Biotech Daily

Thursday August 28, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: EMVISION UP 6%; TELIX DOWN 19%**

*** TELIX: FDA CITES 'DEFICIENCIES' IN TLX250-CDx RESPONSE LETTER**

*** TRAJAN REVENUE UP 7% TO $166.5m; LOSS DOWN 82% TO $4.5m**

*** SOMNOMED REVENUE UP 22% TO $111m; LOSS DOWN 72% TO $3.5m**

*** SDI REVENUE FLAT AT $110m; PROFIT UP 17% TO $12m**

*** CLINUVEL REVENUE UP 8% TO $95m; PROFIT UP 1.5% TO $36m**

*** ALCIDION RECORD REVENUE UP 10% TO $41m; LOSS TO $1.65m PROFIT**

*** CYCLOPHARM RECORD H1 REVENUE UP 26% TO $15m; LOSS UP 2% TO $8m**

*** NOVA EYE RECORD REVENUE UP 25% TO $29m; LOSS UP 3% TO $9m**

*** LUMOS REVENUE UP 11% TO $19m; LOSS UP 16% TO $11m**

*** MICRO-X REVENUE DOWN 14% TO $13m; LOSS UP 42% $14m**

*** IMPEDIMED REVENUE UP 23% TO $12.7m; LOSS UP 17% TO $23m**

*** CURVEBEAM REVENUE UP 85% TO $12.1m; LOSS DOWN 27% TO $17m**

*** CLEVER CULTURE REVENUE UP 77% TO $5m; LOSS TO $1.7m PROFIT**

*** VITASORA REVENUE UP 6-FOLD TO $3.1m; LOSS UP 42% TO $10m**

*** DIMERIX $6m REVENUE FROM DMX-200 LICENCES**

*** CONTROL BIONICS $2.1m RIGHTS OFFER**

*** RHYTHM: 'KNOW YOUR LEMONS' FOR US GENETYPE BREAST CANCER TEST**

*** STARPHARMA RECEIVES $3.7m FEDERAL R&D TAX INCENTIVE**

*** NEXT SCIENCE EGM 96% BACKS $76m DEMETRA SALE**

*** INHALERX MARIJUANA IRX-616a FOR PANIC TRIAL APPROVED**

*** US ALLOWS AROVELLA PATENT FOR CAR-INKT PLATFORM**

*** INVION TELLS ASX: 'AWARE OF FDA DECISION DAY BEFORE'**

*** DORSAVI APPOINTS ARTRYA'S MATHEW REGAN CEO**

MARKET REPORT

The Australian stock market was up 0.22 percent on Thursday August 28, 2025, with the ASX200 up 19.5 points to 8,980.0 points. Seven of the Biotech Daily Top 40 companies were up, 22 fell, nine traded unchanged and two were untraded. All four Big Caps fell.

Emvision was the best, up 11 cents or 5.8 percent to $2.01, with 112,421 shares traded; followed by Medadvisor, up 0.3 cents or 5.7 percent to 5.6 cents, with 1.75 million shares traded. Imugene improved 3.7 percent; Aroa and Neuren rose more than two percent; with Nanosonics and Polynovo up by less than one percent.

Telix led the falls (see below), down $3.45 or 18.75 percent to $14.95, with 10.6 million shares traded. Atomo lost 10 percent; Clarity, Clinuvel, Compumedics and Cynata shed seven percent or more; Curvebeam and Dimerix were down more than six percent; 4D Medical and Medical Developments were down more than five percent; Alcidion, Impedimed and Prescient fell more than four percent; Botanix and Starpharma were down more than three percent; Mesoblast, Micro-X, Optiscan and Pro Medicus shed two percent or more; CSL, EBR, Paradigm and Resmed were down more than one percent; with Avita, Cochlear and SDI down by less than one percent.

TELIX PHARMACEUTICALS

Telix says a complete response letter from the US Food and Drug Administration cites deficiencies in its biologics licence application for TLX250-CDx for renal cancer.
Telix said the FDA found “deficiencies relating to the chemistry, manufacturing and controls package” of TLX250-CDDx, or Zircaix.
The company said the FDA had “requested additional data to establish comparability between the drug product used in the ‘Zircon’ phase III clinical trial and the scaled-up manufacturing process intended for commercial use”.
In 2023, Telix said it began an FDA biologics licence application for its positron emission tomography (PET) imaging agent TLX250-CDx for clear cell renal cell carcinoma imaging, following a 300-patient phase III trial showing TLX250-CDx had 86 percent sensitivity and 87 percent specificity (BD: Nov 7, 2022; Dec 19, 2023).
Last year, the company said the FDA rejected the application (BD: Jul 31, 2024).
Today, Telix said the FDA “documented notices of deficiency issued to two third-party manufacturing and supply partners that will require remediation prior to resubmission”.
The company said the concerns were readily addressable, with remediation to begin immediately and a type A meeting with the FDA to be requested as soon as possible to address the deficiencies and determine a timeframe for resubmission.
Telix said TLX250-CDx had breakthrough therapy and priority review status “acknowledging its importance in addressing a significant unmet medical need and clinically demonstrating benefit over available diagnostics”.
Telix managing-director Dr Chris Behrenbruch said TLX250-CDx was the first biological PET imaging agent to be submitted to the FDA and “like many radio-pharmaceuticals, it has a complex supply chain, and as the field advances this creates new challenges around the regulatory framework applied to these products”.
The company said the FDA complete response letter did not impact its revenue guidance for 2025, as guidance excluded revenue forecasts from unapproved products.
Telix said it intended to continue providing “patient access to TLX250-CDx through the FDA-approved expanded access program, subject to consultation with the FDA”.
Telix fell $3.45 or 18.75 percent to $14.95 with 10.6 million shares traded.

TRAJAN GROUP

Trajan says revenue for the year to June 30, 2025 was up 7.4 percent to $166,462,000, with net loss after tax down 82.4 percent to $4,460,000.
Trajan said increased revenue from its “products, devices and solutions that are used in the analysis of biological, food, and environmental samples” was “driven by the end of global destocking in 2023-’24 and achieved despite a headwind of $3.9 million caused by the … loss of a specialized biotech syringe revenue stream”.
The company said “during the year, the US announced new tariffs on imports from Australia and trade partners globally [and] as Trajan’s US operations import products from many countries, Trajan is obliged to pay the tariffs”.
Trajan said it had “implemented various strategies to recover the additional costs”.
The company said diluted loss per share was down 82.5 percent to 2.9 cents, net tangible assets per share rose 9.1 percent to 12 cents and it had cash and equivalents of $11,851,000 at June 30, 2025 compared to $11,243,000 at June 30, 2024.
Trajan was up half a cent or 0.5 percent to 93.5 cents.

SOMNOMED

Somnomed says revenue for the year to June 30, 2025 was up 21.6 percent to $111,492,941, with net loss after tax down 71.8 percent to $3,456,329.
Somnomed said revenue was from sales of its Somnodent products for obstructive sleep apnoea, snoring, bruxism and other sleep-related breathing disorders.
The company said Europe sales rose 17.1 percent to $61,431,000, with North America up 31.0 percent to $43,048,000 and Asia Pacific sales up 10.7 percent to $7,014,000.
Somnomed said sales and marketing expenses were down 12.5 percent to $22,913,729 and it had financial costs including interest on borrowings and leases fell 87.4 percent to $398,502 compared to the prior corresponding period.
Last year, the company said its net tangible asset backing per share was 10.0 cents, with no figure disclosed this year (BD: Aug 28, 2024).
Somnomed said diluted loss per share fell 83.9 percent to 1.63 cents and it had cash and equivalents of $17,293,446 at June 30, 2025 compared to $16,178,843 at June 30, 2024.
Somnomed was up 1.5 cents or 1.9 percent to 79 cents.

SDI (FORMERLY SOUTHERN DENTAL INDUSTRIES)

SDI says revenue for the year to June 30, 2025 fell 0.7 percent to $110,384,000, with net profit after tax up 16.7 percent to $12,160,000.
SDI said revenue was from sales of its dental equipment and dental aesthetics, amalgam and whitening products, with reduced sales in the Middle East due to regional conflicts.
SDI chief executive officer Samantha Cheetham said the company saw “continued sales growth in aesthetic products, underpinned by ongoing new product development, and an improvement in whitening sales”.
“We managed our operating expenses well and saw further improvement on gross margins,” Ms Cheetham said.
SDI said it would pay an unchanged fully-franked dividend of 1.9 cents on September 22 to shareholders on the record date of September 8, 2025.
The company said diluted earnings per share was up 16.6 percent to 10.23 cents, net tangible asset backing per share rose 9.1 percent to 58.23 cents and it had cash and equivalents of $8,981,000 at June 30, 2025 compared to $6,275,000 at June 30, 2024.
SDI fell half a cent or 0.6 percent to 89 cents.

CLINUVEL PHARMACEUTICALS

Clinuvel says revenue for the year to June 30, 2025 was up 7.7 percent to $95,017,570, with net profit after tax up 1.5 percent to $36,172,518.
Clinuvel said revenue was “driven by robust demand” for its Scenesse, or afamelanotide 16mg, for adults with erythropoietic protoporphyria, primarily in Europe and the US, with expenses up 20 percent to $53.7 million reflecting costs associated with its vitiligo clinical program.
The company said it was the ninth consecutive year of profit, with expenses controlled to support expansion.
Clinuvel said it would pay a fully-franked dividend equal to the prior year of 5.0 cents a share on September 19, 2025 to investors on the record date of September 5.
The company said diluted earnings per share was up 2.9 percent to 71.8 cents, net tangible assets per share increased 18.7 percent to $4.77 and it had cash, cash equivalents and term deposits of $224,106,000 at June 30, 2025 compared to $183,868,000 at June 30, 2024.
Clinuvel fell $1.02 or 7.5 percent to $12.53 with 205,572 shares traded.

ALCIDION GROUP

Alcidion says that record revenue for the year to June 30, 2025 was up 10.0 percent to $40,786,000 with last year’s $8,417,000 net loss turned to a $1,654,000 profit.
Alcidion said revenue was from sales and contracts of its Miya Precision hospital management and patient care software and electronic patient record systems in the UK, New Zealand and Australia.
Alcidion chief executive officer Kate Quirke said the company “delivered a record result this year across multiple key metrics, revenue, [earnings before interest, taxation, depreciation and amortization] and operating cashflow”.
The company said diluted loss per share of 0.64 cents in the prior corresponding period turned to diluted earnings per share of 0.12 cents, with net tangible assets per share down 60.0 percent to negative 0.2 cents.
Alcidion said that it had cash and equivalents of $17,697,000 at June 30, 2025, compared to $11,798,000 at June 30, 2024.
Alcidion fell half a cent or 4.8 percent to 10 cents with 2.5 million shares traded.

CYCLOPHARM

Cyclopharm says record revenue for the six months to June 30, 2025 was up 25.6 percent to $15,422,971, with net loss after tax up 2.4 percent to $7,687,875.
Cyclopharm said revenue was from sales of its Technegas lung imaging device for pulmonary embolism as well as distribution of third-party products and servicing.
The company said materials and manufacturing costs were up 33.35 percent to $7.2 million, employee expenses increased 14.3 percent to $8.8 million and administrative costs rose 14.8 percent to $5.8 million.
Cyclopharm managing-director James McBrayer said that with record revenues, expanded US adoption and strengthened intellectual property protection the company had “never been better positioned”.
The company said diluted loss per share fell 11.1 percent to 6.96 cents, net tangible assets per security fell 28.9 percent to 27 cents and it had cash and equivalents of $12,410,539 at June 30, 2025 compared to $27,562,359 at June 30, 2024.
Cyclopharm was unchanged at $1.00.

NOVA EYE MEDICAL

Nova Eye says revenue for the year to June 30, 2025 was up 25.5 percent to a record $29,267,000, with net loss after tax up 3.1 percent to $9,059,000.

Nova Eye said increase revenue reflected “continued adoption” of its Itrack Advance consumable surgical device for glaucoma, with improved gross margin and a reduced operating expenditure as a percentage of sales.

Nova Eye managing-director Tom Spurling said the year to June 30, 2025 “was a record year for Nova Eye, marked by continued strong US sales growth”.

“Importantly, our 2024-’25 result demonstrates that the group is nearing [earnings before interest, taxation, depreciation and amortization] positive, validating the strength of our business model,” Mr Spurling said.

The company said diluted loss per share fell 15.1 percent to 3.66 cents, with net tangible asset backing per share down 34.1 percent to 2.9 cents.

Nova Eye said that it had cash and cash equivalents of $5,055,000 at June 30, 2025 compared to $6,151,000 at June 30, 2024.

Nova Eye was unchanged at 14.5 cents.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says revenue for the year to June 30, 2025 was up 11.4 percent to $US12,400,000 ($A19,042,000) with net loss after tax down 16.4 percent to $US7,183,000 ($A11,031,000).

Lumos said revenue from sales of its Febridx and Viradx blood tests for bacterial and viral respiratory infections and influenza and Covid-19, respectively, were up 46.3 percent $US1,823,000, with revenue from its diagnostic test development and manufacturing services up seven percent to $US10,577,000.

The company said general and administration costs were up 32.7 percent to $US4,238,000, with employee expenses up 4.4 percent to $US8,375,000.

Lumos said diluted loss per share fell 42.7 percent to 1.06 US cents, with negative net tangible assets per share down 62.2 percent to negative 0.14 US cents.

The company said that it had cash of $US1,956,000 at June 30, 2025 compared to $US6,479,000 the prior year.

Lumos was up half a cent or 3.85 percent to 13.5 cents with 14.2 million shares traded.

MICRO-X

Micro-X says revenue for the year to June 30, 2025 was down 14.3 percent to $13,053,000, with net loss after tax up 42.3 percent to $13,895,000.

Micro-X said revenue from engineering and contract services rose 18.7 percent to $10,463,0000, sales of its Rover mobile x-ray fell 70.8 percent to $1,561,000 and it had $246,000 in Argus bomb detection x-ray sales compared to no sales the prior year.

The company said its increased loss was “largely driven by reduced product sales and the $1,453,000 impairment of Argus inventory as a result of the discontinuation of the Argus product following the strategic refocus on medical applications”.

Micro-X said diluted loss per share was up 23.2 percent to 2.28 cents, with net tangible assets per share down 53.3 percent to 1.14 cents.

The company said that it had cash and equivalents of $3,242,000 at June 30, 2025 compared to $3,228,000 at June 30, 2024.

Micro-X fell 0.2 cents or 2.5 percent to 7.7 cents with 1.3 million shares traded.

IMPEDIMED

Impedimed says revenue for the year to June 30, 2025 was up 23.3 percent to $12,724,000 with net loss after tax up 17.4 percent to $23,237,000.
Impedimed said revenue was from sales of its Sozo bioimpedance spectroscopy for monitoring body fluid, with a record 74,000 tests conducted in the three months to June 30, 2025, up nine percent on the prior corresponding period.
The company said diluted loss per share was constant at 1.0 cent, with net tangible assets per share down 69.7 percent from 1.22 cents to 0.37 cents and it had cash and cash equivalents of $22,183,000 at June 30, 2025 compared to $24,632,000 at June 30, 2024.
Impedimed fell 0.2 cents or 4.65 percent to 4.1 cents with 3.5 million shares traded.

CURVEBEAM A.I.

Curvebeam says revenue for the year to June 30, 2025 was up 85.3 percent to $12,096,583 with net loss after tax down 27.1 percent to $16,842,748.
Curvebeam said sales of its weight-bearing computed tomography devices rose 97.6 percent to $8,890,876, with warranty services revenue up 38.6 percent to $1,875,728 and “other operating revenue” up 97.8 percent to $1,329,979.
The company said diluted loss per share was down 44.7 percent to 4.49 cents, last year’s negative 0.05 net tangible assets per share was up to negative 0.84 cents in the year to June 30, 2025 and it had cash and cash equivalents of $5,041,148 at June 30, 2025, compared to $6,448,450 at June 30, 2024.
Curvebeam fell one cent or 6.7 percent to 14 cents.

CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture says revenue for the year to June 30, 2025 was up 77.0 percent to $5,461,000, with last year’s $3,740,000 loss turned to a $1,684,000 net profit after tax.
Clever Culture said revenue was from sales, leasing, licencing and maintenance of its automated plate assessment system (Apas) Independence for microbiology analysis.
The company said it had diluted earnings per share of 0.08 cents compared to a diluted loss per share of 0.40 cents in the prior year, with net tangible assets per share even at 0.16 cents and cash and cash equivalents of $1,265,000 at June 30, 2025 compared to $2,347,000 at June 30, 2024.
Clever Culture fell 0.2 cents or 5.9 percent to 3.2 cents with 4.3 million shares traded.

VITASORA HEALTH (FORMERLY RESPIRI)

Vitasora says revenue for the year to June 30, 2025 was up 577.1 percent to $3,093,889, with net loss after tax up 41.7 percent to $10,105,042.
Vitasora said revenue was from service and software fees, subscription sales as well as other charges relating to its remote patient monitoring and chronic care management products.
The company said since its acquisition of Orb Health it had “realized substantial merger synergies”, with annualized savings of about $US1.78 million and it had incurred one-off restructuring and merger-related expenses (BD: Jan 21, 2025).
Vitasora said diluted loss per share was up 2.9 percent to 0.72 cents, net tangible assets per share rose 120 percent to 11 cents and it had cash and cash equivalents of $394,240 at June 30, 2025 compared to $762,874 at June 30, 2024.
Vitasora was unchanged at 2.9 cents.

DIMERIX

Dimerix says revenue for the year to June 30, 2025 was $5,913,803 due to the receipt of licence payments relating to its DMX-200 for focal segmental glomerulosclerosis.
Last month, Dimerix said it had $54,562,000 in customer receipts for the year due to licencing agreements (BD: Jul 23, 2024; Jan 19, Mar 4, May 30, 6, Jul 25, 2025).
Today, the company said it had $55,579,053 in non-current recorded revenue, with net loss after tax was up 85.5 percent to $31,682,144.
Dimerix said diluted loss per share fell 37.4 percent to 2.36 cents, last year's 3.31 cent net tangible assets per share turned to a negative 0.93 cents and it had cash of $68,283,812 at June 30, 2025 compared to $22,141,466 at June 30, 2024.
Dimerix fell three cents or 6.3 percent to 44.5 cents with 3.1 million shares traded.

CONTROL BIONICS

Control Bionics says it expects to raise $2.062 million at 3.5 cents a share in a one-for-five, partially-underwritten, non-renounceable rights offer.
Control Bionics said the issue price was a 12.44 percent discount to the volume weighted average price since August 1, 2025.
The company said the funds would be used for commercializing its Neurostrip including software development, clinical trials, manufacturing, marketing and "strategic investment".
Control Bionics said the offer was underwritten to $1,150,610 by its two largest shareholders Nightingale Partners and Phoenix Development Fund, with distributor Start Beyond and managing-director Jeremy Steele underwriting $300,000 and $40,000 of the offer, respectively, with the underwriters to receive a five percent fee.
Control Bionics said the offer had a record date of September 2, would open on September 4 and close on September 15, 2025.
Control Bionics was up 0.2 cents or 5.3 percent to four cents.

RHYTHM BIOSCIENCES

Rhythm says it has partnered with non-profit organization Know Your Lemons Foundation to market Genetype breast cancer risk assessment test in the US.
Last year, Rhythm said it would acquire Genetic Technologies' Genetype risk assessment test for various diseases for $625,000 in cash; and later, said it had its first commercial sale for an undisclosed price (BD: Jan 19, Mar 19, 2025).
Today, the company said the partnership with the Lewisville, Idaho-based Know Your Lemons was previously with Genetic Technologies and it had formalized and re-established the deal and was "actively collaborating on the rollout, which includes blogs, webinars and education that will promote awareness and uptake of Genetype".
Rhythm said the agreement ensured Genetype breast cancer risk assessment test would "be actively promoted through the Know Your Lemons at Work breast health benefit employee community, reaching hundreds of thousands of women in the US".
Rhythm was unchanged at 10 cents.

STARPHARMA HOLDINGS

Starpharma says it has received $3.7 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.
Starpharma said the incentive related to expenditure for the year to June 30, 2025.
Starpharma fell half a cent or 3.85 percent to 12.5 cents with 1.1 million shares traded.

NEXT SCIENCE

Next Science says its extraordinary general meeting has approved overwhelmingly the $US50 million ($A76 million) sale of its main undertaking to Demetra Holding SpA.
In July, Next Science said it had an asset purchase agreement to sell “substantially all” of its assets and subsidiaries for $US50 million to Milan, Italy’s Demetra Holdings SpA, pending shareholder approval (BD: Jul 1,28, 2025).
At that time, the company said the transaction included the sale of its regulatory approvals, intellectual property, inventory, records and goodwill, but excluded assets related to its durable medical equipment business.
Today, Next Science said that 169,032,162 votes (95.89%) approved the sale, with 7,236,258 votes (4.11%) against.
Next Science was unchanged at 14.5 cents.

INHALERX

Inhalerx says Adelaide’s Bellberry has approved its 24-participant, randomized, blinded, controlled phase I trial of marijuana-based IRX-616a for panic disorder.
Inhalerx said the single ascending dose study at Adelaide’s Cmax clinical research facility was designed to evaluate the safety, tolerability, and pharmaco-kinetics of IRX-616a in healthy adult volunteers across three cohorts, each receiving a single inhaled dose of IRX616a or placebo.
The company said that IRX616a was a synthetic cannabidiol (CBD) aerosol formulated for delivery via a pressurized metered-dose inhaler.
Inhalerx said the mode of administration was “intended to achieve rapid systemic absorption … enabling an on-demand treatment option for acute panic attacks”.
The company said that CBD peak plasma levels were typically observed within three to 10 minutes.
Inhalerx said it expected the first participant dosing “in the coming months”.
The company said that panic disorder was “the experience of recurrent and disabling panic attacks which last up to a few minutes and are accompanied by physical symptoms such as heart palpitations, shaking, shortness of breath and dizziness”.
Inhalerx said there were no effective treatments, with sufferers forced to rely on atypical antidepressants, sedatives and anti-convulsants.
Inhalerx fell 0.4 cents or 11.4 percent to 3.1 cents.

AROVELLA THERAPEUTICS

Arovella says the US Patent and Trademark Office has allowed a patent application protecting its invariant natural killer T-cell (iNKT) platform.
Arovella said that, when granted, the patent, titled ‘Transduction and Expansion of Cells’ would protect its intellectual property until “at least February 28, 2039, subject to any patent term adjustment”.
The company said that the iNKT cell therapy platform was under licence from London’s Imperial College Innovations.
Arovella said that the allowance accompanied granted patents in Europe, Canada and Hong Kong, an accepted patent application in Australia; and additional corresponding applications, including divisional patent applications in Cananda, China, Europe and Hong Kong.
Arovella was up half a cent or 5.95 percent to 8.9 cents with 1.2 million shares traded.

INVION

Invion has told the ASX it became aware of FDA orphan drug status for INV043 for anal cancer the afternoon prior to its announcement of the information.
The ASX asked Invion when it became aware that it had received US Food and Drug Administration orphan drug designation for INV043 for anal cancer and whether it believed the approval was material information.
Invion said it believed the information, announced on August 20, 2025, was material and that “an officer of the company only became aware of the information around the time a trading pause was put in place by ASX in the afternoon of August 19, 2025”.
The company said “the FDA decision was not communicated to Invion prior to becoming available on the FDA website”.
Invion was unchanged at 13 cents.

DORSAVI

Dorsavi says it has appointed former Artrya chief executive officer Mathew Regan as its chief executive officer, effective from November 1, 2025.
Last month, Artrya said it appointed John Konstantopoulos chief executive officer to prepare for the US launch of Salix for coronary plaque identification (BD: Jul 1, 2025).
Today, Dorsavi said Mr Regan’s appointment came “at a pivotal time for Dorsavi as the company advances the commercialization of its next-generation [remote random-access memory]-enabled sensor architecture and explores broader applications through its reflex platform”.
According to his Linkedin profile, Mr Regan held a Bachelor of Science from Perth’s Edith Cowan University and a Master of Information Technology from Perth’s University of Western Australia.
Dorsavi was up 0.4 cents or 9.3 percent to 4.7 cents with 14.3 million shares traded.