# Biotech Daily

Monday September 29, 2025

*Daily news on ASX-listed biotechnology companies*

*** ASX, BIOTECH UP: BOTANIX UP 10%; CURVEBEAM DOWN 15%**

*** CSIRO BIO-BANKING REPORT: 'COORDINATION COULD ADD $39m'**

*** CURVEBEAM $6.5m PLACEMENT; $18m 'FINANCE FACILITY'**

*** CHIMERIC: 'CDH17 FURTHER DISEASE CONTROL, TUMOR SHRINKAGE'**

*** NYRADA PHASE I XOLATRYP TRIAL MEETS SAFETY PRIMARY ENDPOINT**

*** CLINUVEL UNDISCLOSED MELANO-CORTIN PRE-CLINICAL STUDIES**

*** MAYNE: NEXTSELLIS WINS AUSTRALIAN PBS REIMBURSEMENT**

*** ISLAND FILES GALIDESIVIR FDA TYPE C DOCUMENTS**

*** ASX SUSPENDS USCOM FOR 'FINANCIAL CONDITION'**

*** ONCOSIL TELLS ASX: 'TRIAL DATA CONFIDENTIAL UNTIL RELEASE'**

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*** AUSTCO 633k M-D CLAYTON ASTLES RIGHTS AGM**

*** ANATARA APPOINTS DIRK VAN DISSEL DIRECTOR; TRADING HALT**

## MARKET REPORT

The Australian stock market was up 0.85 percent on Monday September 29, 2025, with the ASX200 up 75.1 points to 8,862.8 points. Twenty of the Biotech Daily Top 40 were up, 15 fell, four traded unchanged and one was untraded. The four Big Caps were mixed.

Botanix was the best, up 1.5 cents or 9.7 percent to 17 cents, with 21.25 million shares traded; followed by Imugene, up 2.5 cents or 9.3 percent to 29.5 cents, with 3.3 million shares traded. Proteomics climbed 4.3 percent; Actinogen, Amplia, Optiscan and Paradigm were up more than three percent; Alcidion, CSL, Immutep, Medadvisor and Medical Developments rose two percent or more; Clinuvel, Compumedics, Neuren, Prescient, Resmed and Telix were up more than one percent; with EBR, Mesoblast, Micro-X and Polynovo up by less than one percent.

Curvebeam led the falls, down 1.6 cents or 14.55 percent to 9.4 cents, with 1.5 million shares traded. Impedimed lost 5.6 percent; Cynata, Orthocell and Syntara fell four percent or more; Aroa, Genetic Signatures, Imricor and Nova Eye were down more than three percent; Avita, Clarity and Nanosonics were down more than one percent; with 4D Medical, Cochlear, Cyclopharm, Emvision and Pro Medicus down less than one percent.

## COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

The CSIRO says that coordinating Australia's 200 bio-banks and four million stored samples would increase their value by about $39 million.
The CSIRO report, titled 'Valuation of increased coordination in Australian bio-banking', is available at: https://bit.ly/4nu422j.
The CSIRO said the report "estimates that a national platform for searching and accessing human bio-specimens and data could deliver annual benefits worth $39 million".
The Organisation said the benefits would stem from improved coordination across Australian bio-banks and cohort studies, enhancing research efficiency and outcomes.
The CSIRO said the report was a partnership with the National Collaborative Research Infrastructure Strategy (NCRIS) Health Group, New South Wales Health, Queensland Health, the University of Sydney, the University of New South Wales and Medical Advances Without Animals Trust.
The Organisation said the bio-banks and stored specimens were "critical infrastructure that underpins bio-medical, clinical, public and population health research".
CSIRO Futures health and biosecurity lead Greg Williams said national coordination "offers a range of benefits: reducing the time required to search and access bio-specimens or data; accelerating research progress; promoting the utilization of existing bio-banks; guiding the establishment, expansion or retirement of collections; and improving overall risk management".
"These aspects are essential to promote international collaborations, attract biopharmaceutical companies and increase the outputs of biobanks and cohort studies," Mr Williams said.
The CSIRO said the report provided five major recommendations: conducting a comprehensive survey of bio-banks and cohort studies; implementing a shared national discovery and access platform; establishing a national governance framework for human health bio-banking; promoting a consistent quality management framework at the national level; and establishing a national steering committee to guide coordination initiatives.

## CURVEBEAM A.I.

Curvebeam says it has "commitments" for a $6.5 million placement at nine cents a share and has a EUR10 million ($A18 million) vendor financing facility agreement.
Curvebeam said the issue price was a 24.4 percent discount to the fifteen-day volume weighted average price and a 21.5 percent discount to the five-day volume weighted average price and an 18.2 percent discount to the last closing price.
The company said that the funds would be used for sales and marketing of its Hirise weight-bearing computed tomography device, research and development, supply chain costs and general working capital.
Curvebeam said that the financing facility was with an unnamed "specialist Swiss financing partner specializing in life science and health technology companies".
The company said that, with the financing partner, it would design vendor financing programs expected to support the sale of its devices in orthopaedic surgeon offices.
Curvebeam said the finance would cover the production and deployment costs of Hirise including a $US220,000 allowance for overheads, paid down quarterly over four years from the monthly lease charge to the clinician for the full Hirise purchase price.
The company said that by "introducing the ability for surgeons to use vendor financing to access the Hirise device those practices that may be capital constrained will now have ability to purchase the company's Hirise device".
Curvebeam fell 1.6 cents or 14.55 percent to 9.4 cents with 1.5 million shares traded.

## CHIMERIC THERAPEUTICS

Chimeric says its 15-patient, phase I/II trial of CDH17 has led to “further disease control and tumor shrinkage” and is safe for colorectal, gastric and neuro-endocrine tumors.
Last year, Chimeric said it enrolled the first of 15 patients in its phase I/II trial of CDH17 chimeric antigen receptor (CAR) T-cell therapy, or CHM2101, for colorectal and gastric cancer and intestinal neuroendocrine tumors (BD: Jul 22, 2024).
Last month, the company said it began level two dosing at 150 million cells in its phase I/II trial of CDH17 CAR T-cells for gastro-intestinal cancers (BD: Aug 4, 2025).
Today, Chimeric said four patients had been treated at dose level two, with two “having undergone tumor assessments showing ‘mixed responses’ with their total burden of disease decreasing by 12 percent in colorectal cancer and between six-to-16 percent in neuro-endocrine tumor, resulting in … stable disease for both patients”.
The company said a “mixed response” was described when some tumors get smaller, but others do not, with one tumor decreasing in size by 37 percent.
Chimeric said stable disease meant the cancer had shrunk up-to 30 percent.
The company said it would follow the responses and await the results of two additional patients, with no evidence of off-target effects or gastro-intestinal toxicity.
Chimeric said one of four colorectal cancer patients who received 50 million cells at dose level one continued to showdemonstrate stable disease more than 10 months after receiving a single dose of CDH17, with one of the patient’s tumors decreasing by 18 percent “and the response continuing to deepen over time”.
Chimeric was up 0.1 cents or 33.3 percent to 0.4 cents with 71.8 million shares traded.

## CLINUVEL PHARMACEUTICALS

Clinuvel says it will conduct in-vivo studies of sustained-release liquid drug formulations to extend the duration of peptide drugs, with an initial focus on melano-cortins.
In 2023, Clinuvel said it would launch melanocortin products under the Neuracthel name for neurological, endocrinological and degenerative disorders (BD: Jan 23, 2023).
At that time, the company said that Neuracthel was the third of its melanocortin-based drugs, and contained ACTH as the active pharmaceutical ingredient, while Scenesse and Prénumbra contained afamelanotide.
Today, Clinuvel said research and development at its Singapore laboratories Vallaurix had provided “positive, consistent results demonstrating the potential for depot formulations to extend the duration of release of peptide drugs”.
The company said its formulation development had “sought to lengthen the duration of time that peptides are detectable in blood levels and arrive at predictable kinetics, optimizing patient exposure to active pharmaceutical ingredients while minimizing dosing to achieve therapeutic effects”.
Clinuvel said the advantage of the formulations under review was “to facilitate flexible dosing by adjusting the injection volume for delivery of peptides to infants, children and adults according to body weight”.
The company said that if the technology was “confirmed in-vivo, the new depot formulations would serve as a platform for the delivery of various peptides, with an initial focus on melano-cortins”, with the pre-clinical program expected to complete in 2026.
Clinuvel chief scientific officer Dr Dennis Wright said it had “been challenging to realize the journey from drug delivery concepts to effective formulations containing the right drug loading, but recent reproducible in-vitro results at Vallaurix have given us confidence to pursue the pre-clinical program”.
Clinuvel was up 18 cents or 1.6 percent to $11.48 with 99,803 shares traded.

## MAYNE PHARMA GROUP

Mayne Pharma says its Nextsellis oral contraceptive will be reimbursed in Australia by the Pharmaceutical Benefits Scheme from October 1, 2025.
Mayne said Nextsellis was approved by the Australian Therapeutic Goods Administration in November 2021 and was the first and only approved contraceptive pill containing oestetrol, and a progestin, namely drospirenone.
The company said oestetrol was a natural oestrogen produced by the human body during pregnancy and in Nextsellis was derived from a plant source to match the body's naturally occurring oestetrol.
Mayne said without listing on the Pharmaceutical Benefits Scheme, Nextsellis would cost more than $328 a year.
The company said that with the Pharmaceutical Benefits Scheme listing, women would able to access Nextsellis for $31.60 for three months' supply, which would reduce to $25 from January 1, 2026.
Mayne Pharma said that concession card holders able would be able to access Nextsellis for $7.70 for three months' supply.
Mayne Pharma fell four cents or 0.8 percent to $5.12 with 317,412 shares traded.

## NYRADA INC

Nyrada says its 48-participant, phase I trial shows Xolatryp, formerly NYR-BI03, met its primary endpoint and is safe and well-tolerated, with no dose-limiting safety issues.
Earlier this year, Nyrada said it had begun recruiting its 40-volunteer, phase I trial of NYR-BI03; and last month, said it had safety review committee approval to dose the sixth and final cohort in the trial (BD: Mar 17, Jul 14, 2025).
Last month, the company said the trial showed Xolatryp was safe and well-tolerated at all six dose levels and concentrations, with no dose-limiting toxicities (BD: Aug 6, 2025).
Today, Nyrada said it had completed unblinded safety and pharmaco-kinetic data from the contract research organization, with the data to be used for its human research ethics committee submission to support a planned phase IIa study.
The company said 10 adverse events were recorded after dosing in eight participants, with 14 percent of dosed patients reporting adverse events and 25 percent of placebo patients reporting adverse events, with only four considered related to Xolatryp.
Nyrada said it was on-track to begin dosing its phase IIa trial by April 2026.
Nyrada was up 1.5 cents or 5.3 percent to 30 cents.

## ISLAND PHARMACEUTICALS

Island says it has submitted its briefing documents to the US Food and Drug Administration for a type C meeting for galidesivir for Marburg virus disease.
In July, Island said that it had acquired the Durham, North Carolina-based Biocryst Pharmaceuticals' galidesivir for up-to $US2.5 million ($A3.8 million) (BD: Jul 31, 2025).
Earlier this month, the company said it would have a type C meeting with the US Food and Drug Administration for its investigational new drug application for galidesivir for Marburg virus disease (BD: Sep 19, 2025).
Today, Island said the documentation included background on galidesivir's historical clinical development, pharmacokinetic and safety data, non-human primate study results and the use of 'Animal Rule' for approval.
Island fell one cent or 2.4 percent to 40 cents with 1.1 million shares traded.

## USCOM

The ASX has suspended Uscom under Listing Rule 17.3, “not at entity’s request”, as it is in breach of Listing Rule 12.2 regarding “an entity’s financial condition”.
The ASX said it determined Uscom’s financial condition was “not adequate to warrant the continued quotation of its securities”.
Last month, Uscom said revenue for the year to June 30, 2025 fell 30.6 percent to $2,620,450 with net loss after tax up 59.2 percent to $3,302,759, saying revenue fell 25 percent “due to global market disruptions … [including] tariff wars, geopolitical instability, constrained health budgets, and tougher regulatory environments”. (BD: Sep 2, 2025).
Today, the ASX said in making its determination it regarded Uscom’s financial statements for the year to June 30, 2025 and the disclaimer in the auditor’s report.
In its annual report filed to the ASX on September 26, 2025, Uscom’s auditor BDO (Binder Dijker Otte) said the company’s ability to continue as a going concern depended on funding from capital markets and continued financial support from its shareholders, including the renewal or extension of loans and its ability to attract equity or debt funding.
The auditor said it had “been unable to obtain sufficient appropriate audit evidence to support the feasibility of management’s plans … [including] management’s inability to provide support to evidence the ability and willingness of related parties to provide ongoing financial support to the group”.
Uscom last traded at 1.2 cents.

## ONCOSIL MEDICAL

Oncosil has told the ASX trial results were confidential until presented and it requested a trading halt to release the data before the market open on September 17, 2025.
The ASX asked Oncosil whether it considered data from a trial of its pancreatic cancer device by the Netherlands’ Amsterdam University Medical Center were material, when it first became aware of the information and the time and date the results were presented at a conference in Barcelona, Spain held from September 13 to 17, 2025.
Oncosil said it considered the ‘Pancosil’ trial results were material and that the data was collected and owned by Amsterdam University Medical Center and remained confidential and not available to the company until the time of the presentation at 4:15pm (Spanish time) on September 16, or 12:15am (AEST) on September 17, 2025.
The company said that on September 5 it had announced that preliminary results would be presented on September 16, 2025 and it had put in place an ASX trading halt pre-open on September 17, 2025 “to undertake the necessary analysis and interpretation of the results and their meaningfulness to Oncosil’s operating business”.
Oncosil said its board approved the release of an ASX announcement on the morning of September 18, 2025 and requested the removal of the ASX trading halt.
The company said it was not aware of what the data presentation would contain.
Oncosil was up 1.5 cents or 0.9 percent to a post 400-to-one consolidation $1.67.

## INVEX THERAPEUTICS

Invex has requested an extension to its voluntary suspension pending an acquisition announcement and responses to an ASX price query (BD: Sep 23, 25, 2025).
Last week, Invex requested a suspension following the trading halt which it requested on September 23 (BD: Sep 23, 25, 2025).
Today, the company said it expected to resume trading on September 30, 2025.
Invex last traded at 16 cents.

## AUSTCO HEALTHCARE

Austco says its annual general meeting will vote to issue managing-director Clayton Astles 632,649 long-term incentive performance rights.
Austco said the rights were valued at about $234,080 and were in addition to Mr Astles' $595,329 annual salary, fees and commissions, $290,073 cash bonus, $53,911 other benefits and $87,051 equity in settled options and performance rights.
The company said investors would vote to adopt the remuneration report, re-elect directors Graeme Billings and Ann Larkins, ratify the issue of shares under its Amentco acquisition, approve the incentive plan and its 10 percent placement capacity.
The meeting will be held online on October 29, 2025 at 11am (AEDT).
Austco fell half a cent or 1.4 percent to 36 cents.

## ANATARA LIFESCIENCES

Anatara says it has appointed Dirk van Dissel as a director replacing Jonathan Lindh who returns to company secretary and has requested a capital raising trading halt.
Anatara said Mr van Dissel had more than 20 years of experience in private equity, boutique investment banking and stockbroking and had "particular expertise in the identification and evaluation of early-stage healthcare projects".
Separately, Anatara requested a trading halt "pending an announcement regarding a capital raising".
Trading will resume on October 1, 2025, or on an earlier announcement.
Anatara last traded at 1.6 cents.