# Biotech Daily

Wednesday August 9, 2023

*Daily news on ASX-listed biotechnology companies*

*** ASX UP, BIOTECH DOWN: PATRYS UP 11%; UNIVERSAL BIOSENSORS DOWN 7%**

*** NEXT SCIENCE: 'XPERIENCE REDUCES TOTAL KNEE INFLAMMATION'**

*** UNIVERSAL BIOSENSORS WINS XPRECIA PRIME ITALY CONTRACT**

*** CYCLOPHARM: FDA INSPECTS SYDNEY TECHNEGAS FACTORY**

*** FIREBRICK RECRUITS 500 PHASE III NASODINE COLD TRIAL PATIENTS**

*** ANTERIS STARTS US DURAVR VALVE FEASIBILITY STUDY**

*** IMMURON: TGA CLEARS TRAVELAN PACKAGING SUPPLIER**

*** INOVIQ EXCLUDES OLD SAMPLES FROM OVARIAN CANCER TEST**

*** AEGROS SINGAPORE, CAMBODIA PLASMA FRACTIONATION FACILITIES**

*** QIMR VACCINE PROTECTS MICE FROM EPSTEIN-BARR VIRUS**

*** FEDERAL NATIONAL RECONSTRUCTION FUND BOARD APPOINTED**

*** PHARMAUST DOSES 3rd MONEPANTEL FOR MND COHORT**

*** RHINOMED: US ALLOWS MUTE NASAL DILATOR PATENT**

*** ANTERIS US ADR PROGRAM**

*** RESPIRI REQUESTS 'PLACEMENT OF NEW SHARES' TRADING HALT**

*** M&G PLC REDUCES TO 7% OF MESOBLAST**

*** M&G INVESTMENT FUNDS REDUCES TO 5% OF MESOBLAST**

## MARKET REPORT

The Australian stock market was up 0.37 percent on Wednesday August 9, 2023, with the ASX200 up 26.9 points to 7,338.0 points. Twelve of the Biotech Daily Top 40 stocks were up, 17 fell, 10 traded unchanged and one was untraded. All three Big Caps fell.

Patrys was the best, up 0.1 cents or 11.1 percent to one cent, with 3.2 million shares traded. Next Science climbed 8.3 percent; Amplia rose 7.2 percent; Micro-X was up five percent; Alcidion improved 4.35 percent; Nanosonics was up 3.9 percent; Impedimed and Orthocell rose more than two percent; Cyclopharm, Paradigm and Polynovo were up more than one percent; with Neuren up by 0.4 percent.

Yesterday's 17.4 percent best, Universal Biosensors led the falls, down two cents or 7.4 percent to 25 cents, with 27,440 shares traded. Medical Developments, Mesoblast, Pharmaxis and Volpara lost six percent or more; Resmed fell 4.6 percent; Atomo, Kazia and Opthea were down more than three percent; Avita, Dimerix, Proteomics and SDI shed more than two percent; 4D Medical, Nova Eye, Prescient and Telix were down more than one percent; with Cochlear, CSL and Pro Medicus down by less than one percent.

## NEXT SCIENCE

Next Science says a 60-patient pilot study of Xperience for surgical irrigation following total knee replacement shows it reduces inflammation statistically significantly.

Next Science said that swelling reduction comparing Xperience to a standard-of-care three-minute sterile dilute iodine lavage reduced swelling at day-14, significantly and at several time points ($p = 0.01$).

The company said that within 14 days of the total knee replacement, Xperience showed a 54 percent lower inflammation than the reference standard.

Next Science said the Xperience patients had a five degree increase in range of motion, and 10 percent to 20 percent improvement in pain scores and an 18 percent lower opioid use at day-7 “improving to 70 percent less [opioid] usage at day-42, with Xperience patients eliminating opiate (sic) use in half the time of control patients”.

The company said the two-arm, prospective, randomized study was led by New York orthopaedic surgeon Dr Andrew Wickline, with the first group of 30 patients receiving a three-minute sterile dilute iodine lavage, the industry standard, and the second group of 30 patients receiving its Xperience wound care product.

Next Science said the results could help surgeons and hospitals improve patient outcomes, reduce healthcare costs and health system financial performance, and expected the findings to assist with its value assessment committee process in larger hospital groups to approve the use and adoption of Xperience.

Next Science managing-director Harry Hall said that the study showed “the impact of our Xbio technology on inflammation and the positive way it can impact a patient’s post-operative outcome and accelerate return to normal function”.

“I look forward to evaluating further clinical challenges where we can have a similar impact on patient outcomes,” Mr Hall said.

Next Science was up five cents or 8.3 percent to 65 cents.

## UNIVERSAL BIOSENSORS

Universal Biosensors says it will supply more than one hundred of its Xprecia Prime blood coagulation diagnostics and 130,000 strips a year to Italy from October 2023.

Universal Biosensors did not name the buyer of the blood coagulation tests, nor the commercial terms of the two-year contract.

Universal Biosensors chief executive officer John Sharman said Xprecia Prime was “the flagship of our coagulation portfolio and this tender win follows our distribution partnership with Ebos group in Australia which we announced last month” (BD: Jul 3, 2023).

Universal Biosensors fell two cents or 7.4 percent to 25 cents.

## CYCLOPHARM

Cyclopharm says the US Food and Drug Administration (FDA) has inspection its manufacturing facility at Kingsgrove, Sydney.

In May, Cyclopharm said the FDA would inspect its Sydney Technegas manufacturing facility between July 24 and August 4, 2023 (BD: May 9, 2023).

Cyclopharm chief executive officer said James McBrayer said “Technegas will be regulated in the US as [a] combination product”.

“The inspection covered both the drug and device elements of Technegas,” he said.

Mr McBrayer said that the inspection report would require further internal FDA review but the company was confident that the goal review date of September 29, 2023 was on track.

Cyclopharm was up four cents or 1.7 percent to $2.37.

## FIREBRICK PHARMA

Firebrick says it has recruited 500 patients for its phase III trial of its Nasodine nasal spray for the common cold, completing enrolment.
In May, Firebrick said it hoped to recruit 196 patients with early-stage colds confirmed by polymerase chain reaction (PCR) tests to have viral infections, not including Covid-19 (BD: May 31, 2023).
Today, the company said the results would be used for international regulatory filings for Nasodine, including a European approval submission.
Firebrick executive chair Dr Peter Molloy said: “Subject to availability of the complete efficacy data and timely completion of the statistical analysis, we expect to report headline results of the trial by the end of September”.
Firebrick was up 3.5 cents or 19.4 percent to 21.5 cents.

## ANTERIS TECHNOLOGIES

Anteris says it has begun enrolment in a US “early feasibility” study of its Duravr transcatheter heart valve, with the valve “used to successfully treat patients”.
Anteris said the study was an “essential step” towards receiving US Food and Drug Administration approval.
The company said the first group of sever aortic stenosis patients were treated with its Duravr valve had, intra-operatively, post implant effective orifice area (EOA) of 2.2cm$^2$, and average mean gradients of 4mm/Hg.
Anteris said the primary endpoint at 30 days post-implementation would be to assess safety and device feasibility, with completion expected by about October and study completion being a 10-year follow up in December 2033.
Anteris chief executive officer Wayne Paterson said “the successful treatment of these patients in the United States is yet another important milestone on our path to commercialization of the Duravr [transcatheter aortic valve replacement] system”.
“The patients enrolled at Montefiore Hospital in New York this week add to our body of evidence that supports the use case of Duravr [transcatheter heart valve] and its clinical superiority and validates the reproducibility of our data and the stellar performance to date,” Mr Paterson said.
“Today’s patients had excellent outcomes with intra-operative mean gradients of 4mmHg,” Mr Paterson said.
“This further supports the case that Duravr is both clinically viable and will be an important product for the treatment of aortic stenosis in the future, giving patients and physicians alternatives to current therapies,” Mr Paterson said.
Anteris was up 22 cents or 1.1 percent to $20.21.

## IMMURON

Immuron says the Australian Therapeutics Goods Administration has cleared its Travelan packaging supplier for good manufacturing practice, allowing its sale.
In July, Immuron said it had supplies of Travelan but needed ‘good manufacturing practice’ clearance from the Australian Therapeutic Goods Administration, and had transferred and validated packaging to another supplier which had a valid and current GMP certificate from the TGA (BD: Jul 5, 2023).
Today, the company said its resolution of supply and stock outages would help continue anticipated growth of sales in Australia and the US.
Immuron was up 1.2 cents or 16.2 percent to 8.6 cents.

## INOVIQ

Inoviq says old bio-bank sample exosome biomarkers do “not discriminate between case and control”, prohibiting such samples from future research.
Inoviq said it conducted an equivalence study, in preparation for further research of its Exo ovarian cancer exosome algorithmic test, comparing 250-paired serum and plasma samples from long-term storage, meaning from 14 years to 17 years old.
Inoviq said that its exosome-based ovarian cancer test, Exo-OC, had been developed using only plasma samples stored for one to five years, which meant it had to determine if long-term, bio-banked serum samples could be used for further development.
The company said previous studies had “reported degradation of non-exosome biomarkers during long-term storage” but that no data was available on the effect of long-term storage (up-to 17 years).
Inoviq said the lack of data meant that before proceeding to a large cohort study it had to confirm that Exo-Net worked similarly in both plasma and serum and that exosome biomarkers were not impacted by long-term storage.
The company said its test was able to identify exosomal plasma protein and micro-RNA biomarkers identified in previous research, but that the exosomal biomarkers did not effectively discriminate between case and control.
Inoviq said the study established that bio-banked samples stored for 14 years to 17 years were not suitable for exosome-based biomarker discovery and validation.
Inoviq chief scientific officer Dr Gregory Rice said that “prior to commencing a large cohort study of bio-banked serum samples it was imperative to establish the equivalence of serum and effects of long-term storage.
“The study identified significant differences in the behavior of long-term storage samples when compared to recently collected samples,” Dr Rice said.
“These differences are sufficient to necessitate the use of recently collected samples for further test development and validation,” Dr Rice said.
Inoviq chief executive officer Dr Leearne Hinch said Inoviq planned to source suitable plasma samples to inform further development and validation of the Exo-OC test.
The company said development of its exosome ovarian cancer test was expected to begin by July 2024, on sourcing up-to 1,000 suitable samples, and complete within 12 months.
Inoviq fell six cents or 7.9 percent to 70 cents.

## AEGROS

Aegros says it will build a 1,000,000 litre, $US400 million Haemafrac plasma fractionation facility in Singapore, with a sterile “fill and finish” facility in Cambodia.
Aegros said the facility would be owned and funded by a consortium led by the Phnom Penh-based The Royal Group of Companies and the Melbourne-based Fresh Start Group.
The company said the facilities would be used to supply local plasma to Asia, and would convert discarded plasma into “plasma derived medical products”.
Aegros said that the group would set up plasma collection centres and work with local blood collection and transfusion centres to lift their standards to “world best practices”, ensuring long term sustainability and supply of plasma derived medical products.
The Royal Group chief executive officer Neak Oknha Kith Meng said that “the world, especially Asia, has a shortage of plasma products which is impacting the well-being of so many individuals across all countries”.
Aegros co-founder Prof Hari Nair said his company’s technology would just change the way Australia undertakes plasma fractionation and how plasma was fractionated globally.
Aegros is a public unlisted company.

## QUEENSLAND INSTITUTE OF MEDICAL RESEARCH BERGHOFER

Queensland Institute of Medical Research says it has developed a vaccine that provided "potent and durable" protection against Epstein-Barr virus, in mice.

The Institute said the vaccine candidate combined two arms of the immune system to target the virus in both acute and latent infection.

QIMR said that recent research had established Epstein-Barr virus (EBV) to be a likely leading cause of multiple sclerosis, with prevention of EBV-associated infectious mono-nucleosis to potentially prevent multiple sclerosis in the future.

The Institute said that, although more research was needed, the vaccine was potentially complementary to ATA188, a cell-based therapy targeting the root cause of multiple sclerosis currently in phase II clinical development by the Thousand Oaks, California-based Atara Biotherapeutics.

The research, titled 'Lymph node targeted multi-epitope subunit vaccine promotes effective immunity to EBV in HLA-expressing mice' was published in Nature Communications and is at: https://www.nature.com/articles/s41467-023-39770-1.

QIMR scientist Prof Rajiv Khanna said that "other vaccine efforts have focused on inducing neutralizing antibodies against the virus which blocks infection of immune B cells during primary acute infection."

"But [Epstein-Barr virus] in its latent state hides inside B cells, turning them into tiny virus factories ready to divide and spread whenever our immune defences are down," Prof Khanna said.

"It is our killer T-cells that detect and control these infected B-cells … our vaccine formulation induces that killer T-cell immune response as well as the neutralizing antibody immune response," Prof Khanna said.

## FEDERAL GOVERNMENT, NATIONAL RECONSTRUCTION FUND

The Federal Government says it has appointed an eight-member National Reconstruction Fund board to make "independent investment decisions".

A media release from the Federal Minister for Industry and Science Ed Husic and the Minister for Finance Senator Katy Gallagher said the board would provide "high-calibre stewardship" with specialist knowledge across the Fund's seven priority investment areas.

In March, the Government said the Fund would invest $15 billion across priority areas of the economy including medical science, renewables and low emissions technologies, transport, value-adding in resources, value adding in agriculture, forestry and fisheries, defence capability and enabling technologies (BD: Mar 10, 2023).

The Government said the board would be chaired by the former chair of the Australian Renewable Energy Agency and Clean Energy Finance Corp director Martijn Wilder.

The Government said the other directors would be former Australia Post managing-director Ahmed Fahour, Oncores Medical managing-director Dr Katharine Giles, former Liberal Member of the House of Representatives for Higgins in Melbourne Kelly O'Dwyer, technology industry executive Daniel Petre, South Australian Department of Treasury and Finance's risk and performance committee chair Kathryn Presser, Regional Investment Corporation chair Karen Smith-Pomeroy and Australian Super director Daniel Walton.

Senator Katy Gallagher said the appointments were "an important step in implementing the Albanese Government's Future Made in Australia agenda".

Mr Husic said that "with these appointments, the ball is now rolling for the [Fund]".

"The board's collective experience brings to bear the independence and industry experience that taxpayers, project proponents and co-investors expect of this critical national project," Mr Husic said.

## PHARMAUST

Pharmaust says it has completed dosing cohort three of its phase I trial of monepantel for motor neuron disease.
In June, Pharmaust said it had begun dosing the third cohort for its monepantel for motor neuron disease trial at 6.0mg/kg (BD: Jun 9, 2023).
Earlier that month, the company said interim results from the monepantel trial for motor neuron disease showed the tablets to be well-tolerated and reached bloodstream therapeutic levels, and said the trial safety committee had approved the dose-escalation of cohort one patients to cohort three (BD: June 7, 2023).
Pharmaust fell 0.1 cents or 1.3 percent to 7.4 cents.

## RHINOMED

Rhinomed says the US Patent and Trademark Office has allowed a patent for its Mute nasal dilator for improved sleep, to reduce snoring and improve breathing.
Rhinomed said the patent, titled 'Nasal Dilator Devices', would provide intellectual property protection until December 2036.
The company said that the Mute dilators were sold in America at Walgreens, CVS, Rite Aid, Ingles Markets and online through Amazon.
Rhinomed said the Mute patent was one of about 250 patents and trademarks both awarded and pending, covering the US, Australia and Europe, and providing protection in specific markets in South America and Asia.
Rhinomed was up half a cent or 7.1 percent to 7.5 cents.

## ANTERIS TECHNOLOGIES

Anteris says it has established an American depositary receipt (ADR) program for the US with one ADR equal to one Australian share.
Anteris said the program had been set up to "improve US investor access" to its shares.
The company said Deutsche Bank was appointed as the depositary bank for the program.

## RESPIRI

Respiri has requested a trading halt "regarding the placement of new shares over and above the recently completed share purchase plan announced on 8 August".
Earlier this week, Respiri said it had raised a total of $3,000,000 through a share plan at 3.4 cents a share (BD: Aug 8, 2023).
Trading will resume on August 11, 2023 or on an earlier announcement.
Respiri last traded at 4.2 cents.

## MESOBLAST

M&G Plc says it has reduced its substantial shareholding in Mesoblast from 76,996,783 shares (9.46%) to 58,312,858 shares (7.16%).
London's M&G Plc said that between July 28 and August 4, 2023 it sold shares, with the single largest sale on August 4 of 1,863,156 shares for $911,359 or 48.9 cents a share.
On Friday, August 4, Mesoblast emerged from a trading halt to announce that the US Food and Drug Administration had again refused its biologics licence application for remestemcel-L for paediatric graft versus host disease.
Mesoblast fell 2.5 cents or 6.7 percent to 35 cents with 25.0 million shares traded.

## MESOBLAST

M&G Investment Funds says it has reduced its substantial shareholding in Mesoblast from 51,954,410 shares (6.38%) to 41,562,523 shares (5.10%).

The London-based M&G Investment Funds said that between August 4 and 7, 2023 it sold shares, with the single largest sale on August 4 of 4,953,209 shares for $2,470,235 or 49.9 cents a share.