# Biotech Daily

Thursday October 26, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH DOWN: PATRYS UP 14%; CYNATA DOWN 11%**

*** ANTERIS RAISES $40m; 'POSITIVE' DURAVR VALVE TRIAL RESULTS**

*** AUSCANN TAKES $1.25m NOTES; RENEWS $8m EURO CANNABIS LOAN**

*** MICRO-X ROVER, ROVER PLUS WIN CE MARK**

*** IMUGENE DOSES 1st PATIENT IN CD19 PHASE I TRIAL**

*** CLARITY, PSI SITE SEARCH FOR PHASE III PROSTATE IMAGING TRIAL**

*** PARADICE INCREASES, DILUTED TO 7.3% OF IMPEDIMED**

*** VISIONEERING 'LACK OF QUORUM' POSTPONES EGM**

*** CANN-OPPOSED CHRISTOPHER FEDDERSEN WINS 28% OF AGM**

*** MGC 97% OKAYS 1,000-TO-1 CONSOLIDATION**

*** RACE: 580k DIRECTOR OPTIONS AGM**

## MARKET REPORT

The Australian stock market fell 0.61 percent on Thursday October 26, 2023, with the ASX200 down 42.0 points to 6,812.3 points. Eleven of the Biotech Daily Top 40 stocks were up, 21 fell, seven traded unchanged and one was untraded.

Patrys was the best, up 0.1 cents or 14.3 percent to 0.8 cents, with 2.1 million shares traded. Actinogen and Alcidion climbed five percent or more; Genetic Signatures and Micro-X improved four percent or more; Compumedics was up 3.2 percent; Proteomics rose 2.3 percent; Antisense, Mesoblast, Orthocell and Resonance were up more than one percent; with Resmed up by 0.4 percent.

Cynata led the falls, down 1.5 cents or 11.1 percent to 12 cents, with 9,982 shares traded. Next Science lost 8.3 percent; Neuren was down 7.3 percent; Imugene fell 4.55 percent; Emvision, Immutep, Prescient, SDI, Starpharma and Telix were down more than three percent; 4D Medical, Avita, Nova Eye and Volpara shed more than two percent; Kazia, Medical Developments, Paradigm and Pro Medicus were down more than one percent; with Clinuvel, Cochlear, CSL, Nanosonics and Polynovo down by less than one percent.

## ANTERIS TECHNOLOGIES

Anteris says it has raised $40 million through a placement at $20.00 a share and has "positive early results" from a 15-patient trial of its Duravr aortic valve replacement.

Anteris said the placement would settle in two tranches of $33.8 million on November 1 and $6.2 million on November 14, 2023, and Evolution Capital had managed the raise.

The company said the funds would be used for a US Food and Drug Administration pivotal trial of its Duravr transcatheter heart valve for sever aortic stenosis, continued "valve-in-valve" trials and general working capital expenses.

Separately, Anteris said it had "unprecedented positive hemodynamic results" from its US early feasibility study of its Duravr heart valve, including a mean effective orifice area at discharge of 2.36cm$^2$, A mean pressure gradient of 7.8mm/Hg (millimetres of mercury) and a doppler velocity index of 0.71 V (volts).

In August, Anteris said it had begun enrolment in a US "early feasibility" study of its Duravr transcatheter heart valve, with the first group of severe aortic stenosis patients treated having intra-operatively, post implant effective orifice area (EOA) of 2.2cm$^2$, and average mean gradients of 4mm/Hg (BD: Aug 9, 2023).

Today, the company said the interim analysis showed that 14 of the 15 patients had no paravalvular leaks post-implantation, no strokes, no myocardial infarctions or life-threatening bleeds and no deaths at discharge.

Anteris said other primary and secondary endpoints included safety and efficacy assessments such as success of implantation at the anatomically accurate position.

Anteris said it expected to publish the 30-day results in support of its FDA pivotal trial application by the end of 2023.

Anteris chief medical officer Dr Chris Meduri said while the company awaited 30-day haemodynamic and all-cause mortality results "the discharge timepoint is a key early indicator of how interventional cardiologists judge the success of a [transcatheter aortic valve replacement] implantation".

"The unparalleled haemodynamic results show that our single-piece biomimetic product, Duravr, can restore healthy normal pre-disease blood flow in acutely symptomatic patients," Dr Meduri said. "This data surpasses what is seen with commercial bio-prosthetic valves available to date."

Anteris managing-director Wayne Paterson said the study "was a critically important milestone … [and] surpass all expectations".

Anteris fell 15 cents or 0.7 percent to $20.50.

## AUSCANN GROUP HOLDINGS

Auscann says it has subscribed for $1,250,000 in convertible notes and refreshed the documentation of its European Cannabis Corporation $8,050,000 loan.

Auscann said that the 1,250,000 $1.00 notes were convertible at one cent a share, or a 20 percent discount to European Cannabis Corporation or its subsidiary Hapa Pharma BV's next capital raise price, 12.5 percent per month compounding monthly.

The company said that the $8,050,000 loan had an interest rate of 10 percent a year to be repaid by June 30, 2024.

Auscann said the European Cannabis Corporation and its subsidiary would use the fundings for capital expenditure and general working capital, as well as the commercialization of medicinal marijuana in Germany and Europe.

Biotech Daily understands that the loan was already in place and the company had refreshed the documentation and security deeds.

Auscann was in a suspension at four cents.

## MICRO-X

Micro-X says it has Conformité Européenne mark to sell its Rover and Rover plus mobile x-ray systems for medical use.

Micro-X said the issue of the mark under the European Medical Device Regulation meant the product had been assessed and deemed to meet European safety, health and environment protection requirements, which was mandatory to legally market and sell medical devices in the European Economic Area.

The company said receiving the mark for the Rover was “a significant achievement” and enabled opportunities in the 32 countries in the European Economic Area as well as the UK and Switzerland.

Micro-X said it already had several Europe-based distributors and dealerships and expected to sign additional dealers in the short term as these have been awaiting approval for sale.

The company said that the European Union comprised about 500 million people and an addressable mobile x-ray market of about $80 million a year.

Micro-X chief executive officer Kingsley Hall said “receiving this CE marking opens a huge market opportunity for our mobile [digital radiography] range in Europe, where we have distributors and direct sales staff already in place”.

“The team are now ramping up discussions with potential customers that were awaiting this certification with a view to securing near term sales,” Mr Hall said.

“With our proprietary Micro-X Rover now able to be sold commercially in all key global markets, we look forward to executing our strategy to grow commercial sales and bring our technology to the world,” Mr Hall.

Micro-X was up half a cent or four percent to 13 cents.

## IMUGENE

Imugene says it has dosed the first of up-to 52 patients in its US phase I trial of its CD19 oncolytic virus therapy Oncarlytics with blinatumomab for solid tumors.

Imugene said the trial of adult patients with advanced or metastatic solid tumors, aimed to evaluate the safety and efficacy of both intra-tumoral injection and intravenous infusion of Oncarlytics alone and in combination with blinatumomab.

The company said when combined with the CD19 bispecific monoclonal antibody blinatumomab, or Blincyto, Oncarlytics had “the potential to target and eradicate solid tumors that otherwise cannot be treated with Blincyto therapy alone”.

The company said the first patient in the dose escalation trial was an ovarian cancer patient dosed at the Duarte, California-based City of Hope’s Comprehensive Cancer Center.

Imugene chief executive officer Leslie Chong said: “This is a milestone we’ve been eagerly anticipating, given the encouraging signs we have seen from the pre-clinical work performed to date”.

“We believe Oncarlytics may provide a new solution for clinicians treating solid tumors that have previously been untreatable using CD19-targeting biological drugs, and we hope our technology can bring much needed relief to patients in want of new treatments,” Ms Chong said.

“I am particularly pleased with the speed at which our team drove the pre-clinical data from a novel therapy, into a phase I trial in a little over two years, and reflects the enthusiasm for this promising therapy, from all involved,” Ms Chong said.

Imugene fell 0.2 cents or 4.55 percent to 4.2 cents with 29.7 million shares traded.

## CLARITY PHARMACEUTICALS

Clarity says it has appointed the Zug, Switzerland-based PSI CRO AG to identify sites for its 383-patient, phase III trial of 64-copper-Sar-bis-PSMA for prostate cancer.

Clarity said the PSI contract research organization would conduct the single-arm, open-label, non-randomized trial to assess the diagnostic performance of copper-64 sarcophagene-bis-prostate specific membrane antigen (Sar-bis-PSMA) with positron emission tomography in detecting prostate cancer within lymph nodes in the pelvic region.

The company said evaluation would take place on the day of administration and 24 hours post-administration, and it expected to begin recruitment by the end of 2023.

Clarity did not disclose the commercial terms of the agreement with PSI.

PSI operations director Rhonda Critchlow said that using their database of more than 400 radio-pharmaceutical sites PSI would identify sites with the best resources for the trial.

Clarity chair Dr Alan Taylor said “with recent positive and valuable guidance from the US [Food and Drug Administration] in relation to our copper-64-Sar-bis-PSMA program, we look forward to commencing recruitment into the Clarify trial shortly and to gathering more data on this next-generation product to confirm the compelling preclinical and clinical trial results to date”.

“The positive results from our completed ‘Propeller’ trial showed that copper-64-Sar-bis-PSMA is safe and its uptake in PSMA-expressing cancer lesions was significantly higher compared to an approved standard-of-care PSMA imaging agent for prostate cancer in Australia and the US,” Dr Taylor said.

“This may enable diagnosis of additional and smaller lesions, which we observed in our ‘Propeller’ trial, and we are eager to investigate the further benefits of delayed imaging, particularly in this patient population, a characteristic not available to the first generation of PSMA diagnostic agents,” Dr Taylor said.

“Furthermore, we believe that the additional shelf-life of up-to 48 hours will not only allow clinics greater flexibility in scheduling of the scans, but also improve patients’ access to care in clinics and geographic areas where the short half-life of current PSMA [positron emission tomography] tracers restrict the use of radio-pharmaceuticals,” Dr Taylor said.

Clarity fell two cents or two percent to $1.00.

## IMPEDIMED

Paradice Investment Management says it has increased and been diluted in Impedimed from 144,301,807 shares (8.358%) to 147,906,911 shares (7.319%).

The Sydney-based Paradice said it bought and sold shares between February 11, 2022 and October 23, 2023, buying 39,355,230 shares for $5,667,446, or 14.4 cents a share and selling 35,750,126 shares for $3,738,967, or 10.5 cents a share.

In May and June, Impedimed said its placement and share purchase plan at 13 cents a share raised $30 million (BD: May 19, Jun 21, 2023).

Impedimed was unchanged at 12.5 cents.

## VISIONEERING TECHNOLOGIES

Visioneering says it has postponed today’s extraordinary general meeting until next Thursday, November 2, 2023 “due to the lack of the required quorum”.

The extraordinary general meeting resolutions include the variation of the conversion price of convertible notes and the issue of placement shares to directors and the issue of 425,000 restricted stock units to Dr Juan Carlos Aragón.

Visioneering fell three cents or 11.5 percent to 23 cents.

## CANN GROUP

Cann Group says all resolutions were passed at its annual meeting except the election of Christopher Feddersen as a director which faced 71.88 percent opposition.
Cann Group said 16,966,960 votes (28.12%) were in favor of electing Mr Feddersen as a director, with 43,369,810 votes (71.88%) opposed the election.
In its notice of meeting, the Cann Group board said it opposed the election of Mr Feddersen who had nominated himself for the position.
The company said the employee share gift plan had 16.48 percent opposition with the 10 percent placement capacity opposed by 14.77 percent of votes.
Cann Group said all other resolutions were passed with more than 90 percent of votes in favor.
According to its most recent filing, Cann Group had 426,004,085 shares on offer, meaning that the votes against Mr Feddersen amounted to 10.18 percent of the company, sufficient to requisition extraordinary general meetings.
Cann Group was unchanged at 11.5 cents.

## MGC PHARMACEUTICALS

MGC says 96.6 percent of extraordinary general meeting votes supported its 1,000-to-one consolidation.
Last month, MGC said its extraordinary general meeting would vote for a 1,000-to-one consolidation and to issue 31,000,000 post-consolidation shares (BD: Sep 26, 2023).
Yesterday, the company said the consolidation would have a record date of October 31, with normal post-consolidation trading to begin on November 8, 2023.
MGC said that its current 4,427,968,187 shares on issue would become 4,427,969 shares and today's closing price of 0.02 cents would become 20 cents a share.
The company said that 96.7 percent of votes supported the share issue.
MGC was unchanged at 0.02 cents with 1.6 million shares traded.

## RACE ONCOLOGY

Race says its annual general meeting will vote to issue 139,516 options to chair Mary Harney and 440,019 options to executive director Dr Peter Smith.
Race said the options were part of the incentive plan, exercisable at a 48 percent premium to the 20-day volume weighted average price to the day prior to the issue within five years.
The company said the options were in addition to Ms Harney's $155,400 yearly pay and Dr Smith's $210,900 annual salary.
The company said shareholders would also vote to adopt the remuneration report, elect directors Dr Smith and Phillip Lynch.
The meeting will be held online and in person at the Dixon Room, State Library of New South Wales, 1 Shakespeare Place, Sydney on November 25, 2023 at 12pm (AEDT).
Race was up 1.5 cents or 1.5 percent to $1.005.