



Biotech Daily

Tuesday May 31, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NOVA EYE UP 5%; NEXT SCIENCE DOWN 7%**
- * **LIVING CELL RAISES \$1.3m FOR NTCELL PARKINSON'S TRIAL**
- * **DIMERIX RECRUITS 1st PHASE III DMX-200 FSGS PATIENT**
- * **ANTERIS COMPLETES 2nd DURAVR TRIAL COHORT**
- * **MESOBLAST REMESTEMCEL-L, DEXAMETHASONE ARDS TRIAL**
- * **CLARITY PAYS \$348k, 400k SHARES FOR 'NANOBODY PLATFORM'**
- * **MEDLAB STARTS NANOCELLE NASAL COVID-19 VACCINE**
- * **EMYRIA: \$450k FOR UWA TO EXPAND MDMA ANALOG PROGRAM**
- * **RESAPP REQUESTS 'PFIZER ACQUISITION EXPERT REPORT' HALT**
- * **AUSTRALIAN ETHICAL TAKES 12.3% OF SOMNOMED**
- * **CARL CHARALAMBOUS TAKES 9.8% OF EXOPHARM**
- * **STEVE SARGENT TO REPLACE NANOSONICS CHAIR MAURIE STANG**

MARKET REPORT

The Australian stock market fell 1.03 percent on Tuesday May 31, 2022, with the ASX200 down 75.4 points to 7,211.2 points. Seven of the Biotech Daily Top 40 stocks were up, 21 fell, 11 traded unchanged and one was untraded. All three Big Caps fell.

Nova Eye was the best, up one cent or five percent to 21 cents, with 50,000 shares traded. Immutep and Patrys climbed more than two percent; Genetic Signatures was up 1.2 percent; with Neuren, Proteomics and Telix up by more than one percent.

Next Science led the falls, down six cents or 7.1 percent to 78 cents, with 154,411 shares traded. Actinogen lost 6.7 percent; Micro-X and Polynovo shed more than five percent; Emvision fell 4.7 percent; Alcidion, Pharmaxis, Resonance, Starpharma and Universal Biosensors were down more than three percent; Avita, Clinuvel and Prescient shed more than two percent; Atomo, Paradigm, Uscom and Volpara were down more than one percent; with Cochlear, CSL, Mesoblast, Nanosonics, Opthea, Pro Medicus and Resmed down by less than one percent.

LIVING CELL TECHNOLOGIES

Living Cell says it has raised \$1.285 million in a placement at 0.5 cents a share to support its trial of NTCCell encapsulated pig brain cells for Parkinson's disease.

Living Cell said it had binding commitments from clients of Melbourne's Alignment Capital Pty Ltd to raise \$1.285 million in its placement, with Alignment receiving a cash fee of six percent on the total amount raised.

Living Cell was up 0.1 cents or 20 percent to 0.6 cents with 12.6 million shares traded.

DIMERIX

Dimerix says it has recruited the first of 286 patients in its phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) kidney disease.

Dimerix said the trial, titled 'Angiotensin II Type 1 Receptor & Chemokine Receptor 2 Targets for Inflammatory Nephrosis' (Action3), was a pivotal, phase III, multi-center, randomized, double-blind, placebo-controlled study of the efficacy and safety of its DMX-200 in patients with FSGS kidney disease.

The company said that the trial had two interim analysis points designed to capture evidence of proteinuria and kidney function to generate sufficient evidence to support accelerated marketing approval.

Dimerix said the first part of the trial would conclude once 72 patients completed 35 weeks of treatment, expected in the first half of 2023, with the second part continuing after patients showed a minimum of six weeks stable dosing of an angiotensin receptor blocker prior to randomization and dosing with DMX-200 (120mg capsule twice daily) or placebo.

Dimerix managing-director Dr Nina Webster said that first dosing in the trial would commence "imminently".

Dr Webster said that "the potential commercial opportunity for Dimerix in this space is very material, given over \$US55 billion (\$A77 billion) is estimated to have been spent on end stage renal failure in the US Healthcare system alone in 2021 and the US Government has issued incentives for physicians to delay patient progression to renal failure as a priority".

"If successful, our drug candidate could make a huge difference globally to patients with this illness and given we have orphan drug designation status, a potential fast track to commercialization is available, highlighting the compelling nature of this trial for the company," Dr Webster said.

Dimerix was unchanged at 14.5 cents.

ANTERIS TECHNOLOGIES

Anteris says it has completed treatment of its eight more patients in its first-in-human study of its Duravr trans-catheter heart valve at Georgia's Tbilisi Heart and Vascular Clinic.

Anteris said that the data from the latest cohort would be reviewed at the 30-day follow-up, the "key inflexion point for indicating ongoing valve performance".

In January, the company said 30-day follow up results of five patients in its initial 10-patient, first-in-human study of Duravr trans-catheter heart valve met or exceeded its study objectives (BD: Jan 24, 2022).

Anteris fell 70 cents or 3.2 percent to \$21.30.

MESOBLAST

Mesoblast says that a 77 percent reduced mortality in Covid-19 patients under 65 years receiving remestemcel-L with dexamethasone, has led to a pivotal trial.

Mesoblast said an exploratory analysis in 73 patients under the age of 65 years who also received dexamethasone as part of their standard-of-care, with its remestemcel-L had reduced 90-day mortality by 77 percent compared to controls (14 percent compared to 48 percent mortality ($p = 0.0037$)).

The company said that early survival outcomes in the remestemcel-L group relative to controls were maintained at later timepoints in those under the age of 65 years, with a 42 percent reduction in mortality at 12 months and with continued observed synergy with dexamethasone ($p < 0.05$).

In 2020 Mesoblast said the data safety monitoring board recommended halting the randomized, controlled trial of remestemcel-L in ventilator-dependent patients with moderate to severe Covid-19-related acute respiratory distress syndrome (Ards), after a third interim analysis of 180 patients found the trial was “not likely to meet the 30-day mortality reduction endpoint at the planned 300 patient enrolment” (BD: Dec 18, 2020).

Today, the company said that through the initial 90 days, remestemcel-L reduced mortality by 48 percent compared to controls in a pre-specified analysis of 123 patients below 65 years ($p = 0.038$), but not in 97 patients over age 65 years, as previously reported.

Mesoblast said the phase II/III trial was randomized to standard-of-care alone or standard-of-care with two doses of remestemcel-L 2,000,000 cells/kg three to five days apart; and the two-dose regimen was the same as in the compassionate use program where 11 of 12 patients were younger than 65 years and 75 percent came off ventilatory support.

Mesoblast said that for steroid-refractory acute graft-versus-host disease (GvHD), remestemcel-L was given at an eight-dose regimen of 2,000,000 cells/kg over four weeks.

The company said that the extended dosing regimen in GvHD, which was also a severe inflammatory condition, provided “a rationale for exploring an extended course of remestemcel-L in older patients with Covid Ards who have higher levels of inflammation”.

Mesoblast said that Ards was a “major cause of mortality for Covid-19 patients who [were] immune-compromised, unvaccinated, or with comorbidities, as well as those with seasonal influenza and other pathogens”.

The company said it was working with investigators from an unnamed US clinical trial network focused on acute lung injury affiliated with Vanderbilt University Medical Center to design and implement a pivotal trial of remestemcel-L to reduce mortality in high-risk patients with Ards.

Mesoblast fell half a cent or 0.5 percent to 98.5 cents.

CLARITY PHARMACEUTICALS

Clarity says it has acquired a “nano-body platform” from Dr Kurt Gehlsen for 400,000 shares, with a strike price of \$1.40, and up to \$US250,000 (\$A348,034) in cash.

Clarity said nano-bodies were “targeting molecules which can be engineered to bind to a wide range of cancers ... [and] by only targeting cancer cells and not healthy cells, this approach aims to kill cancer cells while limiting the side effects elsewhere in the body”.

The company said the nano-body platform included the intellectual property, a provisional patent and know-how and would add “new opportunities to Clarity’s targeted copper [diagnostics and therapeutic] discovery pipeline”.

Clarity said that the agreement was subject to provisions relating to development milestones for new products and Dr Gehlsen would join the company as a consultant.

Clarity was up three cents or 6.5 percent to 49 cents.

MEDLAB CLINICAL

Medlab says laboratory work has begun at Macquarie University's Woolcock Institute for its Nanocelle nasal nucleic acid Covid-19 vaccine program.

Medlab said that in December 2021, it received a non-repayable New South Wales State Government \$100,000 grant to collaborate with Sydney's University of New South Wales and Macquarie University to develop a nasal nano-particle Covid-19 vaccine using nucleic acid.

The company said an interim report from the Woolcock Institute stated that all nanoparticle loading was performed at Medlab, blank nanocelles and insulin nanocelles were assessed and characterized for their physiochemical properties, and that its Nanocelle delivery platform technology was the appropriate particle size and charge and was reported with an insulin active pharmaceutical ingredient nanoparticle.

Medlab said it was awaiting confirmation from the University of New South Wales that the nucleic acid was ready for deployment into the Nanocelle environment for "advanced program readouts around November this year".

Medlab fell 0.1 cents or 1.3 percent to 7.6 cents with 1.4 million shares traded.

EMYRIA

Emyria says it provide a further \$450,000 to the University of Western Australia to expand its 3,4 methylene-dioxy-meth-amphetamine (MDMA) analog program.

Emyria said the funding followed from its initial agreement with the Perth-based University and on completion, it would hold an "exclusive option to licence and commercialize the most promising compounds".

University of Western Australia medicinal chemist Prof Matt Piggott said the collaboration had "identified hits for new disease indications as a result of the screening program".

"We are excited at the prospect of translating these findings to the clinic, where they can improve quality of life for patients with unmet needs," Prof Piggott said.

Emyria was up half a cent or 1.85 percent to 27.5 cents.

RESAPP HEALTH

Resapp has requested a trading halt pending an update on the proposed acquisition by Pfizer "while the company considers the draft independent expert report".

In April, Resapp said Pfizer Australia would offer 11.5 cents a share to buy the company, valuing it at \$100 million (BD: Apr 11, 2022).

Trading will resume on 2 June 2022, or on an earlier announcement.

Resapp last traded at 11 cents.

SOMNOMED

Australian Ethical Investment says it has increased its substantial share-holding in Somnomed from 6,579,750 shares (10.48%) to 10,164,745 shares (12.28%).

The Sydney-based Australian Ethical said it bought and sold shares between July 23, 2019 and May 27, 2022, with the most recent purchase on May 27 of 1,000,000 shares for \$1,452,392 or \$1.45 a share.

Somnomed fell two cents or 1.3 percent to \$1.50.

EXOPHARM

Carl Charalambous says he has increased his substantial holdings in Exopharm from 13,786,272 shares (8.77%) to 15,468,243 shares (9.84%).

The Brisbane-based Mr Charalambous said he bought shares between March 25 and May 30, 2022, with the single largest purchase on April 27 of 330,111 shares for \$65,363 or 19.8 cents a share.

Exopharm was up one cent or 6.45 percent to 16.5 cents.

NANOSONICS

Nanosonics says Steve Sargent will replace Maurie Stang as chair, effective from July 1, 2022, with Mr Stang continuing as deputy chair until he retires in November.

Nanosonics said that Mr Stang was a founder of the company, joining the board in 2000 and chair since 2007.

The company said that Mr Stang would continue as chair of the innovation and infection control advisory committee and as an informal advisory to the company.

Nanosonics said Mr Sargent had been a non-executive director since July 2016 and had more than 22 years of experience in healthcare, energy and financial services, working at General Electric as an executive, and was currently a director of Origin Energy, Ramsay Healthcare and OFX.

Nanosonics fell three cents or 0.8 percent to \$3.83 with 692,839 shares traded.