



# Biotech Daily

Thursday September 23, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ACTINOGEN UP 14%; TELIX DOWN 6%**
- \* **ATMO RAISES \$9.6m FOR GUT GAS MONITOR CAPSULE**
- \* **TELIX: US FDA EXTENDS ILLUCIX REVIEW 3 MONTHS**
- \* **MICRO-X \$8m STROKE ALLIANCE DEAL**
- \* **ANTEO: EUGENI TGA APPLICATION, ROMANIAN DISTRIBUTOR**
- \* **OSPREY: GE HEALTHCARE RESUMES DYEVERT EURO PROMOTION**
- \* **USCOM: BP+ '94% EFFECTIVE FOR AF SCREENING'**
- \* **ZELIRA'S ILERA LAUNCHES MARIJUANA ACNE PRODUCT LINE**
- \* **CHIMERIC: EURO PATENT FOR CAR-CLTX, CHM1101**
- \* **VISIONEERING: USPTO ALLOWS MULTIFOCAL LENS PATENT**
- \* **POLYNOVO POTENTIAL 2<sup>nd</sup> STRIKE BOARD SPILL AGM**
- \* **COGSTATE 1.4m O'CONNOR FAMILY INCENTIVE OPTIONS AGM**
- \* **FMR TAKES 5% OF SOMNOMED**
- \* **MEDIBIO APPOINTS DR ELIZABETH LOMBARDO ADVISOR**

## MARKET REPORT

The Australian stock market was up 1.0 percent on Thursday September 23, 2021, with the ASX200 up 73.3 points to 7,370.2 points. Thirty-two of the Biotech Daily Top 40 stocks were up, four fell and four traded unchanged.

Actinogen was the best, up 1.5 cents or 14.3 percent to 12 cents, with 15.9 million shares traded. Osprey and Paradigm climbed more than 12 percent; Avita was up 8.5 percent; Kazia and Prescient improved more than seven percent; Opthea and Nova Eye rose more than six percent; Amplia, Compumedics, Imugene, Mesoblast, Patrys and Starpharma were up more than five percent; Medical Developments and Volpara climbed more than four percent; Clinuvel, Immutep, Nanosonics, Universal Biosensors and Uscom were up three percent or more; Antisense, Neuren, Optiscan, Orthocell and Polynovo rose more than two percent; Alterity, Cynata, Dimerix, Next Science, Pro Medicus and Proteomics were up more than one percent; with Cochlear and CSL up less than one percent.

Telix led the falls, down 38 cents or 5.6 percent to \$6.42, with 2.7 million shares traded. Oncosil and Pharmaxis fell four percent or more; with Genetic Signatures and Resmed down by less than one percent.

## ATMO BIOSCIENCES, PLANET INNOVATION

The Melbourne-based Atmo says it has closed an oversubscribed \$9.6 million capital raise for its ingestible gas-sensing capsule to monitor gut microbiome and health.

Atmo said that Planet Innovation had invested in, and supported, the company and the capital raise was led by two new, cornerstone investors, Sydney's Alium Capital Management and Japan's Otsuka Pharmaceutical.

The company said the funds would accelerate product development of its gas-sensing capsule, which detected "clinically important gaseous biomarkers produced by the gut microbiome as it travels through a person's gastrointestinal system" and transmit the data to the internet cloud for analysis.

Atmo said it would undertake studies for a US Food and Drug Administration submission for its capsule to assess gut motility and transit time using gas profile-based location signatures, and would continue clinical studies to expand into small intestinal bacterial overgrowth (Sibo) a gastro-intestinal disorder affecting up to 15 percent of the population. The company said the hydrogen breath test was the most common test for SibO, but was "unreliable" and more accurate methods were invasive and expensive.

Atmo said its capsule had "the potential to directly collect functional data from within the small intestine that could assist with the evaluation and management of SibO.

Atmo chief executive officer Malcolm Hebblewhite said there had been "an explosion of interest and understanding about the impact of the microbiome on ... health".

"One of the big challenges is that the gut is very long, with much of it inaccessible, and it is hard to know what is going on in there," Mr Hebblewhite said.

"Otsuka brings not just funding, but a global presence through access to its well established and extensive product development resources, its customer focus, and distribution networks cutting across pharmaceuticals, consumer products and medical devices," Mr Hebblewhite said.

Atmo is a private company.

## TELIX PHARMACEUTICALS

Telex says the US Food and Drug Administration has extended the review of its new drug application for Illucix for prostate cancer imaging to December 23, 2021.

In June, Telex said a late-cycle meeting with the US Food and Drug Administration on its prostate cancer imaging product Illucix application had "no substantive review issues" (BD: June 17, 2021).

Today, the company said the revised target Prescription Drug User Fee Act (PDUFA) date would "allow the FDA to review and consider further manufacturing-related information submitted by the company and conclude the label review" which was "a standard review extension period".

Telex chief executive officer Dr Christian Behrenbruch said "the timing of the [pre-authorisation inspection] relative to the late-cycle review meeting meant that additional review time was needed to address manufacturing-related observations.

"This has pressured the FDA's initial PDUFA review timeline and hence the company has incurred this time extension," Dr Behrenbruch said.

"The final part of the [new drug application] process is the label review, which we consider to be a straightforward matter, given the precedent of PSMA-PET imaging agents in the market and the clear adoption of PSMA PET in clinical practice guidelines," Dr Behrenbruch said.

"The FDA has not requested additional safety or clinical data," Dr Behrenbruch said.

Telex fell 38 cents or 5.6 percent to \$6.42 with 2.7 million shares traded.

## MICRO-X

Micro-X says it has an \$8 million agreement with the Australian Stroke Alliance to develop its Brain Tomo stroke diagnostic for land and air ambulances.

Last week, Emvision said it had an \$8 million agreement with the Australian Stroke Alliance to support the development of its portable brain scanners for stroke in first responder air and road ambulances (BD: Sep 16, 2021).

Today, Micro-X said the funding would provide for technology services and the development of product prototypes, including using its “electronic x-ray tube capabilities to miniaturize diagnostic brain [computed tomography] imaging to allow a scanner to be small enough and affordable enough to generate widespread pre-hospital stroke diagnosis and treatment in ambulances. to be developed”.

Micro-X said that the bulk of the work and payments were in the first two to three years, with an initial \$500,000 due and payable on the execution of the agreement.

The company said it retained all intellectual property generated including the design architecture, image software, prototype and final Brain Tomo product.

Micro-X said the Alliance was granted \$40 million for its ‘Stroke Golden Hour’ project from the Federal Government’s Medical Research Future Fund.

Micro-X managing-director Peter Rowland said the company was “excited that the mobility of our technology, developed here in South Australia, will act as a game changer to pre-hospital stroke care, particularly in remote and rural areas”.

“The proliferation of stroke imaging in air and land ambulances will make a huge impact on stroke survival and recovery rates,” Mr Rowland said.

“We’ve already begun preliminary work which has delivered promising results and look forward to working closely with our partners at the Melbourne Brain Centre, ASA, Johns Hopkins and Fujifilm to turn this concept into a reality,” Mr Rowland said.

Micro-X was up half a cent or 1.7 percent to 29.5 cents.

## ANTEOTECH

Anteo says it has applied for Therapeutic Goods Administration approval for its Eugeni reader and Sars-Cov-2 rapid test and appointed Eromediks Romania distributor.

Anteo said if approved the Eugeni reader and severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) antigen rapid test would be listed on the Australian Register of Therapeutic Goods and “progress the marketing, sale and use of its products in Australia”. The company said TGA approval for registration would be a “significant benchmark for the efficacy and quality of the products in other large markets”.

Anteo said it was seeking registration of the Eugeni reader as a class I in-vitro diagnostic the Sars-Cov-2 test as a class III in-vitro diagnostic.

Separately, the company said it had appointed the Bucharest, Romania-based Eromediks Aparatura Medicala for exclusive sales of the Eugeni reader platform and Sars-Cov-2 antigen rapid diagnostic test in Romania.

In April, Anteo said it had Conformité Européenne (CE) approval for the Eugeni Sars-Cov-2 antigen rapid test, which was a single use, disposable, immuno-chromatographic test (BD: Apr 12, 28, 2021).

Today, the company said the CE marking would enable access in Romania after registration with the National Agency for Medicines and Medical Devices Romania (NAMMD), for which it would apply “in the coming weeks”.

Anteo said the agreement would begin on October 1, 2021, with the initial term of three years, renewable for a further two years after the initial term on mutual agreement.

Anteo fell half a cent or 1.8 percent to 27 cents with 15.7 million shares traded.

### OSPREY MEDICAL

Osprey says distribution partner GE Healthcare has “resumed marketing efforts” of its Dyevert technology for acute kidney injury (AKI) across Europe.

In June 2020, Osprey said GE Healthcare would be its exclusive distributor in Europe, Russia, the Middle East, Africa, Central Asia and Turkey (BD: Jul 30, 2020).

Today, the company said that following the easing of Covid-19 restrictions in Europe, GE Healthcare sponsored a meeting in Florence Italy promoting the Dyevert system and released additional marketing efforts for renal safety in English, German and Italian.

Osprey was up nine cents or 12.2 percent to 83 cents.

### USCOM

Uscom says its BP+ central blood pressure monitor was “94 percent effective” for the detection of atrial fibrillation (AF) in home care environments.

Uscom said its BP+ monitor was compared to a 12-lead electro-cardiogram and detected the cardiac rhythm abnormality atrial fibrillation in a primary care setting and “may be used as a screening investigation”.

The company said the BP+ took 60 seconds for its results, compared to the 12-lead ECG taking “15 to 30 minutes and requires a consultant cardiologist for interpretation”.

Uscom executive chair Prof Rob Phillips said the technology was a “leap forward in the detection and management of hypertension and stroke prevention”.

Uscom was up half a cent or 3.6 percent to 14.5 cents.

### ZELIRA THERAPEUTICS

Zelira says its Plymouth Meeting, Pennsylvania-based dermatology subsidiary Ilera Derm LLC has launched its Raf Five marijuana-based acne treatments.

Zelira said the five-product line included a gel cleanser, a treatment, a hydrating lotion sunscreen, moisturizing lotion and acne treatment pads, and the products included hyaluronic acid, niacinamide, glycerine, thiotaine, peptides and cannabidiol.

Zelira said the products were available in the US through the Raf Five website.

Zelira was up 0.2 cents or 5.3 percent to four cents with 4.7 million shares traded.

### CHIMERIC THERAPEUTICS

Chimeric says the European Patent Office has granted a patent for its chimeric antigen receptor (Car) technology using chlorotoxin (CLTX), including CHM1101.

Chimeric said the patent, titled ‘Chimeric antigen receptors containing a chlorotoxin domain’ would protect its intellectual property until 2036.

Chimeric was up two cents or 6.35 percent to 33.5 cents with 1.5 million shares traded.

### VISIONEERING TECHNOLOGIES

Visioneering says the US Patent and Trademark Office has allowed a patent that covers the design and use of its Naturalvue Multifocal contact lenses.

Visioneering said the patent, titled ‘Induced Aperture Lens and Method’ would protect its intellectual property until 2036.

The company said the patent had been allowed in Australia, Singapore and China, and was pending in Europe.

Visioneering was up 14 cents or 14.9 percent to \$1.08.

## POLYNOVO

Polynovo says its annual general meeting will face a potential second-strike spill motion, following strong opposition to last year's remuneration reports.

Last year, Polynovo said its remuneration report recorded a first strike with 50.30 percent of votes against (BD: November 16, 2020).

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and, if passed by more than 50 percent of votes, the directors must stand for re-election at a subsequent meeting within 90 days.

Today, the company said shareholders would vote on the election of directors Bruce Rathie and Andrew Lumsden, an amendment to the managing-director's long-term incentive and the remuneration report.

The meeting will be held virtually on October 26, 2021, at 1pm (AEDT).

Polynovo was up four cents or two percent to \$2.00 with 2.1 million shares traded.

## COGSTATE

Cogstate says investors will vote to issue 1,000,000 options to chief executive officer Brad O'Connor and 400,000 options to Tanya O'Connor.

Cogstate said that Mr O'Connor's 1,000,000 incentive options would be exercisable at a 10 percent premium to the five-day volume-weighted average price to the date of issue and expire on October 27, 2026.

The company said that one-third of Mr O'Connor options would vest on October 27, 2023 and the balance on October 27, 2024, in four equal tranches, pending a profit before tax of \$US10.0 million, \$US12.5 million, \$15.0 million and \$17.5 million in any of the years to June 30, 2023, 2024 or 2025.

In August, Cogstate reported net profit after tax of \$US5.2 million.

Cogstate said the 400,000 incentive options issued to Ms O'Connor were exercisable at \$1 each by August 31, 2026, vesting in two tranches, with the first tranche of 133,334 options vesting on August 31, 2023 with no performance criteria and the balance on August 31, 2024 pending a cumulative profit before tax of more than \$US24 million for the financial years to June 30, 2024.

Cogstate said shareholders would vote on the remuneration report, the election of directors Kim Wenn, David Dolby and Dr Richard Mohs and the employee share option plan.

The meeting will be held virtually on October 27, 2021, at 11am (AEDT).

Cogstate fell 14 cents or 5.9 percent to \$2.24 with 525,378 shares traded.

## SOMNOMED

The Delaware-based Fidelity Management and Research Company LLC says it has become a substantial shareholder in Somnomed with 4,154,110 shares (5.02%).

The company said between July 30 and September 20, 2021, it bought 255,514 shares at prices ranging from \$2.105 to \$2.380.

Somnomed was up two cents or 0.9 percent to \$2.32.

## MEDIBIO

Medibio says it has appointed Dr Elizabeth Lombardo to its growth and advocacy advisory board for the launch of its Luca mental “wellness” software application.

Medibio said Dr Lombardo was a psychologist and appeared on US television programs. The company said her book titled ‘Get Out of the Red Zone’, was expected to be published on September 30, 2021, with Luca to be launched the next day.

Dr Lombardo’s LinkedIn page said she held a Bachelor of Arts from the Lewisburg, Pennsylvania Bucknell University, a Master of Physical Therapy from the Durham North Carolina-based Duke University and Doctor of Philosophy from the Philadelphia, Pennsylvania Drexel University.

Medibio was unchanged at 0.8 cents with 79.5 million shares traded.