



# Biotech Daily

Tuesday September 24, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH DOWN: AROA UP 9%; ACTINOGEN DOWN 11%**
- \* **EYE CO NEEDS \$5m FOR ALVIZON GEOGRAPHIC ATROPHY TRIAL**
- \* **IMPEDIMED BIS WINS EMBLEM, PRESBYTERIAN HEALTH COVER**
- \* **IMMUTEP RECEIVES \$3.6m FRENCH R&D TAX CREDIT**
- \* **RHYTHM FIND PROMISING GASTRIC CANCER BIO-MARKERS**
- \* **BIOXYNE: BREATHE LIFE TO SELL AURA CANNABIS EDIBLES**
- \* **ALGORAE LAUNCHES A.I. DRUG TARGET PLATFORM**
- \* **TRIVARX REQUESTS FDA PRE-SUBMISSION MEETING**
- \* **MEMPHASYS FILES ROXSTA ASSAY PATENT**
- \* **TISSUE REPAIR 750k CEO TONY CHARARA OPTIONS AGM**
- \* **ALGORAE 40m DIRECTOR PERFORMANCE SHARES AGM**
- \* **USCOM 10m CHAIR PROF ROBERT PHILLIPS PERFORMANCE SHARES AGM**
- \* **RYDER TAKES 8% OF LUMOS**
- \* **PERENNIAL BELOW 5% OF LUMOS**
- \* **OSTEOPORE APPOINTS CEO DR YUJING LIM EXECUTIVE DIRECTOR**

## MARKET REPORT

The Australian stock market fell 0.13 percent on Tuesday September 24, 2024, with the ASX200 down 10.9 points to 8,142.0 points. Twelve of the Biotech Daily Top 40 companies were up, 16 fell and 12 traded unchanged.

Aroa was the best, up 4.5 cents or 8.65 percent to 56.5 cents, with 795,480 shares traded. Curvebeam climbed 5.9 percent; Mesoblast improved 4.5 percent; Alcidion was up 3.6 percent; 4D Medical and Polynovo rose more than two percent; Medadvisor, Pro Medicus, Resmed and Telix were up more than one percent; with Clinuvel, Neuren and SDI up by less than one percent.

Actinogen led the falls, down 0.3 cents or 11.1 percent to 2.4 cents, with 71.15 million shares traded. Amplia and Impedimed lost more than eight percent; Paradigm and Percheron fell five percent or more; Cyclopharm was down 3.5 percent; Avita, Dimerix and Emvision shed more than two percent; Clarity, Genetic Signatures, Immutep, Medical Developments and Nanosonics were down more than one percent; with Cochlear, CSL, Opthea and Proteomics down by less than one percent.

## EYE CO

Eye Co says it has \$400,000 to start a phase II study of Alvizon, or fludrocortisone acetate, for geographic atrophy secondary to dry-age related macular degeneration.

Eye Co said the randomized sham-controlled trial of intra-vitreous Alvizon would begin with nine patients in October 2024, with results expected by June 2025.

Eye Co managing-director Peter Abrahamson told Biotech Daily that the company needed \$5 million to enrol all 126 patients in the trial.

The company said that geographic atrophy was the currently untreatable form of age-related macular degeneration.

Mr Abrahamson said that Eye Co previously had published a pre-clinical and phase Ib safety study for fludrocortisone acetate (BD: Sep 27, Nov 1, 2021).

Mr Abrahamson said that, pending funding, the phase II trial would enrol 126 patients with half randomized to Alvizon and the other half receiving no treatment.

Eye Co said that Alvizon had been shown to improve retinal function in numerous clinical and pre-clinical studies of dry- age related macular degeneration without significant side-effects or intra-ocular pressure rise.

The company said that outcome measures included change in visual acuity providing an early indication of potential efficacy.

Eye Co said that “only very limited treatment options currently exist for this debilitating disease, none of which demonstrated improvement of visual acuity, and all associated with significant side effects”.

“None of these treatments are currently approved in Australia,” the company said.

Eye Co said that Alvizon promoted retinal function in animal and human studies, had anti-inflammatory and anti-exudative effects with the potential to address a number of retinal diseases including diabetic macular oedema, wet age-related macular degeneration and dry age-related macular degeneration.

The company said that the human safety study of Alvizon for end-stage patients

“improved night vision” and reduced the rate of lesion spread against historical controls.

Eye Co said the trial was being conducted at Sydney Retina in Macquarie Street, Sydney.

The company said it currently had 40,135,875 shares on offer valuing it at \$11.2 million.

Contact Peter Abrahamson at [p.abrahamson@eyeco.com.au](mailto:p.abrahamson@eyeco.com.au).

Eye Co is a private company.

## IMPEDIMED

Impedimed says Emblem Health and Presbyterian Health have included coverage for the use of bio-impedance spectroscopy (BIS) for lymphoedema assessment.

Impedimed said Emblem Health operated in New York, Connecticut and New Jersey, and updated its coverage for breast cancer patients with no pre-authorization, resulting in 88 percent payor coverage in New York.

The company said that Presbyterian Health was the largest payor in New Mexico and had updated its policy to include bioimpedance spectroscopy for lymphoedema assessment with no pre-authorization.

Impedimed said that the addition of Emblem Health and Presbyterian Health took the total number of lives covered by reimbursement to 144 million, and 16 states were at what it called “critical mass” with more than 80 percent covered lives).

Impedimed chief executive officer Dr Parmjot Bains said the company was “pleased to see growing coverage, and the achievement of medically necessary status supports the ability of patients across the US to access early lymphoedema screening”.

Impedimed fell half a cent or 8.1 percent to 5.7 cents with 6.4 million shares traded.

## IMMUTEP

Immutep says it has received EUR2,194,918 (\$A3,553,700) from the French Government under the Crédit d'Impôt Recherche (Research Tax Credit) scheme.

Immutep said the Research Tax Credit scheme was a French incentive that reimbursed up-to 30 percent of eligible research and development expenditure in Europe.

The company said it qualified through its subsidiary Immutep SAS for research and development conducted at its laboratory in France in 2023.

Immutep said the funds would support its clinical development of efitlagimod alpha and the preclinical development of IMP761.

Immutep fell half a cent or 1.45 percent to 34 cents with 8.5 million shares traded.

## RHYTHM BIOSCIENCES

Rhythm says a study of immunoassays from 100 gastric cancer patients and 100 healthy volunteers identified "promising combinations" of diagnostic protein bio-markers.

Rhythm said that analysis of the experimental immune-assays identified combinations of six, seven and eight-protein bio-markers, of the 19 quantified in the study, that could distinguish between patients with and without gastric cancer, with more than 75 percent sensitivity and more than 90 percent specificity.

The company said the results warranted "confirmation in a larger and more diverse population" and it hoped to develop a gastric cancer assay with its assay development partner, after which it would clinically validate to produce a "commercially scalable, proprietary blood test" to detect gastric cancer early.

Rhythm was up 0.6 cents or 8.6 percent to 7.6 cents.

## BIOXYNE

Bioxyne says its Breathe Life Sciences will manufacture and supply \$5.94 million of edible cannabis pastilles, or gummies, and double THC supply to Aura Therapeutics.

Bioxyne said Breathe Life Sciences had amended its previous deal with Aura Therapeutics, and that it expected cannabis pastilles to generate up-to \$3.14 million in revenue, while the increased tetrahydrocannabinol (THC) flower products would lead to \$2.8 million in revenue.

Bioxyne was unchanged at 1.3 cents.

## ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has launched its artificial intelligence (A.I.)-based Algorae operating system platform to predict fixed-dose combination drug targets.

Algorae said its platform used four neural networks to analyse datasets and operated on the National Computational Infrastructure's 'Gadi' supercomputer, which had been used for climate modelling and natural disaster prediction.

The company said it was working with the University of New South Wales' artificial intelligence institute as well as the data and digital specialist arm of the Commonwealth Scientific and Industrial Research Organisation (CSIRO).

Algorae said its platform would undergo iterative improvements during the next two and a half years with a second version's development already underway.

Algorae has previously said it was developing marijuana combinations drugs and as Living Cell it was developing pig cells for Parkinson's disease (BD: Oct 25, 2023).

Algorae was unchanged at 0.7 cents with 15.2 million shares traded.

### TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has requested a pre-submission meeting with the US Food and Drug Administration to approve a trial for its MEB-001 depression screening algorithm. In July, Trivarx said that its 400-patient trial showed that its MEB-001 algorithm identified depression from heart rate with 87 percent sensitivity and 72 percent specificity (BD: Jul 30, 2024).

Today, the company said it expected to finalize the trial protocol in the meeting, expected in the next three months, which would be the final step before applying to the FDA under its De Novo pathway in 2025.

Trivarx non-executive chair David Trimboli said the “pivotal trial will be our final clinical step before FDA submission, bringing us closer to commercializing MEB-001”.

Trivarx fell 0.1 cents or five percent to 1.9 cents.

### MEMPHASYS

Memphasys says it has filed a patent for its Roxsta anti-oxidant assay system, covering “the principle by which a fully point-of-care device might be generated”.

Memphasys said the Patent Co-operation Treaty application was filed to IP (Intellectual Property) Australia and the Australian Patent Office, the proposed patent title was ‘Methods and devices for measuring anti-oxidant activity in a fluid sample’ and if granted would provide intellectual property protection until September 4, 2044.

The company said a prototype device had shown “positive results in key opinion leader studies” providing results in six minutes.

Memphasys was up 0.1 cents or 12.5 percent to 0.9 cents.

### TISSUE REPAIR

Tissue Repair says its annual general meeting will vote to grant chief executive officer Tony Charara 750,000 options exercisable at \$1.15 each within 15 years.

In August, Tissue Repair said it appointed co-founder and executive director Mr Charara as chief executive officer, with his fixed annual remuneration of \$50,000 unchanged and he would be eligible to receive a short-term incentive of up-to 20 percent of his yearly salary subject to performance hurdles and be issued 750,000 long-term incentive options, subject to shareholder approval (BD: Aug 8, 2024).

On Friday, the Takeovers Panel said it would not take action on Tissue Repair following an undertaking from Mr Charara not to spill the board (BD: Sep 23, 2023).

In an email from the Takeovers Panel, posted on the Tissue Repair ASX site after the close of the ASX on Friday, September 20, 2024, Takeovers Panel chief executive Allan Bulman said the panel “declined to conduct proceedings on an application dated August 28, 2024 from Tissue Repair in relation to its affairs, after accepting an undertaking from Spark Capital Pty Ltd and Mr Charara”.

In August, the Panel said it had an application from Tissue Repair relating to a potential board spill request concerning an alleged undisclosed association (BD: Aug 30, 2024).

Today, the company said Mr Charara’s options were subject to his continued employment and would vest over three years and expire on October 25, 2039.

Tissue Repair said its investors would also vote to adopt its remuneration report, re-elect independent director Bryan Gray and approve the future issue of securities.

The meeting will be held at Liberty Place, Wework Office, Level 28, 161 Castlereagh Street, Sydney on October 25, 2024 at 10.30am (AEDT).

Tissue Repair fell two cents or 5.1 percent to 37 cents.

### [ALGORAE PHARMACEUTICALS \(FORMERLY LIVING CELL TECHNOLOGIES\)](#)

Algorae says its annual general meeting will vote to issue 20 million performance shares each to chair David Hainsworth and non-executive director Bradley Dilkes.

Algorae said the shares were dependent on market capitalization growth and ethics approval for two clinical trials, with the shares available for vesting until October 27, 2027. The company said investors would vote to adopt the remuneration report, approve the 10 percent placement facility, re-elect Mr Hainsworth as director and appoint an auditor. The meeting will be held at Thomson Geer, Level 23, Rialto South Tower, 525 Collins Street, Melbourne on October 25, 2024 at 11am (AEDT).

### [USCOM](#)

Uscom says its annual general meeting will vote to grant executive chair Prof Robert Phillips up-to 9,670,117 performance shares.

Uscom said the shares were “subject to the achievement of performance and vesting conditions” and valued at about \$250,000, with the rights vesting on July 1, 2025.

The company said investors would vote to re-elect director Christian Bernecker, adopt the remuneration report, ratify placement shares and approve the additional share capacity. The meeting will be held at Suite 2, Level 8, 66 Clarence Street, Sydney on October 25, 2024 at 11:30am (AEDT).

Uscom was untraded at 1.4 cents.

### [LUMOS DIAGNOSTICS](#)

The Sydney-based Ryder Capital says it has increased its substantial shareholding in Lumos from 40,376,502 shares (7.17%) to 46,776,502 shares (8.31%).

Ryder said that on September 20, 2024 it bought 6,400,000 shares for \$198,400 or 3.1 cents a share.

Lumos was unchanged at 3.4 cents with 7.5 million shares traded.

### [LUMOS DIAGNOSTICS](#)

The Sydney-based Perennial says it has ceased its substantial shareholding in Lumos selling 46,179,718 shares between September 18 and 20, 2024.

Perennial said its single-largest sale, on September 20, was 22,514,961 shares for \$696,428 or 3.1 cents a share.

Last week, Perennial said it reduced to 59,169,517 shares or 10.51 percent, with Biotech Daily calculating it retained 12,989,799 shares or 2.3 percent of the company.

### [OSTEOPORE](#)

Osteopore says it has appointed chief executive officer Dr Yujing Lim as an executive director, effective from today.

Osteopore said that Dr Lim held a Master of Engineering from National University of Singapore and Doctor of Philosophy from Nanyang Technology University Singapore.

Osteopore was unchanged at 3.9 cents.