



# Biotech Daily

Thursday March 2, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH UP: KAZIA UP 26%; NOVA EYE DOWN 13%**
- \* **NOVA EYE: 'COMMITMENTS' FOR \$8m PLACEMENT**
- \* **ANTEO, WYON WORK ON MEDICAL TECHNOLOGY MICRO-BATTERIES**
- \* **RACE, NORTH CAROLINA UNI STUDY ZANTRENE HEART PROTECTION**
- \* **CHIMERIC STARTS 4TH CLTX-CAR-T GLIOBLASTOMA STUDY COHORT**
- \* **OPTISCAN: US FDA DE-NOVO ROUTE FOR INVIVAGE ORAL MICROSCOPE**
- \* **MICROBA: SYNLAB TO DISTRIBUTE IN TÜRKIYE, CZECH REPUBLIC**
- \* **PHARMAUST MONEPANTEL MND TRIAL INTERIM ANALYSIS**
- \* **CLINUVEL TO NO LONGER FILE QUARTERLY REPORTS**
- \* **PERPETUAL TAKES 5.1% OF PROBIOTEC**
- \* **NEUREN APPOINTS JOE BASILE DIRECTOR**
- \* **IDT APPOINTS INTERIM CEO PAUL MCDONALD CEO, ON \$310k PA**
- \* **MIKE TONROE REPLACES IMUGENE CO SECS PHILLIP HAINS, NATHAN JONG**

## MARKET REPORT

The Australian stock market edged up 0.05 percent on Thursday March 2, 2023, with the ASX200 up 3.8 points to 7,255.4 points. Nineteen of the Biotech Daily Top 40 stocks were up, 14 fell, six traded unchanged and one was untraded. All three Big Caps fell.

Kazia was the best, up 3.5 cents or 25.9 percent to 17 cents, with 658,918 shares traded. Universal Biosensors climbed 8.9 percent; Neuren improved 4.4 percent; Clinuvel, Cynata, Imugene, Next Science, Oncosil, Paradigm and Telix were up three percent or more; Actinogen, Amplia, Immutep and Proteomics rose more than two percent; Avita, Cyclopharm and Polynovo were up more than one percent; with Nanosonics and Opthea up by less than one percent.

Nova Eye led the falls, down three cents or 13.0 percent to 20 cents, with 782,475 shares traded. Pharmaxis fell 10 percent; Volpara lost 8.8 percent; Compumedics was down 6.25 percent; Dimerix, Resonance and Starpharma fell four percent or more; Atomo shed 2.1 percent; Envision, Impedimed, Medical Developments, Mesoblast, Patrys and Pro Medicus were down more than one percent; with Cochlear, CSL and Resmed down by less than one percent.

## NOVA EYE MEDICAL

Nova Eye says it has “firm commitments” for \$8 million in a placement at 18 cents a share, a 21.7 percent discount to the last traded price on February 24, 2023.

Nova Eye said that the commitments were from sophisticated and professional investors, and that directors had committed to subscribe for \$270,000, subject to shareholder approval.

The company said that Taylor Collison, E & P Corporate Advisory Pty Ltd and MST Financial Services were joint lead managers and would be paid a six percent fee.

Nova Eye said that funds would be used for the expansion of its glaucoma surgical devices in the US, Europe and China.

Nova Eye fell three cents or 13.0 percent to 20 cents.

## ANTEOTECH

Anteo says it has an agreement with Wyon AG to develop and produce “customized, rechargeable miniature and micro batteries” for medical technologies.

Anteo did not disclose the agreement’s commercial terms but said that it would collaborate to improve the Appenzell, Switzerland-based Wyon’s existing range of batteries.

The company said that the agreement would allow it to negotiate and establish a licencing agreement for its silicon anode technology for lithium-ion batteries.

Anteo managing-director David Radford said by partnering with Wyon “we are taking a significant step towards executing our silicon anode growth strategy”.

“Our objective is to develop a product range that becomes the leading cell and battery choice for achieving the highest possible energy capacity in the smallest possible size, to revolutionizing the way medical devices are powered,” Mr Radford said.

Anteo was up 0.3 cents or 6.25 percent to 5.1 cents with 6.9 million shares traded.

## RACE ONCOLOGY

Race says it has a collaboration with the University of North Carolina at Chapel Hill to research how Zantrene protects the heart from chemotherapy, at the molecular level.

In 2022, the company said it had submitted an application for a 50-patient, phase I/IIb trial of Zantrene, or bisantrene dihydrochloride for breast cancer, to inform a subsequent phase I/IIb interventional trial to help patients avoid permanent heart damaged caused by anthracycline chemotherapy and improve anti-cancer outcomes (BD: Dec 9, 2022).

In June, Race said interim data from its cardio-protection program showed that Zantrene protected against chemotherapy-induced heart damage, in mice (BD: Jun 30, 2022).

Today, the company said that “understanding the molecular mechanisms of how Zantrene can mitigate the cardiotoxicity of current standard of care chemotherapies will aid the selection of optimal dosing in the clinic”.

Race said that the University of North Carolina’s Dr Brian Jensen would lead the project, which would use bio-chemical, cellular and mouse models of cardio-protection, was expected to take 12 months and cost about \$US101,262 (\$A150,098).

Race chief executive officer Damian Clarke-Bruce said that “deeply understanding the cardio-protective mechanism of action of Zantrene is a critical aspect of our pharma partnering discussions”.

“The pre-clinical discovery that Zantrene in combination with chemotherapy can protect the heart while better treating cancer has the potential to significantly change standard-of-care cancer treatment and have a meaningful impact on the lives of patients,” he said.

Race was up 13 cents or 6.05 percent to \$2.28.

## CHIMERIC THERAPEUTICS

Chimeric says it has dosed the first patient in the fourth cohort of its up-to 36-patient phase I, dose-escalation trial of CHM1101 CLTX-Car-T-cells for glioblastoma.

Chimeric said the fourth cohort would treat patients with  $440 \times 10^6$  chlorotoxin chimeric antigen receptor T-cells (CLTX-Car-T-cells), or CHM1101, through intra-tumoral and intra-ventricular administration.

Chimeric was up 0.1 cents or 1.45 percent to seven cents with 1.4 million shares traded.

## OPTISCAN IMAGING

Optiscan says the US Food and Drug Administration says the “de-novo classification request pathway” is more suitable for its Invivage oral tissue imaging device.

The company said it received the feedback from the FDA in relation to its pre-market notification 510(k) application for its Invivage microscope for oral tissue imaging.

Optiscan managing-director Dr Camile Farah said the FDA provided feedback that “it could not evaluate substantial equivalence of our device/drug combination product due to the absence of a predicate, and as such they have deemed that the de-novo classification request pathway is more suitable for our purposes”.

“While this advice differs from that previously provided to the company by the FDA in [our] Q-Submission, we are encouraged by the review process and feedback offered in our recent meetings with the FDA which have been extremely positive and productive,” Dr Farah said. “In addition to discussions around novelty, first-in-class, and available pathways for clearance, the FDA recommended additional studies to expedite a future de-novo submission.”

Optiscan said that regulatory clearance of its combination product mandated that “both the fluorescent contrast agent drug and the device used to visualize microscopic structures are cleared for use in the intended clinical setting” and that additional data requested by the FDA for its de-novo submission related “mostly to the novelty of the contrast agent and its intended application to oral tissues”.

Optiscan said that it intended to conduct the additional studies to satisfy the FDA recommendations “in the shortest time possible”.

Optiscan fell 1.1 cents or 12.1 percent to eight cents.

## MICROBA LIFE SCIENCES

Microba says it has an agreement with Synlab International GmbH subsidiaries to distribute its gut microbiome testing technology into Türkiye and the Czech Republic.

Microba said that in 2020, it had a “master agreement” with the Munich, Germany-based Synlab to deliver its testing to healthcare providers in Spain, and in 2022, expanded the agreement to cover additional countries in Europe and Latin America, including Italy and Portugal (BD: Dec 8, 2022).

Today, the company said it had an agreement with Referans M-B Saglik Labopraturvar for non-exclusive rights of its testing technology until December 31, 2028, in Türkiye, and the same agreement with Synlab Czech S R O, in the Czech Republic.

Microba head of services Bernie Woodcroft said “we continue to progress distribution expansion with Synlab, Europe’s largest medical diagnostics company, to drive our testing into the hands of clinicians and patients across Europe”.

“Adding Türkiye and Czech Republic is another positive step forward in the global distribution expansion of Microba’s testing services,” Mr Woodcroft said.

Microba fell 1.5 cents or 3.6 percent to 40 cents.

## PHARMAUST

Pharmaust says it will conduct an interim analysis following dosing the second cohort of its 12-patient, phase I/II trial of monepantel for motor neurone disease.

In February, Pharmaust said it had begun dosing the second cohort with participants receiving 4mg/kg monepantel which was twice the dose of the first patient in the first cohort (BD: Feb 20, 2023).

Last year, the company said it had completed dosing the first cohort of six patients in its trial for motor neuron disease or amyotrophic lateral sclerosis (BD: Dec 2, 2022).

Today, Pharmaust said the interim analysis was an approved amendment to the initial protocol and would include treatment-related changes from baseline, analysis of function rating scales, quality of life, cognitive assessment, prognostic indicators and the measurement of several disease-related biomarkers.

Pharmaust said that following the amendment, it would continue with monepantel dose escalation for patients in the third and fourth cohort, subject to safety committee reviews, and that the process may facilitate the optimum dose level or range for a phase II trial.

Pharmaust fell 0.1 cents or 1.2 percent to eight cents.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it will no longer file Appendix 4C quarterly reports.

Clinuvel filed cash-flow positive Appendix 4Cs for the three months to March 31, June 30, September 30, and December 31, 2022.

The company said that it had lodged quarterly cash flow and activities reports "on a voluntary basis since 2018" when the ASX first advised the company it could be relieved of its quarterly reporting obligations.

Clinuvel said that it was required to lodge preliminary final reports, or Appendix 4Es, and half yearly reports, or Appendix 4Ds, within two months of the end of the relevant accounting period.

Clinuvel was up 76 cents or 3.95 percent to \$20.01 with 176,558 shares traded.

## PROBIOTEC

The Sydney-based Perpetual says it has become substantial in Probiotec with 4,154,424 shares or 5.1085 percent of the company.

Perpetual said that it bought shares between February 8 and 28, 2023, with the single largest purchase on February 28 of 855,768 shares for \$1,968,266 or \$2.30 a share.

Probiotec was up three cents or 1.3 percent to \$2.35.

## NEUREN PHARMACEUTICALS

Neuren says it has appointed Joe Basile as independent non-executive director.

Neuren said Mr Basile had worked in the pharmaceutical industry for more than 30 years, most recently at Inova Pharmaceuticals in Singapore as group chief financial officer and previously at Novartis in finance and commercial sales in Australia and Asia.

Neuren was up 33 cents or 4.4 percent to \$7.83 with 988,499 shares traded.

### IDT AUSTRALIA

IDT says Paul McDonald has been appointed as permanent chief executive officer, effective immediately, after serving on an interim basis for the past five months.

IDT said that Mr McDonald would receive a base salary of \$310,000, excluding superannuation, short term incentives of up-to 50 percent of his base salary on the achieve of performance targets, as well as long term incentives.

IDT was up 0.1 cents or 1.5 percent to 6.8 cents.

### IMUGENE

Imugene says chief financial officer Mike Tonroe will replace Phillip Hains and Nathan Jong as company secretary, effective from March 2, 2023.

Imugene said that Mr Tonroe began working for the company in September 2022 and was previously company secretary of Genetic Technologies and Opthea.

Imugene was up half a cent or 3.85 percent to 13.5 cents with 11.3 million shares traded.