first trial in patients”.

Today, Neuren said the feedback received was consistent with the application of Angelman syndrome.

Neuren said a third investigational new drug application for Pitt Hopkins syndrome was currently under review by the FDA.

Neuren said it would work with the FDA Office of Neuroscience to resolve the common issues across the three planned clinical trials “as quickly as possible”.

Neuren fell 6.5 cents or 3.5 percent to \$1.785.

[SUDA PHARMACEUTICALS](#)

Suda says Chile’s Ministry of Health has approved an application from Teva Pharmaceuticals for Zolpimist for short term insomnia in adults.

Suda said Teva submitted a marketing authorization application to the Chilean authority for Zolpimist in May 2021 and received approval “significantly sooner” than the expected date of April 2022.

In 2017, Suda said that Teva would pay \$US300,000 (\$A394,002) up-front and milestones of up to \$US1,750,000 for a licence to its Zolpimist for insomnia and the licence, through Teva International GmbH, covered Brazil, Mexico and Chile, with an option to licence the product in Argentina, Israel and Australia (BD: Jul 5, 2017).

Last year, the company said that the Australian Therapeutic Goods Administration had approved Zolpimist (BD: Jul 29, 2020).

Today, Suda chief executive officer Dr Michael Baker said the Chile submission “was a combined effort by Suda and Teva”.

“Obtaining the approval indicates the calibre of Suda’s team as well as that of our partner, Teva Pharmaceuticals and is a key benefit to our partners for Zolpimist,” Dr Baker said.

Suda fell 0.1 cents or two percent to 4.8 cents with 1.6 million shares traded.

AVECHO BIOTECHNOLOGY

Avecho says with Sydney University's Lambert Initiative it will conduct a 20-patient, phase IIA trial of its topical marijuana-based cannabidiol for arthritic pain.

Avecho said that Dr Daniel Lewis would be the principal investigator and Lambert Initiative's Prof Iain McGregor would be the co-investigator for the II trial.

The company said about 20 patients with painful arthritis of the fingers or thumb would be asked to apply its tocopheryl phosphate mixture (TPM) formulation daily for four weeks.

Avecho said assessments would include pain scores, functional scores and grip strength using technologies including a dynamometer and a smartphone software application.

Avecho chief executive officer Dr Paul Gavin said the company was "focused on the development of our oral [cannabidiol] soft gel product which has just completed its phase I trial, [but] we are excited to examine further clinical applications of our formulations".

Avecho fell 0.1 cents or 5.6 percent to 1.7 cents with 15.4 million shares traded.

PHARMAUST

Pharmaust says it has manufactured a 500-gram demonstration batch of monepantel for its Covid-19 and motor neurone disease trials and was identifying trial sites.

Pharmaust chief scientific officer Dr Richard Mollard said that "despite delays incurred in manufacture due to the global Covid-19 pandemic, Pharmaust remains on-track to recommence clinical trials in humans with a newly-designed tablet, suitable for dosing regimens in people with Covid19 and motor neurone disease".

The company previously had issues with the palatability monepantel, originally marketed by Elanco for round worm in sheep (BD: Jul 11, 2016; May 28, 2018).

Pharmaust fell 0.1 cents or one percent to 9.6 cents with 1.8 million shares traded.

EPSILON HEALTHCARE

Epsilon says it has been hired by Sydney's Cannim Australia to manufacture its Hummingbud dried marijuana flower products at its Southport Queensland plant.

Epsilon said it had a two-year contract with Cannim which grows marijuana in Australian and Jamaica, and there were no minimum orders but expected "to see ongoing purchase orders from Cannim and its partners over the course of the collaboration".

The company said the Cannim Hummingbud marijuana was "available for prescription now, and can be prescribed by Tetra Health, Epsilon's wholly-owned clinic network".

Epsilon was up 1.5 cents or 12 percent to 14 cents with 3.2 million shares traded.

RHYTHM BIOSCIENCES

Rhythm says its annual general meeting will vote to issue a total of 5,300,000 options to six directors exercisable at \$1.80 by July 31, 2024.

Rhythm said shareholders would vote to issue 2,000,000 options each to chief executive officer Glenn Gilbert and chair Otto Buttula, 500,000 options each to directors Dr Trevor Lockett and David White, and 150,000 options each to directors Louis Panaccio and Eduardo Vom.

The company said shareholders will vote on the remuneration report, the re-election of director Dr Lockett, the approval of a 10 percent placement facility and the ratification of the prior issue of shares and options.

The meeting will be held virtually on November 24, 2021, at 11am (AEDT).

Rhythm was up 14 cents or 11.7 percent to \$1.34.

[NOVA EYE](#)

Nova Eye says its annual general meeting will vote to issue a total of 2,250,000 options to five directors.

Nova Eye said shareholders would vote to issue 700,000 options to managing director Tom Spurling exercisable at 53 cents a share.

The company said it would issue 500,000 options to chair Victor Previn and 350,000 shares each to directors Alex Sundich, Mike Southard and Rahmon Coupe, exercisable at a 135 percent of the 7-day volume weighted average price to the meeting and expiring on November 23, 2024.

Nova Eye said shareholders would vote on the remuneration report, the re-election of directors Mr Sundich and Mr Southard, refresh the employee incentive plan and on amendments to the company constitution.

The virtual meeting will be on November 24, 2021 at 11.30am (ACDT).

Nova Eye was untraded at 41 cents.

[TELIX PHARMACEUTICALS](#)

Telix says 20,947,181 shares will be released from voluntary escrow on November 5, 2021.

Telix said following the release there would be no shares in ASX escrow and according to its most recent filing, Telix had 285,072,908 shares on offer.

Telix fell eight cents or 1.4 percent to \$5.70 with 298,657 shares traded.