



Biotech Daily

Tuesday August 8, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH FLAT: UNIVERSAL BIO UP 17%; MESOBLAST DOWN 8.5%**
- * **VOLPARA: BREAST SCREEN SA TO USE BREAST DENSITY TEST**
- * **RECCE: 2 R-327 GEL PATIENTS 'POSITIVE RESPONSE'**
- * **TELIX DOSES 1st TLX101 PHASE I GLIOBLASTOMA PATIENT**
- * **RESPIRI SHARE PLAN RAISES \$3m**
- * **ATOMO SHARE PLAN, SHORTFALL RAISE \$1m; TOTAL \$2.25m**
- * **DIMERIX: REVIEW BOARD OKAYS PHASE III DMX-200 FSGS TRIAL**
- * **RACE SHIFTS FOCUS TO BISANTRENE RC220 FOR BREAST CANCER**
- * **UNIVERSAL BIOSENSORS: 5 NEW PETRACKR DISTRIBUTION DEALS**
- * **PHARMAXIS: \$4.4m PADDINGTON STREET LOAN**
- * **ANTERIS 1m DIRECTOR OPTIONS EGM**
- * **EMYRIA: KETAMINE ASSISTED DEPRESSION THERAPY**
- * **INCANNEX, CLARION OPEN PSYCHEDELIC PTSD REGISTRATION**
- * **REGAL TAKES 10.9% OF ADHERIUM**

MARKET REPORT

The Australian stock market edged up 0.03 percent on Tuesday August 8, 2023, with the ASX200 up 1.9 points to 7,311.1 points. Seventeen of the Biotech Daily Top 40 stocks were up, 16 fell, five traded unchanged and two were untraded.

Universal Biosensors was best, up four cents or 17.4 percent to 27 cents, with 116,179 shares traded. Actinogen climbed 10 percent; Resonance rose 8.6 percent; Next Science improved 7.1 percent; Nova Eye was up 6.1 percent; Cynata climbed 3.6 percent; Amplia, Clinuvel, Medical Developments and Pharmaxis rose more than two percent; Antisense, CSL, Dimerix, Orthocell and Volpara were up more than one percent; with Cochlear, Cyclopharm, Nanosonics and Pro Medicus up by less than one percent.

Mesoblast led the falls, for the third trading day in a row, losing a further 3.5 cents or 8.5 percent to 37.5 cents - its lowest share price - with 26.2 million shares traded. Opthea and Prescient lost more than five percent; 4D Medical, Alcidion and Micro-X fell more than four percent; Avita and Immutep were down more than three percent; Emvision, Impedimed, Neuren, Polynovo, Proteomics, Resmed and Telix shed more than two percent; with Genetic Signatures and Imugene down by less than one percent.

[VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says Breast Screen South Australia will use its software to inform women of their breast density, starting August 8, 2023.

Volpara said this would be the first time in public breast screening in Australia that all women would be notified of their individual breast density regardless of its category.

Volpara chief executive officer Teri Thomas said "Breast Screen SA's move to notify women screened in the public program of their breast density is a significant development for all women who want to know more about their breast health and the role that breast density can play in both the development and challenges in detecting breast cancer".

"The use of Volpara's [artificial intelligence]-based software to measure breast density in the [South Australia] trial gives us encouragement that it may prove useful in other Australian public screening programs, should they move towards breast density notification," Ms Thomas said.

Volpara was up 1.5 cents or 1.9 percent to 80 cents.

[RECCE PHARMACEUTICALS](#)

Recce says two patients using its R-327 gel for antibiotic resistant bacterial infections have indicated "positive clinical response".

Recce said both patients were treated under the Australian Therapeutic Goods Administration special access scheme, with the first patient's wound healed and closed by 30 days, with the second patient's wound "significantly improved" by day-14.

The company said that, separately, an independent research organization showed R-327 achieved a 99.9 percent reduction in infection in a pig skin model study of R-327 for efficacy against methicillin-resistant *Staphylococcus aureus*.

Recce chief executive officer James Graham said "antibiotic resistance is globally recognized as one of the greatest threats to human health today".

"To see Recce making a difference to patients in such great medical need before us, is another welcomed sign of new hope in the fight against drug-resistant superbugs," Mr Graham said.

Recce was up nine cents or 14.75 percent to 70 cents.

[TELIX PHARMACEUTICALS](#)

Telix says it has dosed the first of 12 patients in its phase I study of TLX101 in combination with post-surgical standard-of-care treatment for glioblastoma.

In an email to investors not released to the ASX, Telix said the dose-escalation study would confirm the safety profile of TLX101 in combination with external beam radiation therapy and evaluate its suitability before progressing to a proof-of-concept phase II study.

The company said the trial was building on previous research that showed safety and tolerability of intravenous TLX101 with external beam radiation therapy and would be conducted at six sites in Australia, New Zealand and Europe.

In April, Telix said it had China approval for an up-to 30 patient, phase I trial of TLX101 for glioblastoma (BD: Apr 11, 2023).

Today the company said TLX101 was also being investigated in a phase II study that dosed a patient in November 2022 and had since exceeded 70 percent of the patient enrolment target.

Telix fell 23 cents or 2.2 percent to \$10.38 with 1.3 million shares traded.

RESPIRI

Respiri says its share plan has raised \$2,385,420 and the shortfall raised \$614,580, for a total of \$3,000,000 at 3.4 cents a share.

In May, Respiri said it would raise \$4.5 million in convertible notes, plus a further \$2 million in a share plan at 3.4 cents a share (BD: May 24, 2023).

In June, the company said it hoped to raise about \$3 million through the share plan.

Today, Respiri said the proceeds would be mostly used for the upfront payment necessary to acquire Access Managed Services LLC, as well as working capital for US commercialization and the subsequent three-month tranche of Access acquisition.

Respiri was up 0.2 cents or five percent to 4.2 cents.

ATOMO DIAGNOSTICS

Atomo says its share plan at 3.0 cents has raised \$1,000,000, including a \$540,000 shortfall, taking the total raised with its recent placement to \$2.25 million.

In July, Atomo said it had raised \$1.25 million in a placement at 3.6 cents a share, with a share plan at the same price for \$2.75 million more, and that the share plan included a "binding commitment for up-to \$1.0 million of shortfall should it raise less than \$1 million" (BD: Jul 13, 2023).

Today, the company said the share plan raised \$460,000 from investors and \$540,000 from its shortfall to institutional investors, with new shares under the plan offered at the lower of 3.6 cents or a 2.5 percent discount to the volume weighted average price, which was 3.0 cents a share.

Atomo said Bell Potter Securities was the lead manager and bookrunner for the capital raise.

Atomo was unchanged at three cents with 1.3 million shares traded.

DIMERIX

Dimerix says a second data safety monitoring board review recommends its 286-patient, phase III trial of DMX-200 for focal segmental glomerulo-sclerosis continue.

Last year, Dimerix said it had begun recruitment in the pivotal, multi-center, randomized, double-blind, placebo-controlled trial, titled 'Angiotensin II Type 1 Receptor & Chemokine Receptor 2 Targets for Inflammatory Nephrosis' (Action3), to study the efficacy and safety of its DMX-200 in patients with focal segmental glomerulo-sclerosis (FSGS) (BD: May 31, 2022).

Today, the company said data safety monitoring board had evaluated the study data for participant safety, study conduct and progress, and recommended it continue unchanged, with "no safety concerns".

Dimerix said it expected the last patient data to be collected on February 26, 2024, with first interim data expected to be reported about March 15, 2024.

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

Dimerix said that a successful outcome in the first interim analysis, expected on or around March 15, 2024 would allow it to announce a clinically significant and statistical meaningful improvement in proteinuria in patients on DMX-200 versus placebo and that the trial is continuing to part 2.

Dimerix was up 0.1 cents or 1.45 percent to seven cents.

RACE ONCOLOGY

Race says it will investigate using a peripherally-administered bisantrene formulation, RC220, for metastatic breast and other cancer indications.

Race said that following a strategic review it would transition from its RC110 formulation, primarily for acute myeloid leukaemia (AML) and start a phase I/II trial of RC220 with the chemotherapy agent anthracycline doxorubicin for metastatic breast cancer.

The company said the trial would begin once RC220 was available and following toxicology studies and approvals, expected by about September 2023.

Race said its "secondary focus" would be the bisantrene for acute myeloid leukaemia study, with a phase Ib/IIa trial expected to investigate it in combination with decitabine in dose escalation, followed by a triple combination with standard-of-care treatment, with the initial phase providing a "transition" from the central vein administered RC110 to RC220.

The company said the acute myeloid leukaemia trial would begin by about December 2023, with its transitional phase expected in 2024.

Race chief executive officer Damian Clark-Bruce said "Race's revised development program has been designed in such a way that our new bisantrene formulation can fit straight into a global pharmaceutical partner's pipeline".

"Through our rigorous clinical development plan, Race will investigate bisantrene RC220 in both metastatic breast cancer and continue our clinical experience in AML, while investigating and expanding our knowledge of its mechanism of action," Mr Clarke-Bruce said.

"We have a clear regulatory pathway and a program that is supported by international key opinion leaders, for a drug candidate which has already been shown to improve patients' lives," Mr Clark-Bruce said.

"We look forward to presenting the strategy to existing and potential new shareholders over the coming weeks as we seek to advance our position as a commercial partner with a life-changing therapeutic asset in bisantrene RC220," Mr Clark Bruce said.

Race fell 11 cents or 8.7 percent to \$1.15.

UNIVERSAL BIOSENSORS

Universal Biosensors says it has five distribution deals for its Petrackr blood-glucose monitor for diabetic dogs and cats, bringing the total to eight deals worth \$480,000.

Universal Biosensors said that the first year sales from the agreements was expected to exceed \$4 million.

Universal Biosensors chief executive officer John Sharman said the company was "confident that Petrackr provides customers with a better alternative in terms of price, accuracy, latest technology, user mobile application and overall performance compared to the current products available in the market".

Universal Biosensors was up four cents or 17.4 percent to 27 cents.

PHARMAXIS

Pharmaxis says it has a \$4.4 million loan from Paddington Street Finance, secured by its assets, and to be used for working capital and clinical development.

Pharmaxis did not disclose the loan's interest rate or fees, but said it was an advance against its expected \$5.2 million Federal Research and Development Tax Incentive.

The company said the loan term was the earlier of December 31, 2023 or receiving the Tax Incentive.

Pharmaxis was up 0.1 cents or two percent to five cents.

ANTERIS TECHNOLOGIES

Anteris says investors will vote to issue 1,018,500 options to chair John Seaberg, chief executive officer Wayne Patterson and directors Stephen Denaro and Wenyi Gu.

Anteris said an extraordinary general meeting would vote to issue Mr Paterson 700,000 options, on top of his \$US655,987.5 (\$997,422) annual salary, along with 157,000 options for Mr Seaberg, and 80,500 options each to Mr Denaro and Dr Gu.

The company said the options would be exercisable at \$24.00 each within five.

The meeting will be held online and at the Hilton Brisbane, 190 Elizabeth Street, Brisbane, on September 6, 2023 at 10am (AEST).

Anteris fell 14 cents or 0.7 percent to \$19.99.

EMYRIA

Emyria says it has launched a ketamine-assisted therapy program for severe and treatment-resistant depression.

Emyria said the program would be run through its Perth-based Pax Centre trauma-focused psychiatric service, under the guidance of scientific advisor Dr Ben Sessa.

In April, the company said that it had appointed psychiatrist and 3,4-methylene-dioxy-methamphetamine (MDMA) researcher Dr Ben Sessa to provide therapist training at the Pax Centre (BD: Apr 18, 2023).

Today, Emyria said patients would pay for a package of drug treatment and therapy, with the program to measure cost effectiveness.

The company said it would work with Dr Sessa over the next two to three months to refine protocols for the program and train clinicians for the administration and monitoring of ketamine.

According to Wikipedia, ketamine was a dissociative anaesthetic used medically for induction and maintenance of anaesthesia, a treatment for depression, a pain management tool, and as a recreational drug, and at anaesthetic doses, it induced a state of dissociative anaesthesia, a trance-like state providing pain relief, sedation and amnesia. Emyria fell one cent or 10.3 percent to 8.7 cents with 1.5 million shares traded.

INCANNEX HEALTHCARE

Incannex says its subsidiary Clarion Clinics is accepting registrations of interest for its psychedelic-assisted therapy at its clinic in Abbotsford, Melbourne

Incannex said treatment would begin following final approval from the Australian Therapeutic Goods Administration, with the clinic expected to open by October 2023.

The company said that to be able to prescribe psychedelic compounds, psychiatrists must be approved under the Therapeutic Goods Administration authorized prescriber scheme.

Clarion chief scientific officer Dr Paul Liknaitzky said that "for people who have suffered with certain conditions that have not responded to available treatments, psychedelic-assisted therapies may provide substantial improvements to negative symptoms and quality of life".

"For people who have suffered with certain conditions that have not responded to available treatments, psychedelic-assisted therapies may provide substantial improvements to negative symptoms and quality of life," Dr Liknaitzky said.

The company said about 390,000 Australians had post-traumatic stress disorder (PTSD), and 280,000 had treatment-resistant depression.

For more information and to register go to: <https://www.incannex.com>.

Incannex fell 0.1 cents or 1.1 percent to 8.7 cents with 2.8 million shares traded.

ADHERIUM

Regal Funds says it has increased its substantial shareholding in Adherium from 234,359,947 shares (9.15%) to 545,518,201 shares (10.91%).

Regal Funds said that between October 28, 2022 and August 3, 2023 it bought 311,158,254 shares, with the single largest purchase on August 3 of 50,000,000 shares for \$175,000 or 0.35 cents a share.

In December, Adherium said it had raised \$13.73 million through a share plan and placement at 0.5 cents a share (BD: Dec 9, 2022).

Adherium fell 0.05 cents or 11.1 percent to 0.4 cents with 2.6 million shares traded.