Biotech Daily

Tuesday September 9, 2025

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: IMRICOR UP 17%; 4D MEDICAL DOWN 27.5%**

*** ARTRYA RAISES $75m, SHARE PLAN FOR UP-TO $5m MORE**

*** TELIX, FDA AGREE RE-ANALYSIS FOR TLX101-CDx (PIXCLARA) RE-FILING**

*** NEUREN, 'HOPE FOR HIE' PARTNER ON NNZ-2591**

*** CANN: NAB NON-WAIVER FOR $1.4m UNPAID INTEREST, FEES**

*** LUMOS APPOINTS AMTECH 2nd AUSTRALIA, NZ FEBRIDX DISTRIBUTOR**

*** LUMOS COMPLETES $5m TENMILE, RYDER LOAN**

*** CORRECTIONS: PROTEOMICS, PATRYS**

*** OSTEOPORE, TAN TOCK SENG $59k HIP-JOINT PARTNERSHIP**

*** PROTEOMICS TO LOSE M-D DR RICHARD LIPSCOMBE; CEO WANTED**

*** TRAJAN TO LOSE DIRECTOR SARA WATTS AT AGM**

*** PATRICK COOK REPLACES ATOMO INTERIM CHAIR JOHN KELLY - TO M-D**

*** DR THOMAS DUTHY TO REPLACE ONCOSIL CHAIR DOUG CUBBIN**

*** DORSAVI APPOINTS EDWARD DOLLER RRAM ADVISOR**

MARKET REPORT

The Australian stock market fell 0.52 percent on Tuesday September 9, 2025, with the ASX200 down 46.1 points to 8,803.5 points. Nine of the Biotech Daily Top 40 companies were up, 25 fell and six traded unchanged.

Imricor was the best, up 23.5 cents or 17.2 percent to $1.60, with 473,845 shares traded. Curvebeam climbed 13.0 percent; Emvision was up 11.6 percent, Amplia improved 6.45 percent; Micro-X was up 5.75 percent; Actinogen rose 3.7 percent; Medical Developments, Mesoblast and Telix were up more than one percent; with Resmed up 0.7 percent.

4D Medical led the falls, having climbed from 77 cents for four trading days in a row, down 63.5 cents or 27.5 percent to $1.675, with 29.3 million shares traded. Cynata and Starpharma lost more than seven percent; Immutep and Nova Eye were down more than six percent; Paradigm, Polynovo and Resonance retreated more than five percent; Compumedics, Cyclopharm and Nanosonics fell four percent or more; Botanix, Dimerix, Imugene and Orthocell were down more than three percent; Alcidion, Aroa, Avita, Medadvisor and Neuren shed two percent or more; Clarity, Clinuvel, CSL, EBR, Genetic Signatures and Optiscan were down more than one percent; with Cochlear and Pro Medicus down by less than one percent.

ARTRYA

Artrya says it has “binding commitments” for a $75 million placement at $2.05 a share, with an up-to $5 million share plan to follow.
Artrya said the placement share price was a 4.7 percent discount to the 10-day volume weighted average price, with $60 million to be issued through a first tranche and the remaining $15 million to be issued in a second tranche, subject to shareholder approval at a general meeting on or about October 24, 2025.
The company said proceeds would go to US commercialization and expansion, customer support, market access and reimbursement, product development, research and development, working capital and its ‘Saphire’ plaque study.
Artrya said the share plan had a record date of September 8, 2025, would open September 15 and close October 3, with eligible shareholders entitled to apply for up-to $30,000 at the same price as the placement.
The company said it reserved the right to accept oversubscriptions for the share plan, at the discretion of the board, or place any of the share plan shortfall.
Artrya said Petra Capital was the sole lead manager and bookrunner for the placement.
Artrya fell five cents or 2.3 percent to $2.13 with three million shares traded.

TELIX PHARMACEUTICALS

Telix says the US Food and Drug Administration has agreed to an existing data analysis for its new drug application resubmission for TLX101-CDx (Pixclara) for glioma imaging.
Telix said that it had “reached agreement” with the FDA for its TLX101-CDx, or floretyrosine-18, new drug application for “an additional confirmatory efficacy study analysis of existing data to supplement the NDA and address the review matters cited in the complete response letter (CRL)”.
Last year, Telix said the US Food and Drug Administration had granted fast-track designation for Pixclara positron emission tomography (PET) for glioma, or brain cancer, imaging; and later filed an NDA for the imaging agent with the FDA, which had granted ‘priority review’ for the submission (BD: Apr 16, Aug 28, Oct 24, 2024).
In April, the company said that in “a complete response letter” the FDA required “additional confirmatory clinical evidence” for TLX101-CDx for glioma, and said the FDA ruled that the application could not be approved in its “current form”, requiring additional confirmatory clinical evidence (BD: Apr 28, 2025).
Today, Telix said it had received “detailed feedback” from the FDA regarding its new drug application resubmission, including a type-A meeting with the Administration.
The company said it planned to resubmit the application by January 2026, and said the FDA would advise it of a new prescription drug user fee act (PDUFA) goal date following successful resubmission.
The company said the FDA “acknowledged the unmet medical need” and “indicated that an expedited review is likely to be granted on this basis, subject to submission review”
Telix chief medical officer Dr David Cade said “Telix had multiple options for delivering additional data requested by the FDA in the CRL response”.
“This flexibility has enabled us to work with relative speed to reach a mutually agreed path forward for resubmission of the NDA,” Dr Cade said. “We remain steadfastly focused on our goal of bringing this important imaging agent to patients in the US to support improved diagnosis and management of glioma.”
Telix said it remained “committed to providing ongoing patient access to TLX101-CDx through the FDA-approved expanded access program up until US regulatory approval”.
Telix was up 22 cents or 1.6 percent to $13.82 with 5.2 million shares traded.

NEUREN PHARMACEUTICALS

Neuren says it has partnered with Detroit, Michigan's Hope for Hypoxic-Ischemic Encephalopathy (HIE) to develop NNZ-2591 for the condition.

Earlier this year, Neuren said it was developing NNZ-2591 to treat multiple neuro-developmental disorders for which there are no approved treatments, including Pitt Hopkins and Angelman syndromes as well as hypoxic-ischemic encephalopathy, with a phase III Phelan-McDermid syndrome trial being prepared, and later included SYNGAP1-related disorder (SRD) (BD: Feb 24, Mar 27, May 13, Aug 8, 2025).

Today, the company said Hope for HIE connected families, researchers, clinicians and biotechnology, among others, to improve the quality of life for children and families impacted by neo-natal and paediatric-acquired hypoxic ischemic encephalopathy.

Neuren said HIE was a brain injury from when a baby's brain does not receive enough oxygen or blood flow before or shortly after birth, and said that it was one of the leading causes of neo-natal death and neuro-developmental disability, with thousands of children suffering every year.

The company said HIE could lead to symptoms in surviving children including developmental delays, cognitive impairment, cerebral palsy and seizures, as well as potential serious long-term complications that could impact them into adulthood.

Neuren said the only approved treatment for HIE was temporary hypothermia, which meant cooling the head or whole body to lower the baby's metabolic rate and give the brain time to recover from the hypoxic event, but said that 40 to 45 percent of children had "significant neuro-development impairment at two years of age" after treatment.

Hope for HIE executive director Betsy Pilon said "the collaboration with Neuren Pharmaceuticals reflects a powerful alignment in values, placing family perspectives and lived experiences at the centre of research to meet critical unmet needs".

Neuren chief science officer Larry Glass said that the company had "a long history of partnerships with patient advocacy organizations which have contributed significantly to our progress in other indications".

"Hope for HIE's knowledge, experience and commitment will contribute meaningfully to an innovative development program," Mr Glass said.

Neuren fell 60 cents or 2.9 percent to $20.20 with 1.2 million shares traded.

CANN GROUP

Cann says it has a letter of non-waiver from the National Australia Bank (NAB) for $1,378,152 in quarterly and six-monthly interest and facility fees due in "late August 2025".

Cann said that the National Australia Bank (NAB) had confirmed that, while "reserving its rights and remedies it will not be taking any action at this time".

Last year, the company said it had extended its fully-drawn $15.6 million NAB loan to March 31, 2025, and NAB agreed to defer the quarterly repayment of the principal loan amounts of its $49.4 million construction facility to May 2025 (BD: Mar 18, 2024).

Later, Cann said NAB would defer $900,000 in quarterly interest and facility fee payments, which was due November 22, 2024 (BD: Nov 27, 2024).

Earlier this year, the company said the National Australia Bank would extend the maturity dates of its construction and working capital loans from May 31 to September 30, 2025 (BD: Feb 11, 2025).

Today, Cann said it continued to "engage constructively with NAB and other financiers in relation to its financing arrangements" including the interest and facility fee, and expected to update the market by the end of September 2025.

Cann fell 0.1 cents or 8.3 percent to 1.1 cents with 3.4 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says it has appointed the Whanganui, New Zealand-based Amtech as its second Australia and New Zealand distributor for its Febridx finger-prick blood test.

Lumos said its Febridx point-of-care test helped healthcare professionals differentiate between bacterial and viral acute respiratory infections in about 10 minutes, supporting clinical decision-making and potentially reducing unnecessary antibiotic prescriptions.

The company said Amtech was part of Yes Group, an Australia and Asia medical and safety supplies network, that operated in both Australia and New Zealand, with more than 150 employees and 25,000 products.

Lumos chief executive officer Doug Ward said “we are delighted to expand Febridx distribution in Australia and New Zealand through this new partnership with Yes Group”.

“With their reach and long-standing presence in the local healthcare market, alongside our existing agreement with Henry Schein, we are well positioned to make Febridx more widely accessible to clinicians,” Mr Ward said.

In 2023, Lumos said Henry Schein would sell Febridx test in Spain, Portugal and the Netherlands; and in 2024, said the deal included the US, Australia, New Zealand and Belgium (BD: Jul 18, Aug 16, 2023; Feb 12, Jul 4, Jul 9, 2024).

Lumos fell half a cent or 3.3 percent to 14.5 cents with 7.5 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says it has completed the $5.0 million loan from major shareholders Dr Andrew ‘Twiggy’ Forest’s Tenmile Ventures and Ryder Capital Management.

In July, the company said it taken a $5.0 million loan from Tenmile and Ryder to fund operations as it progressed towards US Food and Drug Administration clinical laboratory improvement amendments (CLIA) waiver for its Febridx finger-prick blood test differentiating viral from bacterial respiratory infections (BD: Jul 17, 2025).

Lumos said all drawdowns would be “at the discretion of the company and based on funding needs”.

In August, Lumos said it had filed a clinical laboratory improvement amendments (CLIA) waiver with the US Food and Drug Administration for its Febridx, and that it had an ASX Listing Rule 10.1 waiver allowing it to grant “a first-ranking general security over its assets” without shareholder approval for a $5 million loan (BD: Aug 13, 18, 2025).

Today, the company said it extinguished the previous convertible note arrangement, with an unused second tranche of $4.0 million with New York’s Lind Global Fund II and Melbourne’s SBC Global Investment Fund terminated (BD: Nov 21, 2022).

CORRECTION: PROTEOMICS INTERNATIONAL LABORATORIES

Last night’s edition misunderstood the Proteomics announcement and quoted old data rather than the news that the oesophageal cancer test was 81 to 100 percent accurate.

The headline and first sentence were incorrect and should have read:

* ‘Proteomics: Promarker Eso Sensitivity 81% TO 100%’

Proteomics says a 350-patient study of its Promarker Eso blood test for oesophageal cancer shows sensitivity from 81 percent to 100 percent depending on cancer stage.

Biotech Daily apologizes unreservedly for the error.

The Monday sub-editor is no more.

Proteomics was unchanged at 32 cents with 1.0 million shares traded.

CORRECTION: PATRYS

Last night's edition included an incorrect number of redundancy shares to be issued to Dr James Campbell, with the gross and nett numbers appearing as separate resolutions.
If approved by the annual general meeting, director and former managing-director Dr Campbell will receive a total of 160,526,930 shares, without the incorrectly reported additional 117,525,790 shares.
Biotech Daily apologizes to Patrys and Dr Campbell for the error.
The Monday sub-editor absconded in a Westerly direction.
Patrys fell 0.05 cents or 25 percent to 0.15 cents with 1.7 million shares traded.

OSTEOPORE

Osteopore says it has a $S50,000 ($A59,101) grant to partner with Singapore's Tan Tock Seng Hospital to develop an implant to treat avascular necrosis at the hip joint.
Osteopore said that under the 12-month partnership it would work with Tan Tock Seng's Dr Michael Yam to design and perform the necessary proof-of-concept tests for an implant that provided better outcomes for core decompression of avascular necrosis of the hip.
The company said avascular necrosis occurred when the blood supply was interrupted, leading to death of bone tissue, and occurred in joints, and mostly at the hip joint.
Osteopore said avascular necrosis could cause pain and discomfort, with conditions to worsen over time and the potential for the hip joint bone to collapse without treatment, at which point total hip replacement was the most effective treatment.
Osteopore said the grant was from Tank Tock Seng's owner NHG Health, with the collaboration to begin September 2025 and ending with "potential first-in-human milestones".
Osteopore fell 0.05 cents or 4.35 percent to 1.1 cents with 52.0 million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says founder and managing director Dr Richard Lipscombe will retire in February 2026, coinciding with his 25th anniversary with the company.
Proteomics said Dr Lipscombe would continue as managing-director until his successor was appointed and the transition completed.
Proteomics chair Dr James Williams said "we thank Richard for his outstanding contribution as founder and managing director over the past 25 years".
"Under his leadership, Proteomics International has grown into a global leader in precision diagnostics and precision medicine," Dr Williams said.
"We also recognize the importance of planned succession," Dr Williams said.
"This transition provides an opportunity to further strengthen the company's leadership in support of the commercialization of our world-class technology," Dr Williams said.
Dr Richard Lipscombe said "I am deeply proud of all we have accomplished since founding Proteomics International back in 2001".
"When we started … precision medicine was a concept and now our world-leading innovations are helping to make it a reality," Dr Lipscombe said.
"It has been an honor to lead this organization through a period of technological break-throughs and commercial progress to the cusp of rolling-out multiple tests on two continents," Dr Lipscombe said.
Proteomics said it would recruit a chief executive officer with experience in diagnostics, medical technology and digital health commercialization.

TRAJAN

Trajan says non-executive director Sara Watts will retire at its annual general meeting on October 28, 2025.
Trajan said Ms Watts joined the board in March 2021, prior to its initial public offer.
Trajan fell half a cent or 0.6 percent to 79.5 cents.

ATOMO DIAGNOSTICS

Atomo says it has appointed non-executive director Patrick Cook as chair, with interim chair John Kelly returning to managing-director.
Earlier this year, Atomo said it was restructuring and appointed Anthony May and Patrick Cook as directors, with chair John Keith and directors Deborah Neff and Dr Paul Kasian to resign, and managing-director John Kelly as interim chair (BD: Apr 24, May 23, 2025).
Today, the company said Mr Cook had more than 35 years' experience as an executive in medical devices and point-of-care diagnostics sectors, including as a non-executive director and chair at Workplace Drug Testing Australasia and E Waste Connection.
According to Linkedin, Mr Cook held a Bachelor of Applied Science from the New South Wales Institute of Technology.
Atomo was unchanged at 1.9 cents with 1.1 million shares traded.

ONCOSIL MEDICAL

Oncosil says non-executive director Dr Thomas Duthy will replace chair Doug Cubbin, on $150,000 a year, effective from October 1, 2025.
Oncosil said Dr Duthy joined the board as director on July 11, 2025 and was the founder and director of corporate advisory firm Nemean Group, as well as the former head of corporate development and investor relations at Sirtex Medical.
The company said Mr Cubbin had been chair since August 2023, and would continue as a non-executive director.
Oncosil was up 36 cents or 29.0 percent to $1.60.

DORSAVI

Dorsavi says it has appointed Edward Doller as an advisor for its resistive random access memory (RRAM)-enabled sensors, robotics and neuromorphic computing.
Earlier this year, Dorsavi said it would pay $S1,100,000 ($A1,320,000) for the Singapore Nanyang Technological University's resistive random-access memory (RRAM) technology to extend the battery life of its wearable sensors (BD: Jun 12, 2025).
Today, Dorsavi said Mr Doller had more than 35 years of experience in the computer storage and memory industry, including senior executive and technology leadership roles at companies including Micron Technology and International Business Machines Corp (IBM), as well as a chief technology officer at Numonyx and Intel.
The company said Mr Doller held a Bachelor of Science from West Lafayette, Indiana's Purdue University.
Dorsavi was up 0.1 cents or 2.3 percent to 4.5 cents with 2.7 million shares traded.