Biotech Daily

Thursday July 10, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH DOWN: CYNATA UP 7%; ACTINOGEN DOWN 8%**

*** MACH7 EXPECTS $33m-34m FY2025 REVENUE**

*** KAZIA: 'PAXALISIB COMBINATION HALVES TUMOR CELLS' IN 1 PATIENT**

*** ARTRYA $600k TANNER HEALTH SALIX DEAL**

*** ECHO IQ: SARC MEDIQ US ECHOSOLV RESELLER**

*** ORTHOCELL 1st US REMPLIR REVENUE**

*** IMRICOR NORTHSTAR FDA FILING**

*** RACE: 2 HONG KONG SITES OKAY PHASE I RC220 COMBO TRIAL**

*** IMAGION: FDA 'POSITIVE' ON PHASE II MAGSENSE BREAST CANCER TRIAL**

*** NEURIZON: FDA WANTS 2 PRE-CLINICAL STUDIES TO LIFT NUZ-001 HOLD**

*** MAYBANK TAKES 6% OF NEUROTECH**

*** XIAOYI LIN, AUSTRALIA NORTH, AUSTRALIA WEST TAKE 8% OF ATOMO**

*** EPSILON APPOINTS DANIEL KAPLON CFO**

MARKET REPORT

The Australian stock market was up 0.59 percent on Thursday July 10, 2025, with the ASX200 up 50.6 points to 8,589.2 points. Twelve of the Biotech Daily Top 40 companies were up, 18 fell, eight traded unchanged and two were untraded.

Yesterday's 9.1 percent worst, Cynata, was today's best, up one cent or 6.7 percent to 16 cents, with 105,237 shares traded; followed by Starpharma, up 6.4 percent to 10 cents, with 3.5 million shares traded. Mesoblast climbed 4.4 percent; Neuren was up 3.0 percent; both 4D Medical and Clarity rose 2.2 percent; Dimerix, EBR, Emvision, Medadvisor, Orthocell and Pro Medicus were up one percent or more; with Polynovo up by 0.4 percent.

Actinogen led the falls, down 0.2 cents or eight percent to 2.3 cents, with 2.1 million shares traded. Amplia and Universal Biosensors lost more than five percent; Genetic Signatures, Immutep, Optiscan and Prescient fell four percent or more; Medical Developments and Telix were down more than three percent; Botanix and Cyclopharm shed more than two percent; Clinuvel, Curvebeam, Nanosonics, Paradigm, Proteomics and SDI were down one percent or more; with Aroa, Cochlear, CSL and Resmed down by less than one percent.

MACH7 TECHNOLOGIES

Mach7 says it expects revenue for the year to June 30, 2025 to be up 13.35 percent to 16.8 percent, to about $33 million to $34 million, compared to the prior year.
Last year, Mach7 said its revenue for the year to June 30, 2024 from licencing its Enterprise imaging software, diagnostic viewing and workflow applications and data management systems was $29,112,863 (BD: Aug 28, 2024).
Today, the company said the increase in revenue was in line with 2024-'25 guidance of 15 percent to 25 percent and reflected "strong growth in recurring revenue".
Mach7 said contracted annual recurring revenue was "expected to finalize at approximately $30 million to $31 million, slightly below 2024-'25 guidance for …growth of 15 to 25 percent".
The company said it was "in a strong financial position with no debt and expects to be operating cash flow positive for 2024-'25".
Mach7 said in the six months to June 30, 2025 it had acquired about 6,300,000 shares for $2.2 million in an on-market share buy-back and expected to have cash and cash equivalents of about $21 million to $23 million at June 30, 2025.
Mach7 was unchanged at 34.5 cents.

KAZIA THERAPEUTICS

Kazia says breast cancer patient in its up-to 24-patient, phase Ib trial of paxalisib with standard-of-care had "a more than 50 percent reduction in circulating tumor cells".
Earlier this year, the Queensland Institute of Medical Research Berghofer said with Kazia it would conduct a 24-patient, phase Ib trial of paxalisib with pembrolizumab, or olaparib, for metastatic, triple-negative breast cancer (BD: Jan 30, 2025).
Today, the company said the patient was a 61-year-old woman with metastatic triple-negative breast cancer localized to the left upper lobe of the lung and had completed the first cycle, or 21 days, of dosing.
According to Wikipedia, triple-negative breast cancer lacks or shows low levels of oestrogen receptor, progesterone receptor and human epidermal growth factor receptor 2 (HER2) over-expression and comprises 15 percent to 20 percent of all breast cancers.
Kazia said the patient had a "comparable reduction in [circulating tumor cell] clusters" which were associated with heightened metastatic potential.
The company said the patient had a "reduction in the mesenchymal phenotype of the remaining [circulating tumor cells and that] … this phenotype is one of the hallmarks of aggressive metastatic seeding cancer cells".
Kazia said that "standard chemotherapy has been shown in some studies to transiently increase [circulating tumor cells] and cluster counts within the first cycle, with levels sometimes doubling before normalizing after cycle two".
The company said the combination led to "a rapid reduction in both [circulating tumor cell] numbers and clusters as well as a reduction in the mesenchymal phenotype, an outcome not typically seen with chemotherapy or immunotherapy alone after only 21 days".
Kazia said it continued to enrol the phase Ib study, expanding cohort size to assess safety, tolerability and pharmacodynamics, with longer-term follow-up to include imaging, progression-free survival, and assessment of biomarkers.
Kazia managing-director Dr John Friend said it was "very exciting to see our extensive pre-clinical research translate into such positive early data in this first patient receiving a combination of paxalisib and immunotherapy".
On the Nasdaq, Kazia climbed as much as 57.8 percent to $US10.76 ($A16.43) before closing up $US2.70 or 39.6 percent at $US9.53 with 10.65 million shares traded.

ARTRYA

Artrya says it has a $600,000, five-year contract with the Carrolton, Georgia-based Tanner Health for the use of its Salix coronary anatomy platform.

In March, Artrya said it had US Food and Drug Administration 510(k) clearance for its Salix coronary anatomy software for coronary plaque identification (BD: Mar 28, 2025).

Today, the company said Tanner Health was “a five-hospital non-profit health system providing convenient, personalized health care to communities across west Georgia and east Alabama”.

Artrya said the deal provided a software as a service licence with a monthly subscription fee for Salix coronary anatomy and future fee-per-scan revenues once additional modules such as Salix coronary plaque and Salix coronary flow received FDA clearance, with both eligible for US reimbursement.

The company said the Salix coronary anatomy platform was integrated in Tanner Health's picture archiving and communications system and electronic medical record systems.

Artrya said Salix coronary anatomy would be available for clinical use in patients with known or suspected coronary artery disease who had undergone a coronary computed tomography angiogram as it was rolled-out at Tanner Health’s locations.

Artrya chief executive officer John Konstantopoulos said the Tanner Health contract was “a major milestone for Artrya as it will deliver our first US commercial revenues”.

Artrya was up 4.5 cents or five percent to 95 cents.

ECHO IQ

Echo IQ says it has appointed Smart Affordable Reliable Care (SARC) Mediq as a reseller of its Echosolv echo-cardiogram for detecting aortic stenosis.

Last year, Echo IQ said it had US Food and Drug Administration 510(k) clearance for its artificial intelligence-based Echosolv for detecting aortic stenosis (BD: Oct 8, 2024).

Today, the company said the Dublin, California-based SARC Mediq had more than 20 years of combined medical software development experience and provided partnership-based picture archiving and communication systems.

Echo IQ said SARC Mediq provided imaging workflow systems to more than 300 healthcare facilities, with more than 1,500 physicians, including many cardiologists.

The company said SARC Mediq would act as a reseller of its Echosolv AS (aortic stenosis) to a network of existing healthcare facilities which included university hospitals and other multi-clinic sites and use Echosolv to “drive new business growth and further expand its reach into US hospitals and clinics”.

Echo IQ said it would receive payment on a per scan basis from hospital and clinics that use Echosolv within SARC Mediq’s network, with the per scan amount to be renegotiated when it receives a category III common procedural terminology code (CPT) to reflect the increased reimbursement rate.

Earlier this year, the company said it would resubmit its application for a category III CPT code for reimbursement of its Echosolv for aortic stenosis (BD: May 21, 2025).

Today, Echo IQ said the deal was “expected to considerably reduce Echo IQ’s sales and distribution costs, provide faster market access and scale across the US and has the potential to provide a predictable and ongoing revenue stream in the coming quarters”.

Echo IQ head of US Don Fowler said the deal was “an important development for the company as it advances its US commercialization strategy and highlights the potential opportunity for third party Echosolv AS sales to deliver consistent revenue, on a lower cost base for the company”.

Echo IQ was up two cents or 8.5 percent to 25.5 cents with 2.4 million shares traded.

ORTHOCELL

Orthocell says it has recorded its first US sales revenue for its Remplir collagen membrane-based nerve repair product following the first use in the US.
Earlier this year, Orthocell said it had US Food and Drug Administration 510(k) clearance to begin commercial distribution of Remplir (BD: Apr 4, 2025).
Last month, the company said the first US commercial surgery using Remplir was completed at an unnamed Ohio hospital (BD: Jun 27, 2025).
Today, Orthocell managing-director Paul Anderson said taking Remplir from US regulatory clearance to first sales revenue in three months was a testament to the company.
Orthocell was up two cents or 1.6 percent to $1.24 with one million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has submitted a US Food and Drug Administration 510(k) application for its Northstar system for use with interventional cardiac magnetic resonance imaging.
Last month, Imricor said it had Conformité Européenne (CE) mark approval for Northstar, which included a computer workstation and software (BD: Jun 10, 2025).
Today, the company said the FDA submission maintained the prioritization of the US commercialization plan of Northstar, with approval still expected in 2025.
Imricor said the FDA had "communicated that the reviewer of the company's second pre-market approval module for its ablation catheter and frequency generator was "no longer with the agency and a new reviewer has been appointed".
The company said it had submitted an updated pre-market approval schedule, called a "PMA Shell" to the FDA, targeting final clinical trial data submission to the FDA following submission of the third module by July 2026.
Imricor executive chair Steve Wedan said that in the US the company continued "to advance the entire platform through the various regulatory pathways with our FDA".
"The timelines associated with each of these pathways can be somewhat unpredictable, of course," Mr Wedan said. "For instance, we were pleasantly surprised at the faster-than-expected approval of the first [premarket approval] module."
"However, we were disappointed in the loss and replacement of the second [pre-market approval module's reviewer, and we were disappointed to find clinical trial enrolment slow this summer," Mr Wedan said.
"But even with these ups and downs, we are moving with great speed in the right direction, and our regulatory and clinical teams continue to shepherd our broad multi-device platform technology onto global markets with great urgency and skill," he said.
"The EU market is primed, and the US market is quickly following," Mr Wedan said.
Imricor fell 23.5 cents or 15.1 percent to $1.32 with three million shares traded.

RACE ONCOLOGY

Race says it has ethics approval to begin its phase I trial of RC220 bisantrene with doxorubicin at Hong Kong's Prince of Wales and Queen Mary Hospitals.
Last month, Race said it dosed the first of up-to 53 patients in its phase I combination trial of RC220 bisantrene and doxorubicin for solid tumors (BD: May 1, 2025).
Today, the company said site activation was expected in "late July/mid-August 2025 enabling patient recruitment to begin".
Race said it expected additional human research ethics committee approvals for up-to four additional trial sites in South Korea "over the coming months".
Race fell half a cent or 0.4 percent to $1.165.

IMAGION BIOSYSTEMS

Imagion says it has “positive feedback” from the US Food and Drug Administration about the study plan and outcomes for its phase II trial of Magsense for breast cancer.
In 2023, Imagion said a 13-patient, phase I trial showed its Magsense human epidermal growth factor receptor-2 (HER-2) for detecting breast cancer with magnetic resonance imaging was “safe and well tolerated”, with an investigational new drug application expected to be filed to the FDA by March 31, 2024 (BD: Oct 18, 2023).
Earlier this year, the company said it was manufacturing Magsense HER2 agent for use in a US phase II breast cancer detection study, which was required for the FDA application, expected to be filed in mid-2025 (BD: Feb 19, 2025).
Today, the company said it had received “formal written feedback from the FDA which included positive feedback and constructive input regarding the study plan and outcomes”.
Imagion said it would “be meeting with the FDA in person in the coming week to complete this process, ahead of the formal [investigational new drug] submission”.
The company said it expected to file the FDA application by October 2025.
Imagion executive chair Bob Proulx said he was “very pleased with the trajectory of our communications with the FDA”.
“We view the feedback from the FDA as very encouraging and can now confidently press forward with the formal submission and plans for undertaking the phase II clinical study knowing we are in good shape regarding the regulatory path,” Mr Proulx said.
Imagion was up 0.65 cents or 52.0 percent to 1.9 cents with 287.9 million shares traded.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says the US Food and Drug Administration has confirmed it will lift the clinical hold on NUZ-001 pending two pre-clinical pharmaco-kinetic studies.
Last year, the then Pharmaust said Massachusetts General Hospital had accepted the then monepantel, now NUZ-001, into its phase II/III ‘Healey’ amyotrophic lateral sclerosis (ALS), or motor neuron disease (MND) platform trial (BD: Jul 15, 2024).
Later, the company said it filed an investigational new drug application to the FDA to conduct a phase II/III trial of NUZ-001 for ALS “within the ‘Healey’ ALS platform trial framework”; and earlier this year, the FDA put its application on clinical hold due to “certain concerns about the sufficiency information” (BD: Dec 18, 2024; Jan 19, 2025).
Later, Neurizon said the FDA requested “additional animal exposure data to assess the adequacy of systemic exposure to NUZ-001”; and in March, said it had requested advice from the FDA on lifting the clinical hold (BD: Feb 17, Mar 17, 2025).
Today, the company said it had “already completed the two necessary [pharmaco-kinetic] studies ahead of schedule” with the study reports being finalized.
Neurizon said it expected to submit a complete response containing data from these studies to the FDA “in the coming weeks as part of the formal hold resolution process”, with activating participation in the ‘Healey’ ALS platform trial expected by 2026.
Neurizon managing-director Dr Michael Thurn said the company was “delighted to receive written confirmation from the FDA affirming our strategy to resolve the clinical hold for NUZ-001”.
“By proactively progressing and completing the required [pharmaco-kinetic] studies ahead of schedule, we’ve maintained strong momentum and demonstrated our commitment to advancing NUZ-001 with urgency and scientific precision,” Dr Thurn said.
“We are well-positioned to submit the complete response in the coming weeks and anticipate that the clinical hold will be lifted in August 2025,” Dr Thurn said.
Neurizon was unchanged at 16 cents.

NEUROTECH INTERNATIONAL

Maybank Securities Pte Ltd says it has become a substantial shareholder in Neurotech with 60,697,522 shares, or 5.78 percent.
The Singapore-based Maybank did not disclose the nature, date or consideration of its acquisition of its share-holding as required under the Corporations Act (2001).
Neurotech was unchanged at 1.9 cents.

ATOMO DIAGNOSTICS

Xiaoyi Lin says with Australia North Holdings Pty Ltd and Australia West Holdings Pty Ltd he has become substantial in Atomo with 64,392,433 shares, or 8.38 percent.
The Sydney-based Mr Lin said that with Australia North and Australia West he bought 32,432,433 shares in a placement on July 3, 2025 at 1.85 cents a share.
Earlier this year, Atomo said it had “binding commitments” to raise about $2,113,000 in a placement at 1.85 cents a share, a six percent discount to the 15-day volume weighted average price (BD: Apr 24, 2025).
Atomo was unchanged at 1.4 cents.

EPSILON HEALTHCARE

Epsilon says it has appointed Daniel Kaplon as its chief financial officer effective from July 8, 2025.
Epsilon said Mr Kaplon had more than 25 years of experience and had worked for Ramsay Health Care, had been chief operating officer and chief financial officer at Medisecure and chief financial officer of Adherium.
According to his Linkedin profile, Mr Kaplon held a Bachelor of Commerce from Melbourne’s La Trobe University, a Bachelor of Business from the Royal Melbourne Institute of Technology and a Master of Entrepreneurship and Innovation from Melbourne’s Swinburne University of Technology.
Epsilon was in a suspension and last traded at 2.4 cents.