



Biotech Daily

Thursday March 3, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX UP, BIOTECH DOWN: MICRO-X UP 6%; PARADIGM DOWN 7%**
- * **REDHILL ORAL RHB-107 'HIGHLY PROMISING' FOR COVID-19**
- * **WOKE: MONASH TO DEVELOP 'HIGH DOSE PSILOCYBIN'**
- * **AVITA, PREMIER RECELL SPRAY-ON-SKIN SUPPLY DEAL**
- * **PALLA LIQUIDATION: 'NOTHING FOR INVESTORS'**
- * **TRUSCREEN: ZIMBABWE ORDERS 11k CERVICAL CANCER SENSORS**
- * **EMYRIA READY FOR PHASE I EMD-RX5 O-T-C MARIJUANA TRIAL**
- * **INCANNEX: MONASH \$800k PSYCHEDELIC, VIRTUAL REALITY FOR ANXIETY**
- * **CHAIR PAUL HOPPER INCREASES, DILUTED TO 21% OF CHIMERIC**
- * **OPTHEA APPOINTS DR JOEL NAOR CMO**
- * **NEUROTECH APPOINTS DR ALEXANDRA ANDREWS CEO, ON \$250k PA**
- * **ANTERIS APPOINTS DR KARL POON MEDICAL ADVISER**

MARKET REPORT

The Australian stock market was up 0.49 percent on Thursday March 3, 2022, with the ASX200 up 34.7 points to 7,151.4 points. Eleven of the Biotech Daily Top 40 stocks were up, 19 fell, seven traded unchanged and three were untraded. All three Big Caps fell.

Micro-X was the best, up one cent or 6.1 percent to 17.5 cents, with 307,885 shares traded. Avita and Immutep climbed more than five percent; Atomo was up four percent; Genetic Signatures improved 3.4 percent; Actinogen rose 2.1 percent; with Clinuvel, Cyclopharm, Emvision, Kazia and Universal Biosensors up by more than one percent.

Paradigm led the falls, down eight cents or 6.8 percent to \$1.10, with 889,858 shares traded. Polynovo lost 6.4 percent; Medical Developments and Patrys fell more than five percent; Antisense, Opthea, Orthocell, Proteomics and Telix were down three percent or more; Alcidion, Cochlear, Oncosil and Prescient shed more than two percent; Compumedics, CSL, Next Science, Resmed and Starpharma lost one percent or more; with Mesoblast, Nanosonics, Neuren and Pro Medicus down by less than one percent.

REDHILL BIOPHARMA

Redhill says its 61-patient phase II trial of once-daily oral RHB-107, or upamostat, in non-hospitalized symptomatic Covid-19 patients showed “highly promising efficacy”.

Redhill said the trial was conducted mainly in the US with one patient in South Africa.

The company said that “although not powered for efficacy assessment” none of the 41 patients treated with RHB-107 were hospitalized, compared to three of 20 patients in the placebo arm requiring hospitalization providing a “nominal p-value = 0.0317”.

Redhill said the study showed a reduction in reported new severe Covid-19 symptoms, with one of 41 patients on RHB-107, compared to four of 20 in the placebo-controlled arm experiencing new COVID-19 related severe symptoms ($p = 0.036$).

The company said that the study met its primary outcome measure, showing a favorable safety and tolerability profile for RHB-107.

Redhill medical director Dr Terry Plasse said the efficacy results were “very promising ... despite a small overall sample size”.

“Coupling the efficacy results with successfully meeting the primary endpoint of good safety and tolerability and convenient once-daily dosing, positions oral RHB-107 as a potential highly beneficial treatment for Covid-19 outpatients early in the course of disease in order to reduce symptom severity and prevent disease progression and hospitalization,” Dr Plasse said.

“Given the limitations of current options for early treatment of Covid-19, we are excited to progress the development of RHB-107, subject to additional discussions with regulatory authorities,” said Dr Plasse.

“Equally important is our expectation that RHB-107, with its human cell factor targeting, would maintain its action irrespective of spike protein mutations, thus likely making it a highly desirable variant-agnostic potential treatment option,” Dr Plasse said.

Redhill said the next steps for the study would follow data submission and discussion with regulators.

In 2010, Israel's Redhill bought Myoconda (RHB-104), Heliconda (RHB-105) and Picoconda (RHB-106) from Sydney's Giaconda (BD: Aug 17, 2010).

On the Nasdaq, Redhill was up four US cents or 2.03 percent to \$US2.01 (\$A2.76) with 588,761 shares traded.

WOKE PHARMACEUTICALS

Woke says Monash University's Medicines Manufacturing Innovation Centre will develop a 'high dose' 25mg psilocybin tablet WP002 for treatment-resistant depression.

Last year, Woke said it would work with Monash University to develop the WP001 low dose 1.0mg psilocybin capsule for moderate depression (BD: Oct 19, 2021).

Today, the company said that the Centre would engage additional in-house expertise to support the work to begin two phase IIb trials in 2022.

Woke said that psilocybin was “a naturally occurring psychedelic pro-drug produced by more than 200 fungi [and] when used at a sub-hallucinogenic dose, or at a higher dose in combination with psychotherapy, it has been shown to be effective for the treatment of patients with depression and other mental health disorders”.

The company said it planned to begin a 100-patient, randomized, controlled, phase IIb trial of WP002-assisted psychotherapy for treatment-resistant depression late this year, at multiple Australian sites.

Woke said that the primary endpoint would be a depression rating scale, with secondary endpoints evaluating neuro-physiological and physiological measures.

Woke is a private company.

AVITA MEDICAL

Avita says it has a US supply agreement with the Charlotte, North Carolina-based group purchasing organization Premier Inc for its Recell spray-on skin.

Avita said the agreement would allow Premier's more than 4,400 member hospitals to buy Recell at unspecified "special pricing and terms pre-negotiated by Premier".

Avita chief executive officer Dr Mike Perry said that Premier was "a trusted partner among their alliance of members and ... [we are] committed to building on that trust by providing quality products to help ensure the best patient care possible".

Dr Perry said the agreement was "a major milestone ... as it puts our innovative Recell system into the hands of those caring for burn patients across the US," Dr Perry said.

Avita was up 16 cents or 5.25 percent to \$3.21 with 918,578 shares traded.

PALLA PHARMA (FORMERLY TASMANIAN POPPY INDUSTRIES ENTERPRISES)

The administrators of Palla say they "do not anticipate a return to shareholders" following the liquidation of the company.

In February, Korda Mentha administrators said that Palla had been unable to attract a buyer, and that they intended to 'wind-down' Australian operations (BD: Feb 16, 2022).

Today, Korda Mentha administrators Craig Shepard and Bryan Webster said they expected that "priority employee creditors" would receive 100 percent, with unsecured creditors to receive between six and 84 percent of what they were owed by the company.

The administrators said that the second meeting of creditors on March 9, 2022 would be asked to end the administration or wind-up the company.

According to Commsec, Palla has traded as high as \$3.77 in 2015 and as low as 20 cents in December 2021, with major investors including Australian Ethical and Thorney.

Palla last traded at 29.5 cents.

TRUSCREEN GROUP

Truscreen says the Zimbabwe National AIDS Council has ordered 10,800 units of its single use cervical cancer sensors, following the conclusion of a pilot program.

Truscreen said the program screened 500 women in seven clinics over one month, and following the program it received a contract for 10,800 single use cervical cancer sensors.

The company said it had issued a total of 2,250,000 options to seven of its distributors, exercisable at 10 New Zealand cents by September 7, 2024.

Truscreen said the measure was intended to incentivise distributors towards further sales. In New Zealand, Truscreen was up 0.7 cents or 11.1 percent to seven cents.

EMYRIA

Emyria says it has approval for a 12-person, phase I trial of the safety and bio-availability of its EMD-RX5 marijuana capsules compared to Epidyolex.

In 2020, the Australian Therapeutic Goods Administration said it would down-schedule low-dose cannabidiol (CBD) from a schedule 4 to a schedule 3 drug, allowing for over-the-counter sales pharmacy sales up to 150mg/day (BD: Dec 15, 2020)

Today, the company said the phase I trial of its EMD-RX5 capsules for symptoms of psychological distress was expected to begin imminently at Adelaide's Cmax Clinical Research Facility, and compare it with Epidyolex "the only CBD-only medicine formally registered with the TGA and [US Food and Drug Administration]".

Emyria was up one cent or 3.1 percent to 33 cents.

INCANNEX HEALTHCARE

Incannex says it will pay Monash University \$800,000 plus royalties to develop virtual reality-enhanced psychedelic therapies for anxiety disorders.

Incannex said that on execution of the perpetual agreement, it would pay \$300,000 to Monash, followed by \$250,000 for research agreements for a second and third trial of the technology, as well as a royalty of 7.5 percent of net sales on commercialization.

Last year, Incannex said it would begin a 72-patient, phase IIa trial of psilocybin with psychotherapy for generalized anxiety disorder, with Monash University approving the triple-blind, placebo-controlled trial to be led by Monash head of clinical psychedelic research Dr Paul Liknaitzky, expected to begin in 2022 (BD: Oct 28, 2021).

Today, the company said it was in discussions with the University towards a research agreement for the first of the two new trials, to assess the optimal dose, safety, and tolerability of the combination treatment method.

Incannex said that the virtual reality treatment involved providing triggering stimuli in a graded and controlled manner, alongside specialized clinical support and the administration of a psychedelic drugs.

The company said it believed such an approach may allow for the “development of new skills, changes in mental and biological responses” in confronting triggering stimuli, as well as “reductions in pathological symptoms and behaviours”.

Incannex said it would fund the research and development project.

Incannex fell half a cent or 0.7 percent to 72.5 cents with 8.3 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric chair Paul Hopper says his holding has increased but been diluted from 78,152,778 shares (23.29%) to 81,093,954 shares (21.4%).

Mr Hopper said that he bought 2,941,176 shares at 17 cents each in the February institutional placement that raised \$7.37 million (BD: Feb 23, 2022).

In February the company said it hoped to raise \$18.1 million in the one-for-3.15 rights offer, with the retail offer expected to close on March 11, 2022.

Chimeric was up half a cent or 3.3 percent to 15.5 cents.

OPTHEA

Opthea says it has appointed Dr Joel Naor as its chief medical officer, effective from March 1, 2022.

Opthea said Dr Naor had more than 20 years' experience in the clinical development of retinal treatments, most recently as head of clinical science and development operations at the Palo Alto, California-based Kodiak Sciences Inc.

The company said that Dr Naor previously was chief medical officer for the Palo Alto, California-based Macusight Inc until it was acquired by the Emeryville, California-based Santen Inc, where he was the head of medical affairs.

Opthea said Dr Naor held a Doctor of Medicine from Israel's Technion, a Master of Science from the University of Toronto and a Masters of Business Administration from the Vancouver, British Columbia-based Simon Fraser University.

Opthea fell three cents or three percent to 97 cents with 2.1 million shares traded.

NEUROTECH INTERNATIONAL

Neurotech says it has appointed Dr Alexandra Andrews as its chief executive officer, effective from March 8, 2022, beginning on \$250,000 a year, plus options.

Neurotech said that Dr Andrews would receive 5,000,000 options exercisable at eight cents each within two years vesting in 12 months, 5,000,000 options exercisable at 12 cents each within two years vesting in 18 months and 5,000,000 options exercisable at 16 cents each within two years vesting in 24 months.

The company said that Dr Andrews was previously Neuroscientific Biopharmaceuticals director of operations and had for the Nedlands, Western Australia-based Linear Clinical Research.

Neurotech chair Brian Leedman was formerly the chair of Neuroscientific.

The company said that Dr Andrews held a Doctor of Philosophy from the University of Western Australia.

Neurotech fell 0.1 cents or 2.2 percent to 4.4 cents.

ANTERIS TECHNOLOGIES

Anteris says it has appointed Dr Karl Poon to its medical advisory board.

Anteris said Dr Poon was an interventional cardiologist with “experience in structural heart disease interventions”, including trans-catheter aortic valve implantations.

Anteris was unchanged at \$19.00.