Biotech Daily

Tuesday September 2, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH EVEN: POLYNOVO UP 10%; STARPHARMA DOWN 8%**

*** PRO MEDICUS WINS US VETERANS 'AUTHORITY TO OPERATE'**

*** USCOM REVENUE DOWN 25% TO $3.2m; LOSS UP 59% TO $3.3m**

*** 4D MEDICAL RECEIVES $6m FEDERAL R&D TAX INCENTIVE**

*** BARDA $9.5m FOR LUMOS FEBRIDX FOR CHILDREN TRIAL**

*** LUMOS WINS $2.3m APTATEK PHENYLKETONURIA MONITOR CONTRACT**

*** IMRICOR FILES VISION-MR 510(k) TO US FDA**

*** RACE OPENS PHASE I HONG KONG RC220, COMBO TUMOR TRIAL**

*** AMPLIA: US ADOPTED NAMES COUNCIL OKAYS 'NARMAFOTINIB'**

*** POLYNOVO: US SKIN SUBSTITUTE FLAT RATE COULD BOOST REVENUE**

*** CAMBIUM: TAIWAN'S KEKE MEDTECH $3m LICENCE**

*** CHALLENGER BELOW 5% OF TELIX**

*** MA FINANCIAL (MOELIS) TAKES 10.5% OF TRAJAN**

*** PERENNIAL INCREASES, DILUTED TO 12% OF MICROBA**

*** GZ FAMILY HOLDINGS REDUCES TO 9.7% OF FIREBRICK**

*** BERGEN, NEW LIFE, EUGENE TABLIS TAKE 13% OF ADALTA**

*** IMAGION APPOINTS DIMERIX M-D DR NINA WEBSTER DIRECTOR**

MARKET REPORT

The Australian stock market fell 0.3 percent on Tuesday September 2, 2025, with the ASX200 down 27.1 points to 8,900.6 points. Fifteen of the Biotech Daily Top 40 companies were up, 16 fell, eight traded unchanged and one was untraded.

Polynovo was the best (see below), up 13.5 cents or 10.3 percent to $1.45, with 9.9 million shares traded. Immutep climbed 6.5 percent; Clarity improved 5.1 percent; Amplia, Aroa, Medical Developments and Nova Eye were up more than three percent; Emvision and Neuren rose more than two percent; Imricor, Imugene and Micro-X were up more than one percent; with Avita, EBR, Nanosonics and Resmed up by less than one percent.

Starpharma led the falls, down one cent or 8.3 percent to 11 cents, with 310,171 shares traded. Optiscan lost 6.7 percent; Proteomics and Telix fell four percent or more; Actinogen, Botanix, Compumedics and Paradigm were down more than three percent; Clinuvel, Cyclopharm, Cynata, Medadvisor and Resonance shed more than two percent; Alcidion, Cochlear, Pro Medicus and SDI were down more than one percent; with 4D Medical and CSL down by less than one percent.

PRO MEDICUS

Pro Medicus says wholly-owned US subsidiary Visage Imaging Inc has been granted authority to operate (ATO) for the Veterans Affairs Enterprise Cloud (VAEC).

Pro Medicus said that the US Department of Veterans' Affairs granted the authority to operate for its Visage 7 and internet cloud picture archiving and communication system (Cloud PACS), the cloud-based implementation of the Visage 7 Enterprise imaging platform.

The company said that the authority to operate from the US Department of Veterans' Affairs meant that Visage "demonstrated, documented, tested and validated rigorous Federal security controls".

Pro Medicus said that achieving the authority to operate was "a significant, multi-year milestone" in Visage Imaging's working with the Veterans' Health Administration (VHA).

Pro Medicus chief executive officer Dr Sam Hupert said the company was "honored to work with VHA on their journey to the cloud".

"The [authority to operate], has been years in the making and is the final sign-off to enable us to transition our current on-premise implementation of Visage 7 to the VAEC which we believe will be a first," Dr Hupert said.

"Once completed, we aim to use this as a reference site for other Veterans' Integrated Service Networks looking to migrate to the VAEC," Dr Hupert said.

Pro Medicus said that Visage exhibited last week at the 2025 Defense Health Information Technology Symposium in Nashville, Tennessee.

The company said that Visage 7 was shown to Federal health information technology physicians and professionals from the Veterans' Health Administration and Defense Health Agency.

Pro Medicus fell $4.29 or 1.4 percent to $294.67 with 129,412 shares traded.

USCOM

Uscom says revenue for the year to June 30, 2025 was down up 30.6 percent to $2,620,450 with net loss after tax up 59.2 percent to $3,302,759.

Uscom said revenue was from sales of its Uscom 1A ultra-sonic cardiac output monitors, blood pressure monitors and lung spirometry devices,

The company said that revenue fell 25 percent "due to global market disruptions" and said that global headwinds included "tariff wars, geopolitical instability, constrained health budgets, and tougher regulatory environments".

Uscom said that there had been a reduction in US healthcare spending post-election and China sales were "down 50 percent due to tariff and trade restrictions".

The company said diluted loss per share was up 50.0 percent to 1.8 cents, with net tangible asset backing per share down from 0.015 cents to zero cents.

Uscom said it had cash and equivalents of $966,657 at June 30, 2025 compared to $2,519,911 at June 30, 2024.

Uscom was untraded at 1.1 cents.

4D MEDICAL

4D Medical says it has received $6.0 million from the Australian Taxation Office under the Federal Government's Research and Development Tax Incentive program.

4D Medical said the incentive related to research and development expenditure for the year to June 30, 2025.

4D Medical fell half a cent or 0.65 percent to 77 cents with 12.6 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says the US Biomedical Advanced Research and Development Authority (BARDA) will support a trial and regulatory submission to expand Febridx to children.

Lumos said that BARDA would provide $US6,198,000 ($A9,473,000) to support a study to expand the Febridx test differentiating viral from bacterial respiratory infections to children aged two years to 12 years under the Clinical Laboratory Improvement Amendments (CLIA)-waived system, with the trial expected to begin by October 2025.

Lumos said Febridx was FDA cleared for patients aged 12 to 64 years presenting to urgent care or emergency care settings for evaluation of acute respiratory infection who have had symptoms for less than seven days and within three days of fever onset.

The company said that last month, supported by BARDA, it applied to the US Food and Drug Administration, to expand Febridx use to CLIA-waived settings (BD: Aug 18, 2025).

Lumos said that if a CLIA waiver was granted, it would increase its total addressable US market 15-fold to more than US$1 billion, providing access to 270,000 clinical sites (currently 18,000), and covering about 80 million annual acute respiratory consultations.

The company said that the proposed age eligibility extension would enable the 60,000 clinicians treating children aged two to 12 years of age, to access an additional diagnostic aid for differentiating bacterial from non-bacterial acute respiratory infections.

Lumos said that on completion of the CLIA-waiver study on patients aged 12 to 64 years, BARDA exercised the option to start the paediatric CLIA-waived study.

The company said that it hoped to complete enrolment “within a single 12-month respiratory season” followed by dual 510(k)/CLIA waiver submission.

Lumos said BARDA milestone payments would be triggered by 12 events, including clinical trial set-up, patient recruitment, FDA application submission, and FDA granting of 510(k) clearance and CLIA-waiver categorization for children two to 12 years of age.

Lumos chief executive officer Doug Ward said the company appreciated BARDA’s support “both in the recently completed CLIA waiver study and now in advancing this important paediatric study”.

Lumos was up one cent or eight percent to 13.5 cents with 7.8 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos says it has a $US1.5 million ($A2.3 million) follow-on contract with Aptatek Biosciences for the Phecheck aptamer-based, in-home monitor for phenylketonuria.

In 2022, Lumos said it would receive $US500,000 to develop an at-home phenylketonuria screening test for the Princeton, New Jersey-based Aptatek (BD: Jun 17, 2022).

Today, the company said that phenylketonuria (PKU) was a “rare inherited disorder affecting approximately 1 in 12,000 newborns … [causing] a build-up of the amino acid phenylalanine in the body, which, if untreated, can lead to intellectual disabilities, seizures, behavioral issues, and mental health disorders”.

Lumos said that the co-developed Aptatek device was “designed to enable PKU patients to measure their phenylalanine levels in real time from home or at the point of care, enabling faster detection and improved ongoing management”.

The company said the device had been granted US breakthrough device status and Aptatek would complete development and verification and validation studies.

The company said that under the new contract, it would focus on maturing the design of the tests, blood processing unit, and readers; conducting formal verification testing to ensure the device meets product requirements for clinical trials and FDA submission.

Lumos said the contract was expected to begin this month and run for about 10 months, with additional revenue through its support of clinical trials and instrument manufacturing.

IMRICOR MEDICAL SYSTEMS

Imricor says it has filed its Vision-MR (magnetic resonance imaging) diagnostic catheter 510(k) premarket application to the US Food and Drug Administration.

Imricor said that the Vision-MR diagnostic catheter was designed to be used under magnetic resonance imaging (MRI) guidance and was a "key component of Imricor's full platform of MRI-compatible electrophysiology devices".

The company said the submission followed last month's FDA submission of Northstar "the world's first and only MRI native [three-dimensional] mapping and guidance system … together, these submissions are stepping stones toward FDA clearance for the full [s interventional cardiac magnetic resonance] suite, ultimately unlocking the … US".

Imricor executive chair Steve Wedan said the Vision-MR diagnostic catheter filing to the FDA was "another important step toward our goal of transforming cardiac ablation by enabling procedures to be performed in the MRI environment … [and] with Northstar and the diagnostic catheter now both under FDA review, we are advancing toward … delivering a fully integrated, radiation-free platform."

Imricor was up 1.5 cents or 6.5 percent to 24.5 cents with 5.2 million shares traded.

RACE ONCOLOGY

Race says it has opened the first Hong Kong site in its up-to 53 patient, open-label phase I combination trial of RC220 bisantrene with doxorubicin for solid tumors.

In May, Race said it dosed the first of up-to 53 patients in its phase I combination trial, in Australia, South Korea and Hong Kong, and in July said it had approval to begin the trial at Hong Kong's Prince of Wales and Queen Mary Hospitals (BD: May 1, Jul 10, 2025).

Today, the company said the Queen Mary Hospital had begun screening patients, with treatment of the first Hong Kong patient expected this month, and site activation of the Prince Wales Hospital scheduled in the "coming weeks".

Race said trial progress in Australia was "on track", with two patients treated at the Sydney's Southside Cancer Care Centre, and 12 patients evaluated for inclusion.

The company said stage one of the trial would administer escalating doses of RC220 in up-to 33 patients, with doxorubicin, to evaluate safety, tolerability, pharmaco-kinetics, and determine the maximum tolerated combined dose of RC220; with stage two evaluating the optimal dose on an additional 20 patients to examine safety, tolerability and preliminary indications of cardio-protective and anti-cancer efficacy.

Race fell 3.5 cents or 2.8 percent to $1.215.

AMPLIA THERAPEUTICS

Amplia says the US Adopted Names Council has approved 'narmafotinib' as the non-proprietary name for AMP945, its lead (focal adhesion kinase) FAK inhibitor.

Amplia said the US Adopted Names Council's adoption of the name was separate to its previously reported World Health Organization approval, and formalized the non-proprietary name for the molecule in the US.

Amplia chief executive officer Dr Chris Burns said "obtaining a [US adopted name] is an essential step for any drug molecule intended for the US, and it [is] an important step in the drug's commercial development as we begin our trial of narmafotinib in the US".

Last year, the company said that the US Food and Drug Administration approved its investigational new drug application for its 50-patient, 'Accent', phase IIa trial of narmafotinib with gemcitabine and Abraxane for pancreatic cancer (BD: Jan 21, 2024).

Amplia was up half a cent or three percent to 17 cents with two million shares traded.

POLYNOVO

Polynovo says that proposed changes to US Medicare reimbursement for outpatient wound care might boost revenue.

Polynovo said that under the existing reimbursement model, doctors were paid a percentage of the price for each skin substitute used in outpatient wound care.

The company said that “this has dis-incentivised the selection of lower priced product as it reduces the physician/surgeon payment with a decrease in product cost”.

“As a result, the market has favoured expensive products - driving significant [US] Medicare outlays and making it harder for cost-effective options to compete,” Polynovo said, quoting one report saying that “spending on skin substitutes exceeded $US10 billion in 2024, more than double the figure in 2023”

Polynovo said that the Trump administration proposed a plan to lower reimbursements to a fraction of what some companies currently earn and said the Centers for Medicare & Medicaid Services (CMS) proposed a flat reimbursement for outpatient skin substitutes of $US806 ($A1,232) per square inch.

“This … change is designed to remove the economic incentive for surgeons to use higher-cost products and to create a more level, value-oriented market,” the company said.

“CMS currently treats skin substitutes as biologicals for the purposes of Medicare payment, which can reach as high as $US2,000 per square inch,” Polynovo said, quoting a CMS media release.

The company quoted the CMS saying said that the change was “expected to reduce spending on these products by nearly 90 percent”.

“These proposed savings would not come at the expense of patient access or quality of care… This will save billions for Medicare and taxpayers and incentivize the use of products with the most clinical evidence of success,” Polynovo quoted the CMS saying.

The company said the impact would be sustained margins with Novosorb BTM and MTX products “profitable under the proposed flat rate”; enhanced competitiveness with the removal of price-based incentives potentially reducing “the presence of higher-cost competitors, benefiting clinically robust, cost-effective products”; and growth potential, with physicians’ decision-making to “increasingly focus on proven clinical outcomes, where Polynovo products compete strongly”.

Polynovo acting chief executive officer Dr Robyn Elliott said that the “majority of Polynovo’s current business has to date been in-patient product application”.

“Outpatient product application, the focus of the CMS proposed changes, is a significant potential growth area for Polynovo’s products,” Dr Elliott said.

“We are currently assessing the optimal commercial model for accessing this market opportunity,” Dr Elliott said.

Polynovo chair David Williams said the company was “well-positioned to benefit from changes to the US outpatient reimbursement landscape”.

“We have always placed importance on quality as well as value and the proposed new flat reimbursement will suit our value-oriented offering,” Mr Williams said.

“There are a number of things to play out before it is clear what the full benefit for Polynovo will be with plastic surgeons and podiatrists, but I am excited by the possibilities,” Mr Williams said.

“In particular, we are very keen to bring our technology to help American serviceman and women, veterans and others with chronic wounds exacerbated by diabetes,” Mr Williams said.

Polynovo said that the CMS proposal was open for consultation, with a decision expected in November for a January 1, 2026 start.

Polynovo was up 13.5 cents or 10.3 percent to $1.45 with 9.9 million shares traded.

CAMBIUM BIO

Cambium says Keke Medtech will pay $US2 million ($A3.06 million) to licence its fibrin biologic regenerative component, derived from its human platelet lysate platform, to
Cambium said the deal gave Keke Medtech the exclusive, international right to develop and commercialize the fibrin biologic, marketed as Aurarix, for dental and oral wound-healing applications; and included an upfront payment of $US250,000, with $US25,000 received, and $US1.75 million in milestone payments, including $US1.5 million on first approval and $US250,000 on the first in-human trial initiation, required within two years.
Cambium said it would receive sales royalties, including 10 percent on the first $US10 million a year, 13 percent after that, and a 20 percent share of non-royalty sublicences.
Cambium was unchanged at 47 cents.

TELIX PHARMACEUTICALS

The Sydney-based Challenger Ltd says it has ceased its substantial shareholding in Telix, buying and selling shares between August 21 and 28, 2025.
Challenger said its single largest purchase was 215,121 shares for $3,949,491 or $18.36 a share on August 22, and its single largest sale was 67,106 shares for $983,567 or $14.66 a share on August 28, 2025.
Telix fell 59 cents or four percent to $14.31 with 6.2 million shares traded.

TRAJAN GROUP HOLDINGS

Sydney's MA Financial (formerly Moelis) says it has increased its substantial shareholding in Trajan from 14,520,963 shares (9.53%) to 16,051,646 shares (10.53%).
MA Financial Group said that between March 13, 2024 and August 29, 2025 it bought shares, with the single largest purchase of 105,782 shares for $76,765 or 72.6 cents a share.
Trajan fell two cents or 2.2 percent to 90 cents.

MICROBA LIFE SCIENCES

Sydney's Perennial Value Management says it has increased and been diluted in Microba from 66,271,358 shares (14.80%) to 73,210,184 shares (12.02%).
Perennial said that between February 23, 2024 and August 28, 2025 it bought and sold shares, with the single largest purchase on May 9, 2024 of 6,748,373 shares for $1,199,860.72 or 17.8 cents a share, and said it was diluted by a placement last week.
Earlier this year, Microba said it would raise $12.5 million at 9.0 cents a share in a placement; and had raised a $2 million in a share plan (BD: Jun 23, Aug 11, 2025).
Microba fell 0.9 cents or 9.6 percent to 8.5 cents.

FIREBRICK PHARMA

Sydney's GZ Family Holdings Pty Ltd says it has reduced its substantial shareholding in Firebrick from 24,600,000 shares (12.60%) to 24,255,058 shares (9.71%).
GZ said between September 9, 2024 and August 29, 2025 it bought and sold shares, with the largest sale on January 23 of 1,000,000 shares for $63,952 or 6.4 cents a share.
Last week, Firebrick said it had commitments to raise $1.4 million at 6.3 cents a share in a shortfall placement, taking the total raised to $1.595 million (BD: Aug 26, 2025).
Firebrick fell 0.2 cents or 2.7 percent to 7.2 cents.

ADALTA

Bergen Global Opportunity Fund LP says it has become a substantial shareholder in Adalta with 166,666,667 shares or 12.61 percent.

The Boca Raton, Florida-based Bergen said that with New Life Sciences Capital and Eugene Tablis it acquired 166,666,667 shares for $300,000 through a placement at 0.2 cents a share on August 27, 2025.

In June, Adalta said that it raised $1,090,452 of a hoped for $1,300,000 at 0.3 cents a share, in a two-for-three rights offer; and later said it had placed $193,830 of the $209,548 shortfall to a single, unnamed investor (BD: May 1, Jun 3, 13, 2025).

Adalta was unchanged at 0.4 cents with 4.2 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it has appointed Dimerix managing director Dr Nina Webster as a non-executive director, effective from September 1, 2025.

Imagion said that Dr Webster had “a wealth of experience in the Australian ASX listed pharmaceutical industry, holding leadership roles over a 30-year period”.

The company said that prior to Dimerix, Dr Webster was Acrux’s commercial director and Immuron’s director of commercialisation and intellectual property.

Imagion said that Dr Webster held a Bachelor of Science, A Master of Intellectual Property from the University of Melbourne, a Master of Business Administration from RMIT and a Doctor of Philosophy from Cardiff University.

The company said that Dr Webster was chairperson of Synthesis Bioventures and a non-executive director of Linear Clinical Research.

Imagion fell 0.1 cents or 5.9 percent to 1.6 cents.