Biotech Daily

Tuesday September 23, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: TELIX UP 9%; PROTEOMICS DOWN 9%**

*** VICTORIA: 'MODERNA mRNA FACTORY WORTH $220m A YEAR'**

*** ONE MONTH TO AUSBIOTECH INVEST, CONFERENCE**

*** TELIX: CMS GRANTS GOZELLIX TRANSITIONAL PASS-THROUGH STATUS**

*** ALCIDION ADDS MIZAIC'S MEDIVIEWER TO NORTH CUMBRIA CONTRACT**

*** CLINUVEL SCENESSE EURO EPP RESTRICTIONS LIFTED**

*** MICRO-X WINS $4.4m FEDERAL GRANT FOR STROKE AMBULANCE**

*** NEUROTECH MARIJUANA NTI164 AUTHORIZED PRESCRIBER PROGRAM**

*** NOXOPHARM EXTENDS $2.6m NOTES, TAKES $1.25m CHAIR FRED BART LOAN**

*** AROVELLA RECEIVES $3.2m FEDERAL R&D TAX INCENTIVE**

*** ALGORAE LICENCES 5 GENERIC CANCER DRUGS FROM INDIA**

*** LTR 4m DIRECTOR OPTIONS AGM**

*** INVEX REQUESTS 'ACQUISITION, ASX PRICE QUERY' TRADING HALT**

*** ARTRYA EX-M-D JOHN BARRINGTON DILUTED TO 5.1%**

*** KARST PEAK REDUCES BELOW 5% OF CURVEBEAM**

*** MARK FLADRICH TO REPLACE MEDICAL DEVELOPMENTS CHAIR GORDON NAYLOR**

*** PERCHERON APPOINTS PROF EUGENE KENNEDY CMO, VALENTINA DUBLJEVIC CTO**

MARKET REPORT

The Australian stock market was up 0.4 percent on Tuesday September 23, 2025, with the ASX200 up 35.0 points to 8,845.9 points. Fifteen of the Biotech Daily Top 40 companies were up, 15 fell, nine traded unchanged and one was untraded.

Telix was the best (see below), up $1.38 or 9.2 percent to $16.38, with 9.25 million shares traded. Actinogen and Avita climbed more than six percent; Syntara was up 4.2 percent; Clinuvel rose 3.8 percent; Aroa, Immutep and Impedimed improved two percent or more; Compumedics, Emvision, Nanosonics and Orthocell were up more than one percent; with CSL, EBR, Neuren and Polynovo up by less than one percent.

Proteomics led the falls, down three cents or 8.6 percent to 32 cents, with 964,260 shares traded. Amplia lost 5.7 percent; Curvebeam and Starpharma fell more than four percent; Alcidion and Genetic Signatures shed more than three percent; Medical Developments and Prescient were down more than two percent; 4D Medical, Cyclopharm, Imricor, Mesoblast, Micro-X and SDI were down more than one percent; with Clarity, Cochlear, Pro Medicus and Resmed down by less than one percent.

VICTORIA GOVERNMENT

The Victoria Government says its partnership with Moderna "is supporting around 1,000 jobs across the country and injecting $220 million into the economy each year".

A media release from Victoria Minister for Economic Growth and Jobs Danny Pearson said that a report by the Sydney-based Oxford Economics Australia, commissioned by Moderna, said the mRNA manufacturing facility had the capacity to produce up to 100 million vaccine doses a year and during its two-year construction period, contributed $493 million to national gross domestic product and supported 1,830 jobs each year.

The media release said that the Moderna Technology Centre at Monash University's Clayton campus and Moderna's partnership with the Victoria Government "strengthens Australia's capacity to respond to future pandemics by enabling faster access to locally produced vaccines".

The State Government said that Moderna was investing $266 million directly in national mRNA research and development between 2023 and 2033, supporting research partnerships, clinical trials and workforce development.

The Victoria Government said the activities were expected to generate an additional $267 million in national economic value over 10 years, including $117 million in Victoria.

The Victoria Government said that the state was "the only place in the world where both mRNA global leaders, Moderna and Biontech, have established research and development and manufacturing operations".

The Government said it had invested more than $1 billion in health and medical research over the past decade, "driving growth in the sector, creating jobs and supporting incredible breakthroughs in treatment and care".

Mr Pearson said the Moderna agreement was "a once-in-a-generation investment in medical research positioning Victoria at the heart of advanced biomedical innovation".

"This facility will strengthen our health system, support jobs, and deliver vaccines that Australians can rely on to help protect us against diseases," Mr Pearson said.

The report, titled 'Australia's mRNA Advantage – Jobs, Health and Economic Resilience' is available at: https://bit.ly/4mwuVRR.

The report concluded: "The economic and social returns on this investment are substantial".

"Input-output modelling indicates that the facility will support $220 million in GDP annually during operations and sustain nearly 1,000 national jobs," the Oxford Economics Australia report concluded.

AUSBIOTECH

Ausbiotech says its 'Ausbiotech Invest 2025' event is on October 21, 2025 at Melbourne's Crown Casino, to be followed by its conference at the Melbourne Convention Centre.

Details and registration for the Ausbiotech investment day are available at: https://www.ausbiotech.org/events/event/ausbioinvest-2025.

Last month, Ausbiotech said that its 2025 conference would include more than 250 speakers in more than 60 sessions "exploring the issues and innovations shaping the future of biotech, both here in Australia and around the world" (BD: Aug 20, 2025).

At that time the industry organization said the conference would include a rapid-fire pitch competition for companies to present to partners, investors and collaborators as well as keynote addresses and panel discussions on cell and gene therapies, manufacturing, clinical trials and emerging and innovative technologies.

Ausbiotech said the investor day was October 21, with the conference October 22 to 24.

Registration and ticket prices are available at: https://ausbiotechic.com/register/.

TELIX PHARMACEUTICALS

Telix says the US Centers for Medicare & Medicaid Services (CMS) has granted transitional pass-through (TPT) payment status for Gozellix for imaging prostate cancer.
In March, Telix said the US Food and Drug Administration approved its new drug application for TLX007-CDx, or 'Gozellix', with gallium-68 for positron emission tomography (PET) scanning of prostate-specific membrane antigen (PSMA)- positive lesions in men with prostate cancer and in July said that the CMS granted a permanent healthcare common procedure coding system code for Gozellix (BD: Mar 21, Jul 9, 2025).
Today, Telix said that the TPT designation enabled separate reimbursement for Gozellix under the Hospital Outpatient Prospective Payment System (HOPPS), effective from October 1, 2025, and was "a significant milestone in [its] US commercial strategy" and patients were not subject to the 20 percent patient co-insurance under the TPT.
Telix said that after radio-labelling with 68Ga, Gozellix was indicated for PET scanning of PSMA positive lesions in men with prostate cancer who had suspected metastasis and were candidates for initial definitive therapy, and those with suspected bio-chemical recurrence (BCR) based on elevated serum prostate-specific antigen (PSA) level.
The company said that Gozellix had a longer shelf life of up-to six hours and an extended distribution radius compared to existing gallium-based products, helping to overcome logistical barriers that historically limited access to PSMA-PET imaging.
Telix precision medicine chief executive officer Kevin Richardson said Gozellix TPT status was "a strong endorsement of the clinical value of our next-generation imaging agent".
"Gozellix is already available nationally, and this reimbursement milestone will reduce the out-of-pocket burden for patients, enhance patient access to advanced prostate cancer imaging and simplify payment for providers," Mr Richardson said. "As the only provider with two FDA-approved and reimbursed products in this class, we are pleased to make PSMA-PET/CT imaging accessible to more patients and providers across the US."
Telix was up $1.38 or 9.2 percent to $16.38 with 9.25 million shares traded.

ALCIDION GROUP

Alcidion says it has a contract expansion with North Cumbria Integrated Care NHS Foundation Trust to deliver the Chelmsford England-based Mizaic's Mediviewer.
Alcidion said the addition would expand the Miya Precision electronic patient record (EPR) contract to $6.8 million over 9.4 years and provide "seamless access to scanned and historical documents in clinical workflows".
The company said that Mizaic's Mediviewer was an electronic document management system (EDMS) which would digitize the National Health Service Trust's paper records, making them accessible directly in the Miya Precision EPR.
Alcidion said that the approach meant that all patient records were accessible through a single user interface, whether recorded directly in Miya Precision or uploaded using a healthcare specific EDMS.
The company said that Mediviewer was chosen for its healthcare-specific, intuitive design and clinical usability, offering intelligent indexing, and optical character recognition technology, helping clinicians locate the right documents quickly.
Alcidion said that Mediviewer was in use by more than 20 NHS trusts.
Alcidion managing-director Kate Quirke said Mediviewer inside Miya Precision "provides the seamless user experience that has resulted in Miya Precision being recognized by the NHS for its exceptional usability … [and] digitization of patient health records lays the foundation for the adoption of emerging technologies".
Alcidion fell 0.3 cents or 3.1 percent to 9.4 cents with 1.3 million shares traded.

CLINUVEL PHARMACEUTICALS

Clinuvel says the European Medicines Agency will amend the Scenesse label to enable adult erythropoietic protoporphyria patients to receive treatment every two months.
Clinuvel said that the label "removes a recommended maximum annual dose of four implants per year and harmonizes treatment posology [dose] in Europe with the US, where many patients receive year-round therapy".
The company said that the European Medicines Agency (EMA) Committee for Medicinal Products for Human Use (CHMP) issued a positive opinion on the benefit-risk profile of year-round Scenesse (afamelanotide 16mg), having evaluated two phase III studies and more than 15 years of Scenesse use under compassionate, special access and commercial programs.
Clinuvel said the Committee recognized the clinical need for erythropoietic protoporphyria (EPP) patients to receive year-round treatment and concluded there were "no significant safety concerns with the ongoing administration of Scenesse every two months".
The company said the variation was effective immediately.
Clinuvel chief scientific officer Dr Dennis Wright said the company had "requests from EPP expert physicians to facilitate year-round treatment in Europe and we are pleased that the [Committee's] positive opinion will enable EPP patients to receive year-round treatment for this very debilitating condition".
"There was a strong logic to removing the maximum dose restriction in Europe," Dr Wright said. "It also harmonizes the label with the US."
Dr Wright said physicians were administering Scenesse in vitiligo at one dose every three weeks and the two programs, EPP and vitiligo, would assist the next regulatory dossier".
Clinuvel was up 43 cents or 3.8 percent to $11.65 with 317,894 shares traded.

MICRO-X, FEDERAL GOVERNMENT

Micro-X says the Federal Industry Growth Program has granted it $4.4 million to build and trial a stroke capable ambulance using its Head CT device under development.
Micro-X said that its Head computed tomography (CT), weighed about 70kg, one tenth of a traditional CT device and was capable of being fitted into a standard ambulance.
The company said the grant contract was being finalized and would fund development of the Head CT prototype in partnership with the South Australian Ambulance Service and Royal Adelaide Hospital.
Micro-X said the ambulance trial intended to advance device integration with tele-medicine, develop a paramedic training program, ambulance and hospital emergency protocols, and a reader study showing clinical acceptance of imaging captured by paramedics in the stroke ambulance to support medical device regulatory submissions.
Micro-X chief executive officer Kingsley Hall said the $4.4 million was "a significant step towards getting our stroke diagnosis device into ambulances around the world".
"Stroke is the second leading cause of death globally and we know that time to treatment is pivotal," Mr Hall said. "We must find ways to get patients diagnosed and treated faster."
Micro-X said the funding would be used to manufacture the first ambulance-ready Head CT scanner prototype, build and fit a South Australian ambulance with the prototype, and conduct patient imaging and workflow testing.
The company said that subject to clinical and ethics approval, the second phase will see the launch of a full patient imaging trial to collect data from stroke patients being transported to hospital in the stroke ambulance, with diagnostic decisions to be made based on imaging taken following the patient's arrival at the Royal Adelaide Hospital.
Micro-X fell 0.1 cents or 1.3 percent to 7.8 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has an authorized prescriber (AP) program for its marijuana NTI164, for a range of neuro-developmental conditions for paediatric patients in Australia.
Neurotech said the program would be managed by Melbourne's Monash Medical Centre paediatric neurologist Prof Michael Fahey "ensuring strong clinical oversight and structured implementation".
The company said the program followed "increasing demand from patients and their families seeking access to NTI164, with limited capacity available within the … current clinical trials".
Neurotech said the program was designed to ensure patient access while being cost-neutral, with pricing "set at a level that covers the cost of supply in addition to a modest margin … [allowing] the program to fund itself while generating valuable real-world data, without being positioned as a material revenue driver".
The company said that a central objective of the program was the generation of data on NTI164, to complement the ongoing and planned clinical and registration trials.
Neurotech said that the program established early adoption and market presence for NTI164 ahead of pivotal clinical trials and potential registration.
The company said the AP program followed changes to the National Disability Insurance Scheme (NDIS), which would see children with mild to moderate autism spectrum disorder diverted from the NDIS and into a newly established program by mid-2027.
Neurotech managing-director Dr Anthony Filippis said: the authorized prescriber program "marks an important step forward in our commercial access strategy".
Neurotech was up 0.1 cents or 6.25 percent to 1.7 cents.

NOXOPHARM

Noxopharm says its existing $2,600,000 convertible noteholders have approved the extension of the maturity date to January 2, 2027, subject to shareholder approval.
Noxopharm said the extension would allow access to the Federal Research and Development Tax Incentive of about $2,800,000 for the year to June 30, 2025.
The company said the noteholders would be paid accrued interest of $327,000 in aggregate on the convertible notes in cash for the period ending January 2, 2026, with the interest accruing from January 2, 2026 capitalized daily until maturity.
Noxopharm said "as an incentive, the noteholders would be granted 520,000 additional unlisted options, allocated in the same manner as the original options attached to the convertible notes" exercisable at 14.88 cents each by September 10, 2027.
The company said it had a $1,250,000 unsecured loan at 12 percent a year, with 4F Investments Pty Ltd, an entity owned and controlled by Noxopharm chair Fred Bart, the same interest rate payable to the noteholders and to be used for working capital.
Noxopharm said that the loan would be rolled into a convertible note if approved by shareholders at the upcoming annual general meeting, including the grant of 250,000 options, exercisable at 14.88 cents each by September 10, 2027.
Noxopharm fell one cent or 9.1 percent to 10 cents.

AROVELLA THERAPEUTICS

Arovella says it has received $3.21 million from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.
Arovella said the rebate related to expenditure for the year to June 30, 2025.
Arovella was up 0.1 cents or 1.1 percent to 8.9 cents.

ALGORAE (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says it has a licence with the Ahmedabad, Gujarat, India-based Sakar Healthcare to launch five generic cancer drugs in Australia and New Zealand.
Algorae said it had begun regulatory planning for Australian Therapeutic Goods Administration registration.
The company said that Sakar was a pharmaceutical manufacturing company with a portfolio including sterile injectables, dry powder injectables, oral liquids, tablets and capsules.
Algorae said the agreement was its "first step in establishing a commercial presence in Australia and New Zealand, complementing its ongoing research and development initiatives".
Algorae chief commercial officer Vishal Shah said the Sakar licence agreement was the company's "first commercial deal for the Australian and New Zealand markets with five key generic oncology medicines".
"These products will be marketed under the Algorae brand," Mr Shah said.
Algorae chair David Hainsworth said the agreement with Sakar was "a significant milestone as Algorae expands its commercial footprint, enhances patient access to trusted therapies, and positions the company for long-term growth".
"This partnership allows us to leverage Sakar's established manufacturing capabilities," Mr Hainsworth said.
Algorae was up 0.2 cents or 25 percent to one cent with 16.6 million shares traded.

LTR PHARMA

LTR says its annual general meeting will vote to grant three directors 4.000,000 options exercisable at 50.75 cents within four years.
LTR said that shareholders would vote to issue 2,000,000 options to chair Lee Rodne and 1,000,000 options each to directors Dr Julian Chick and Maja McGuire.
The company said that shareholders would vote on the remuneration report, the re-election of director Ms McGuire, the ratification of the prior and future issue of shares, adoption of the employee incentive scheme and the issue of 8,300,000 options to Alpine Capital, exercisable at 60 cents each within two years from issue.
The meeting will be held at K&L Gates, 16/66 Eagle Street, Brisbane, on October 24, 2025 at 2pm (AEST).
LTR fell 6.5 cents or 8.9 percent to 66.5 cents.

INVEX THERAPEUTICS

Invex has requested a trading halt "pending the release of a material acquisition announcement and responses to an ASX price query".
Trading will resume on September 25, 2025 or on an earlier announcement.
Invex last traded up half a cent or 3.2 percent to 16 cents.

ARTRYA

Artrya co-founder and former managing-director John Barrington says his 7,475,253 share-holding has been diluted from 6.42 percent to 5.08 percent.
Earlier this month Artrya said it had "binding commitments" for a $75 million placement at $2.05 a share, with an up-to $5 million share plan to follow (BD: Sep 9, 2025).
Artrya was up nine cents or 4.1 percent to $2.27 with 1.7 million shares traded.

CURVEBEAM A.I.

Karst Peak Capital Management LLC says it sold shares from February 6, to September 19, 2025 reducing its holding below the five percent substantial level.
The Hong Kong and Cayman Island-based Karst Peak Capital said its most recent sale was 300,000 shares for $34,500 or 11.5 cents a share.
Curvebeam fell half a cent or 4.35 percent to 11 cents.

MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says that Mark Fladrich will replace chair Gordon Naylor, effective from December 1, 2025.
Medical Developments said that Mr Fladrich was appointed a director in April 2025 and had more than 30 years of experience in the pharmaceutical industry.
The company was currently the chair of Qbiotics and was formerly the Aachen, Germany-based Grunenthal's chief commercial officer and prior to that spent 23 years at Astrazeneca as an executive.
According to his Linkedin page, Mr Fladrich held a Bachelor of Pharmacy from the University of South Australia.
Medical Developments fell two cents or 2.9 percent to 66 cents.

PERCHERON THERAPEUTICS

Percheron says it has appointed Prof Eugene Kennedy, based in Philadelphia, as chief medical officer and Valentina Dubljevic as its chief technology officer.
Percheron said that Prof Kennedy received his medical degree from the Richmond, Virginia-based Medical College of Virginia, with postgraduate training in surgical oncology at Johns Hopkins School of Medicine in Baltimore, Maryland.
The company said that Prof Kennedy was appointed professor of surgery at the Thomas Jefferson University in Philadelphia, Pennsylvania.
Percheron said Prof Kennedy was appointed chief medical officer to "a number of oncology-focused biotechnology companies, including several companies focused substantially on the development of immunotherapy programs for cancer" including Carisma Therapeutics.
The company said that Ms Dubljevic completed her scientific training at Griffith University in Brisbane and at the Royal Melbourne Institute of Technology, before a 12-year career as a research scientist at Monash University.
Percheron said that Ms Dubljevic has worked with ASX-listed biotech companies in scientific and operational roles since 2008 and most recently was the head of scientific and clinical development at Patrys.
According to her Linkedin page, Ms Dubljevic held a Bachelor of Biomedical Science from Griffith University and a Master of Biotechnology and Business from the Royal Melbourne Institute of Technology.
Percheron was up 0.1 cents or 11.1 percent to one cent with 1.6 million shares traded.