



# Biotech Daily

Monday July 8, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: MEDICAL DEVELOP UP 16%; CLINUVEL DOWN 11%**
- \* **NSW \$134.5m FOR VIRAL VECTOR MANUFACTURING FACILITY**
- \* **CURIE BIO SEED FUNDING FOR FLOREY SPIN-OUT ALKIRA BIO**
- \* **QUEENSLAND UNI: 'AP-1 GENE LINKED TO AGING'**
- \* **EMVISION RECRUITS STAGE 3 EMU STROKE PATIENTS**
- \* **INHALERX: FDA HOLDS MARIJUANA IRX616A TRIAL ON 'SAFETY CONCERNS'**
- \* **RECCE R327 SHOWS 'SIGNIFICANT BACTERICIDAL ACTIVITY', EX-VIVO**
- \* **NOVA EYE GLAUCOMA PRODUCT SALES UP 37% TO \$23m**
- \* **AUSTCO WINS \$5m CANADA HOSPITAL TACERA CONTRACT**
- \* **TRUSCREEN: GORTON HEALTH PAYS \$91k FOR DEVICES IN VIETNAM**
- \* **4D MEDICAL EXPANDS JONES RADIOLOGY TO XV**
- \* **VICTORIA \$118k FOR ECS MARIJUANA VAPES; EXTENDS NAB LOAN**
- \* **AROA 961k M-D RIGHTS, 140k DIRECTOR SHARES AGM**
- \* **CHAIR PAUL HOPPER DILUTED TO 9% OF RADIOPHARM**
- \* **NANOMAB BELOW 5% OF RADIOPHARM**
- \* **WALKER FAMILY TRANSFERS 18% OF NEXT SCIENCE**
- \* **MARCELO MORA REPLACES XIAO CUI AS EPSILON CO SEC**

## MARKET REPORT

The Australian stock market fell 0.76 percent on Monday July 8, 2024, with the ASX200 down 59.1 points to 7,763.2 points. Eighteen of the Biotech Daily Top 40 stocks were up, 14 were down, seven traded unchanged and one was untraded.

Medical Developments was the best, up seven cents or 16.3 percent to 50 cents, with 158,871 shares traded. Nova Eye climbed 13.7 percent; Actinogen was up 6.15 percent; Atomo and Opthea were up four percent or more; 4D Medical was up 3.8 percent; Alcidion, Clarity, Curvebeam, Pro Medicus and Proteomics rose more than two percent; Amplia, Mesoblast and Percheron were up more than one percent; with Avita, Nanosonics, Neuren, Resmed and SDI up by less than one percent.

Clinuvel led the falls, down \$1.87 or 10.8 percent to \$15.51, with 179,859 shares traded. Cynata lost 5.7 percent; Prescient fell 4.65 percent; Dimerix and Syntara were down more than three percent; Cyclopharm, Emission, Impedimed, Imugene, Orthocell, Starpharma and Telix shed two percent or more; with Cochlear, CSL, Genetic Signatures and Polynovo down by more than one percent.

## [VIRAL VECTOR MANUFACTURING FACILITY, NEW SOUTH WALES GOVERNMENT](#)

The Viral Vector Manufacturing Facility says the New South Wales Government has provided \$134.5 million for its building at the Westmead Health and Innovation District. The Viral Vector Manufacturing Facility (VVMF) said that “future co-investment with an industry partner would support the expansion to its third stage – an even larger scale, clinical and commercial production facility.

A spokesperson for the Facility told Biotech Daily that it had been established by the New South Wales Government as a private, for-profit entity and over time might transition to a public company.

The Viral Vector Manufacturing Facility said it would “produce viral vectors for commercial pharmaceutical and biotechnology customers, as well as research grade vectors and product for use in clinical trials”.

VVMF said it aimed to deliver construct design to the clinical and commercial grade manufacture of lentivirus and adeno-associated virus.

The Facility said that it would “focus on cell and gene therapies, which are relevant across a broad range of therapeutic areas ... from cancer to rare diseases”.

The VVMF said that viral vectors were used in RNA therapeutics but RNA therapeutics would not be its initial focus.

The Facility said its chair was Sue MacLeman with non-executive directors including Dr Jane Ryan, Trevor Danos and Robyn Kruk, with former Baxter International executive Stephen Thompson as its chief executive officer.

The VVMF said that Mr Thompson had previously worked for Icon Group, Pacific Dunlop and Proctor & Gamble.

The Facility said that Mr Thompson held a Bachelor of Engineering from the University of New South Wales.

The VVMF said it was “the first of its kind commercial development and manufacturing facility for viral vectors in Australia and is set to play a significant role in meeting the growing global, Asia Pacific and local demand for clinical and commercial grade viral vectors for use in innovative treatments, like cell and gene therapies”.

The Viral Vector Manufacturing Facility said it would improve supply chain resilience and provide equity of access to treatments for patients.

The Facility said that viral vectors could be programmed to deliver genes to a wide range of cell types, and could treat many diseases affecting a range of different organs.

The Facility said that cancer and rare diseases were “a key focus for this new technology, with a growing pipeline on candidates for autoimmune, neurological, metabolic and musculo-skeletal diseases”.

## [ALKIRA BIO, FLOREY INSTITUTE OF NEUROSCIENCE AND MENTAL HEALTH](#)

Melbourne’s Florey Institute says its spin-out company Alkira Bio has received an undisclosed amount of seed funding from Boston’s Curie Bio to commercialize ‘Laseredd’. The Florey said Laseredd stood for “lentiviral, assisted selection of engineered receptors for drug discovery” and targeted complex membrane proteins, called G protein-coupled receptors, and enabled “the discovery of new therapeutics for a range of diseases”.

A Florey spokesperson told Biotech Daily the Curie Bio investment was confidential.

The Institute said Alkira Bio’s chief executive officer and chief scientific officer were Florey researchers Prof Daniel Scott and Dr Chris Draper-Joyce, respectively.

Florey director Prof Trevor Kilpatrick said: “A vital part of bringing important research to global markets is looking at how we commercialise it, and to do that researchers have to think like founders” and the Florey has supported Alkira Bio at every step.

## UNIVERSITY OF QUEENSLAND

The University of Queensland says analysis of genetic data from humans and mice has shown the activator protein-1 (AP-1) gene is “linked to ageing across cell types”.

The University of Queensland said the study used data from 22 major primary cell types from 11 tissues collected from two-to-24-month-old mice compared to published human datasets across a range of ages.

The University said the research found that the master regulator activator protein-1 “progressively activated adult genes, [while] the activity of ‘early-life’ genes involved in development were dialled down, and this process was shared across cell types”.

The University said the aim of the research was to “prevent diseases of ageing from escalating or occurring in the first place by targeting the underlying ageing process to allow people to grow older in better health”.

The University of Queensland said that “to address the diseases associated with ageing, like Alzheimer's disease, metabolic liver disorders and stroke, researchers must first understand the process causing bodies to age”.

The University said the research, titled “The activity of early-life gene regulatory elements is hijacked in aging through pervasive AP-1-linked chromatin opening”, was published in the journal *Cell Metabolism* and available at: <https://bit.ly/3VON9Tg>.

The University of Queensland's Dr Marina Naval-Sanchez said the study found the process was predictable in different life stages as people mature.

“It was ongoing in adulthood, likely because AP-1 is also activated by a number of stress and inflammatory processes as well as by a protein in our blood that increases with age,” Dr Naval-Sanchez said. “This further dampens genes most active early in life, which may drive many of the predictable changes of ageing.”

The University of Queensland's Dr Ralph Patrick said that “by pinpointing AP-1 as a master controller linked to ageing across cell types, we can now study the effects of drugs that reduce its activity to extend quality of life”.

## EMVISION MEDICAL DEVICES

Emvision says it has recruited its target of 30 haemorrhagic stroke patients in stage three of its trial of the artificial intelligence-based Emu brain scanner for stroke.

Last year, Emvision said it had scanned all 30 participants in its stage one, healthy volunteer trial of its brain scanner at Sydney's Liverpool hospital; and later, said it had begun its up-to 150-patient, stage two trial (BD: Feb 1, May 29, 2023).

Earlier this year, the company said it had enrolled all 180 patients in its stage two study of its artificial intelligence-based ‘Emu’ portable brain scanner for stroke and stroke mimic patients in emergency departments and in May said stage two confirmed the algorithm could “help answer the clinical question of ischaemia or not” (BD: May 27, 2024).

Today, the company said the stage three cohort included “a large number of ischaemic stroke participants” with the final results expected before 2025.

Emvision said it had sent a pre-submission package to the US Food and Drug Administration, and expected a consultation meeting “in the coming months”.

The company said FDA pre-submission was a “critical confirmation of requirements for Emvision's upcoming ... trial to support market entry”, with planning for the trial underway and regulatory filings in Australia, the US and the European Union expected in 2025.

Emvision chief executive officer Scott Kirkland said completing recruitment for the trial was “another significant milestone for Emvision with stage three building on an already extensive dataset for our breakthrough neurodiagnostic product”.

Emvision fell five cents or 2.5 percent to \$1.94.

## [INHALERX \(FORMERLY LIFESPOT HEALTH\)](#)

Inhalerx says the US Food and Drug Administration has placed a “clinical hold” on its planned phase I trial of IRX616a marijuana for panic disorder due to “safety concerns”. Earlier this year, Inhalerx said it had submitted an investigational new drug application to the FDA for IRX616a for mental health (BD: May 30, 2024).

Today, the company said the FDA had “placed a temporary suspension on its application “in order to address certain safety concerns for the purposes of ensuring the highest standards of patient safety”.

Inhalerx said the FDA had “provided only preliminary information and is expected to issue a formal letter within the next 30 days, detailing necessary modifications and additional information required to lift the hold”.

The company said that subject to human research ethics committee approval it expected to continue with its drug development plans in Australia with a phase I pharmaco-kinetics and safety trial of IRX616a.

Inhalerx chief executive officer Darryl Davies said the company was “committed to working closely with the FDA to address its concerns swiftly and thoroughly”.

“Despite the study being placed on clinical hold, we have deliberately prepared the [investigational new drug] application in a way that would not adversely affect the planned Australian trials if not approved,” Mr Davies said.

Inhalerx was untraded at 2.6 cents.

## [RECCE PHARMACEUTICALS](#)

Recce says a study of R327 in human skin cells shows it has “significant bactericidal activity” against the antibiotic-resistant bacteria *Acinetobacter baumannii*.

Recce said that *Acinetobacter baumannii* bacteria clinically manifested as urinary tract infections, ventilator-associated pneumonia, central line-associated bloodstream infections, persistent wound infections and meningitis.

The company said the World Health Organization had listed the bacteria as one of the “top priority pathogens due to its high levels of resistance to multiple antibiotics”.

Recce said the study compared R327 to the antibiotic ciprofloxacin and placebo at one-hour post-treatment and 24-hours post-treatment in primary human epidermal skin cells infected with the bacteria.

The company said in the first hour post-treatment R327 achieved more than a 99.9999 percent reduction, or more than a 6.5 log reduction, in intra-cellular bacteria, meaning the bacteria was below the limit of quantification, while ciprofloxacin “did not show any reduction in intracellular bacterial burden”.

Recce said R327 maintained its efficacy after 24 hours, a critical factor in infection management, while ciprofloxacin treatment resulted in only about one log reduction in bacterial numbers over the same period.

The company said the study was conducted at its anti-infective research unit at the Murdoch Children’s Research Institute in Melbourne.

Recce managing-director James Graham said the results highlighted “the potent efficacy of R327 in combating [multi-drug-resistant] bacteria, a significant global health challenge”.

“The ability of R327 to achieve such substantial reductions in bacterial load and maintain its effectiveness over 24 hours is a testament to its potential as a leading anti-infective treatment,” Mr Graham said.

Recce fell two cents or 4.2 percent to 45.5 cents with 1.6 million shares traded.

### NOVA EYE MEDICAL

Nova Eye says glaucoma products sales for the year to June 30, 2024 rose 37 percent to \$US15.3 million (\$A23.5 million), compared to the prior corresponding period.

Nova Eye said based on unaudited financial statements US sales of its glaucoma products for the year to June 30, 2024 were up 73 percent to \$US11.4 million on the previous corresponding period, with US sales for the six months up 77 percent.

The company said it was the fourth consecutive six-month period with increased sales, and that the improvement was due to the recruitment of sales personnel in the US, continued investments in clinical data collection and marketing programs.

Nova Eye said "with the company prioritizing investment in sales growth in the US during the period, sales revenue in markets outside the US remained in line" with the prior corresponding period.

The company said it expected to focus on sales in markets outside of the US for the year to June 30, 2025, including Western Europe and Asia.

Nova Eye was up 3.5 cents or 13.7 percent to 29 cents with 4.8 million shares traded.

### AUSTCO HEALTHCARE

Austco says it has a \$5.0 million contract to supply its Tacera alarm management and clinical workflow technology to Vancouver, British Columbia's Surrey Hospital.

Austco said the hospital would have more than 650 beds, including 48 intensive care unit beds and 25 neo-natal intensive care unit beds.

The company said construction on the hospital had begun and was expected to be completed in 2029, and that the order would include more than 513 patient stations, 559 clinical workflow terminals and webservice interfaces.

Austco said it expected revenue recognition from the contract to begin in the year to June 30, 2025 and that the deal took its contracted orders to a record \$46.2 million.

Austco chief executive officer Clayton Astles said the contract was "a significant milestone for Austco Healthcare and underscores the importance of the company's investment in developing advanced clinical healthcare solutions for modern healthcare".

"Our Tacera system will enhance patient care by ensuring timely communication and efficient workflow management," Mr Astles said.

Austco was up half a cent or 2.6 percent to 19.5 cents.

### TRUSCREEN GROUP

Truscreen says Ho Chi Minh City's Gorton Health Services will pay \$NZ100,000 (\$A91,000) for 10 cervical cancer screening devices and 1,800 single-use sensors.

Truscreen said Gorton Health Services would roll-out its non-invasive optical-electrical device, as opposed to conventional pap-smear, in Vietnam, targeting 64 leading hospitals for commercial acceptance of the device.

The company said Vietnam had more than 35 million women of screening age, with the deployment to facilitate the screening and early detection and management of cervical cancer in Vietnam, a "significant step" towards nationwide use of the device.

Truscreen chief executive officer Marty Dillon said the deployment of the company's devices would "significantly impact the cervical cancer screening ... in Vietnam".

"We are confident that Truscreen's innovative technology will contribute to achieving the World Health Organization's targets for cervical cancer screening in Vietnam," Mr Dillon said.

Truscreen was unchanged at 1.6 cents.



## 4D MEDICAL

4D Medical says the Adelaide-based Jones Radiology will use its XV technology at its 29 clinics in Adelaide, regional South Australia and Alice Springs.

4D Medical said the contract followed a pilot program of its computed tomography lung ventilation analysis software, or CT LVAS, at three of Jones Radiology's Adelaide clinics, with scans referred by both specialists and general practitioners.

The company said it expected most referrals to be for its CT LVAS product, but that the contract also allowed for the use of its XV LVAS which used fluoroscopy.

4D Medical said ventilation reports would be billed on a "software-as-a-service" model on terms "in line with those of the company's other partners".

The company did not disclose the commercial terms of the agreement.

4D Medical was up two cents or 3.8 percent to 55 cents.

## ECS BOTANICS HOLDINGS

ECS says it has a \$118,000 grant from the Victorian Government for its marijuana vape cartridges and has taken a \$3.4 million loan from the National Australia Bank.

ECS said the grant was part of the State Government's Made in Victoria Manufacturing Growth Program round two, and that it would use the funds as "part of its expansion into production of live rosin cartridges for both own-brand and white label products".

According to the Minister for Health and Aged Care Mark Butler's website from July 1, 2024 "the sale, supply, manufacture, importation, and commercial possession of non-therapeutic vapes will be prohibited, with very serious penalties for those individuals and businesses that contravene the laws".

The company said that vaping medicinal cannabis, or live rosin, cartridges was "popular due to reduced toxin exposure, less odor, throat irritation and increased discretion compared to inhaling dried flower".

ECS said vape cartridges "were more convenient, healthier, and socially acceptable for patients seeking immediate therapeutic benefits".

The company said it had taken a further \$3.4 million in its asset finance facility with the National Australia Bank, which increased its total facility to \$4.4 million.

ECS said the funds would be used to increase its marijuana production and sales.

ECS was unchanged at 1.8 cents with 2.6 million shares traded.

## ARO A BIOSURGERY

Aroa says its annual general meeting will vote to issue managing-director Brian Ward up to 961,255 performance rights and director Darla Hutton 140,110 shares.

Aroa said Mr Ward's performance rights were part of his long-term incentive and would have a maximum total value of about \$NZ568,000 (\$A517,000), subject to performance milestones including three-year revenue and earnings before interest, taxation, depreciation and amortization (Ebitda) results.

The company said the performance shares were in addition to Mr Ward's fixed annual salary of \$NZ585,000, including superannuation; and Ms Hutton would be issued shares worth \$NZ40,000 a year, for two years, in addition to her \$NZ111,500 annual fees.

The company said the meeting would vote to elect Ms Hutton, John Pinion and Philip McCaw as directors and approve the auditor's remuneration.

The meeting will be held online and in person at 64 Richard Pearse Drive, Auckland, New Zealand on July 23, 2024 at 9am (AEST).

Aroa fell half a cent or 0.8 percent to 64.5 cents.

### [RADIOPHARM THERANOSTICS](#)

Radiopharm chair Paul Hopper says his 94,221,428 share-holding in the company was diluted from 20.5 percent to 8.9 percent following a placement.

In June, Radiopharm said it raised \$7.5 million at 5.0 cents a share in a placement to the North Billerica, Massachusetts-based radio-pharmaceutical company Lantheus; and later, said it had “firm commitments” to raise a further \$62.5 million at 4.0 cents a share in a placement, taking the total raised to \$70 million (BD: Jun 20, 25, 2024).

Today, the Melbourne-based Mr Hopper said he held the shares with Deborah Coleman and Kilinwata Investments Pty Ltd.

Radiopharm was up 0.05 cents or 1.4 percent to 3.55 cents with 1.4 million shares traded.

### [RADIOPHARM THERANOSTICS](#)

The Hong Kong-based Nanomab Technology Ltd says it has ceased its substantial shareholding in Radiopharm.

Nanomab said that on July 1, 2024 it acquired 6,117,230 shares for four cents a share in Radiopharm’s placement, with other unrelated parties acquiring 591,013,497 shares in the placement at the same price (see above).

In May, Nanomab said its 28,295,131 share-holding in Radiopharm was diluted from 8.6 percent to 6.1 percent (BD: May 24, 2024).

According to its most recent filing, Radiopharm had 1,057,497,778 shares on offer, meaning that Nanomab’s 34,412,361 shares amounted to about to 3.25 percent of the company.

### [NEXT SCIENCE](#)

The Sydney-based Walker Family No.1 Pty Ltd says it has received 52,276,092 shares (17.94%) in Next Science following the death of Lang Walker.

In January, Biotech Daily reported the death of Mr Walker of the Walker Corporation and Auckland Trust Co, who was a major biotechnology investor, including in Acrux, Atomo, BTC Health, Medical Australia, Neuren and QRX Pharma (BD: Jan 29, 2024).

Today, the Walker Family No.1 Pty Ltd said as trustee for the Walker Family Trust it had received the shares as an “exempt acquisition pursuant to the will of Mr Walker”.

Next Science was unchanged at 21 cents.

### [EPSILON HEALTHCARE](#)

Epsilon says Xiao (Josh) Cui “has been terminated effective immediately” as its company secretary and that Marcelo Mora will continue in the role.

Epsilon was in a suspension and last traded at 2.4 cents.