Biotech Daily

Monday August 17, 2026

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: MESOBLAST UP 11%; IMPEDIMED DOWN 17%**

*** MESOBLAST TREATS PHASE III REXLEMESTROCEL-L BACK PAIN PATIENTS**

*** ONCOSIL BILE DUCT CANCER DEVICE WINS FDA APPROVAL**

*** ECHO IQ, PRO MEDICUS SIGN $20m CONVERTIBLE NOTE**

*** NEURA $1.9m CUREATOR+ GRANT FOR SMARTWATCH REHAB MONITOR**

*** MONASH UNI 'MINI-GUT' MODELS FOR CHILD IBD THERAPIES**

*** DIMERIX TRANSFERS MISSION'S FDA DMX-652 FILINGS**

*** RADIOPHARM, FDA TO MEET ON PHASE III RAD101 DESIGN IN OCTOBER**

*** TISSUE REPAIR ASX DELISTING, SHARE BUY-BACK EGM**

*** CONNEQT 40m MANAGEMENT PERFORMANCE RIGHTS EGM**

*** BIOTRON: 'CELL STUDIES BACK BIT-HBV001 HEPATITIS TRIAL, BY 2028'**

*** CHIMERIC REQUESTS 'TRIAL RESULTS' TRADING HALT**

*** JM FINANCIAL, NO PLAN B TAKE 13% OF MACH7**

*** NEUROTECH CHAIR MARK DAVIES EXECUTIVE**

MARKET REPORT

The Australian stock market fell 0.46 percent on Monday August 17, 2026, with the ASX200 down 42.0 points to 9,073.2 points. Fourteen of the Biotech Daily Top 40 were up, 18 fell, five traded unchanged and three were untraded. All four Big Caps fell.

Mesoblast was the best (see below), up 24 cents or 10.9 percent to $2.45, with 4.7 million shares traded. Amplia climbed 6.9 percent; Atomo was up 5.9 percent; Lumos, Polynovo and Racura were up more than four percent; Syntara was up 3.85 percent; Artrya and Clinuvel rose more than two percent; with 4D Medical, Actinogen, Dimerix, Imugene and Medical Developments up by more than one percent.

Friday's 0.1 cents or 20 percent best, Impedimed, led today's falls, down 0.1 cents or 16.7 percent to 0.5 cents, with 1.3 million shares traded. Saluda lost 5.6 percent; Botanix fell 4.55 percent; Aroa, EBR and Starpharma were down more than three percent; Imricor, Neuren, Optiscan and Paradigm shed more than two percent; Clarity, Cochlear, CSL, Cyclopharm, Emvision, Prescient, Pro Medicus, Resmed and Telix were down more than one percent; with Avita, Nanosonics and Orthocell down by less than one percent.

MESOBLAST

Mesoblast says it has completed enrolment and treated all 350 patients in its pivotal, randomized, controlled phase III trial of rexlemestrocel-L for chronic low back pain.
In 2021, Mesoblast said that a 404-patient, phase III, randomized, controlled trial of rexlemestrocel-L, with and without hyaluronic acid compared to placebo, “did not reach statistical significance across the entire study” for low back pain (BD: Feb 11, 2021).
In 2024, the company said it had begun a 300-patient, phase III trial of rexlemestrocel-L for degenerative disc disease-related chronic low back pain; and later, said it had treated more than 300 patients (BD: Jul 22, 2024; Jul 14, 2026).
Today, Mesoblast said the trial increased from 300 to 350 patients “after strong demand from trial investigators to have their patients enrolled in the innovative program”.
The company said the trial’s primary endpoint aimed “to confirm the durable pain reduction at 12 months from a single intradiscal injection of rexlemestrocel-L”.
Mesoblast said that with 350 treated patients, the trial was “well-powered for showing a greater treatment benefit in patients receiving rexlemestrocel-L compared with controls” and that secondary endpoints included improvements in function, quality of life, and cessation of pain medication, including opioids.
Mesoblast chief executive Prof Silviu Itescu said treating 350 patients in the pivotal low back pain trial was “a momentous milestone … as we now count down to the 12-month read-out for what we hope will be the basis of our first blockbuster product”.
The company said that the indication had potential peak year revenue of more than $US10 billion ($A14.1 billion) for Mesoblast even with single digit market penetration, with top-line results expected in mid-2027 after the last patient’s 12 months follow-up.
Mesoblast was up 24 cents or 10.9 percent to $2.45 with 4.7 million shares traded.

ONCOSIL MEDICAL

Oncosil says it has US Food and Drug Administration humanitarian device exemption approval for its Oncosil device for the treatment of distal cholangio-carcinoma.
In 2020, Oncosil said it filed for a US Food and Drug Administration humanitarian device exemption for distal cholangio-carcinoma, a bile duct cancer (BD: Jul 28, 2020).
Earlier this year, the company said the FDA confirmed all questions about its humanitarian device exemption application for distal cholangio-carcinoma had “been satisfactorily addressed”; and last month, said it had submitted the humanitarian device exemption application to the regulator (BD: Jun 9, Jul 3, 2026).
Today, Oncosil said the approval was conditional on the use and distribution of the device in the US being initially restricted to a maximum of five treatment centres, with trained practitioners as part of an FDA-required post-approval study.
The company said the study was expected to enrol about 30 patients, with 24-month follow-up and final study protocol expected to be confirmed with the FDA.
Oncosil said its radiotherapy device was “the first and only US FDA-approved class III device for the treatment of [distal cholangiocarcinoma], a rare bile duct cancer”.
The company said the approval allowed it to commercialize its device for intra-tumoral implantation into a solid tumor via injection under endoscopic ultrasound guidance in the treatment of patients with unresectable, non-metastatic distal cholangiocarcinoma.
Oncosil said the device was indicated for patients aged 21 years and older, with implantable components supplied sterile and intended for single-patient, single-use.
Oncosil managing-director Nigel Lange said FDA approval was “the most significant milestone in Oncosil’s history and a transformational moment for our company”.
Oncosil fell seven cents or 5.5 percent to $1.20 with 1.2 million shares traded.

ECHO IQ

Echo IQ and Pro Medicus say they have signed the up-to $20 million convertible note debt and option agreement announced on June 25, 2026.
In June, Echo IQ said it had the convertible note facility with Pro Medicus at 12.5 percent annual interest, with Pro Medicus to be a US Echosolv reseller (BD: Jun 25, 2026).
Echo IQ said Pro Medicus would receive 0.75 options for every note acquired, exercisable at $1.35 each within two years from the note issue date.
Echo IQ fell four cents or 2.5 percent to $1.55 with 5.3 million shares traded.
Pro Medicus fell $3.00 or 1.7 percent to $175.86 with 282,302 shares traded.

NEUROSCIENCE RESEARCH AUSTRALIA (NEURA)

Neura says it has a $1.9 million Cureator+ grant to develop a smartwatch-based patient rehabilitation and recovery monitor with Melbourne's Weguide.
Neura said the grant, from the Federal Government-backed incubator Cureator+, delivered by Brandon Capital, would support development of an artificial intelligence-powered platform to validate mobility recovery biomarkers to personalize rehabilitation.
The organization said Weguide would lead the technical platform development and it would lead the research and validation program with the University of New South Wales.
Neura said it would recruit 200 people undergoing rehabilitation and collect continuous movement data from wrist-worn wearables, along with patient-reported outcomes, such as fatigue, confidence and function.
The organization said the results would be validated for mobility, with researchers to show the platform could produce clinically validated digital bio-markers.
Neura said the 18-month project, 'Weguide Biomarkers: Platform for building, validating and commercialising Digital Health & Biomarkers' would "establish a scalable technical framework to support the development of similar tools in other areas of medicine".
The organization said that "the mobility recovery indicator could support earlier intervention, more tailored rehabilitation programs, and improved long-term outcomes for people recovering from injury or stroke".

MONASH UNIVERSITY

Monash University says it has developed a 'mini-guts' intestinal lining laboratory-grown organoid for investigating inflammatory bowel disease (IBD) therapies in children.
Monash University said with the Hudson Institute of Medical Research researchers used live tissue and bacteria from the intestine to develop miniature, 3-dimensional 'organoid' models, nicknamed 'mini-guts', and test "how and where the specific bacteria in a patient's digestive system can affect tissue and cause inflammation".
The University said each person's microbiome was unique "which means an IBD treatment that works for one person may not work for another".
Monash University said the research was "the first to have developed an organoid model that incorporates both the intestinal lining and its bacteria, and pioneers the technology to inject bacteria into the intestinal organoids to study its impact on inflammation".
The University said the research, titled 'Patient-derived intestinal organoids as a model for site-specific mucosal bacterial interactions in paediatric inflammatory bowel disease' was published in the peer-reviewed journal Scientific Reports, with the full article available at https://www.nature.com/articles/s41598-026-46184-8.
Monash University lead researcher Prof Helen Abud said it brought "researchers a step closer to personalized IBD treatments".

DIMERIX

Dimerix says it has transferred the US Food and Drug Administration investigational new drug application for DMX-652 in acute kidney injury from Mission Therapeutics.

Last month, Dimerix said it would pay up-to $US292 million ($A418 million) plus royalties for the Cambridge, England-based Mission Therapeutics' oral small molecule DMX-652 for acute kidney injury (BD: Jul 17, 2026).

Today, the company said it had full ownership over the regulatory filings and was trial sponsor for the ongoing phase II development of DMX-652.

Dimerix said the transfer was "an important milestone in … [the] development of DMX-652 and provided the company with direct control over clinical development activities for the program in the US".

The company said that "with the encouraging safety and pharmaco-kinetic data observed in the extensive phase I trial for DMX-652, and its promising pre-clinical data, Dimerix plans to advance DMX-652 into a phase II clinical trial for acute kidney injury during the second half of 2026".

Dimerix was up half a cent or 1.7 percent to 30 cents with three million shares traded.

RADIOPHARM THERANOSTICS

Radiopharm says it will conduct an end-of-phase II meeting with the US Food and Drug Administration on October 1, 2026 for the design of a phase III RAD101 trial.

Earlier this year, Radiopharm said it dosed all 30 patients in its US, phase IIb trial of its fluorine-18 (18F)-pivalate, or RAD101, for imaging confirmed recurrent brain metastases from solid tumors (BD: Apr 16, 2026).

At the time, the company said clinical data readout on the primary endpoint was expected in June 2026, with plans to open a phase III trial in the US.

Last month, Radiopharm said its phase IIb trial showed RAD101 had 93 percent concordance with MRI for imaging brain tumors (BD: Jul 22, 2026).

Today, the company said the focus of the FDA meeting would be to align on the pivotal phase III clinical trial design criteria, including the number of patients to be enrolled along with primary and secondary endpoints, as well as reviewing the phase IIb data.

Radiopharm managing-director Riccardo Canevari said the end-of-phase II meeting with the FDA for RAD101 was "an important milestone that brings us closer to advancing this promising imaging agent into a pivotal phase III program … [and the] discussion will provide important alignment on the clinical and regulatory pathway forward, enabling us to finalize plans for a registrational study and remain on track to be phase III-ready" this year.

Radiopharm was unchanged at 1.1 cents with 4.5 million shares traded.

TISSUE REPAIR

Tissue Repair says an extraordinary general meeting will vote to approve its removal from the ASX official list and an up-to $1.0 million share buy-back at 13 cents a share.

In July, Tissue Repair said it applied to the ASX requesting its removal from the official list in accordance with Listing Rule 17.11, and to conduct a buy-back (BD: Jul 23, 2026).

At the time, the company said the reasons for its delisting included limited liquidity and utility of listing, concentrated shareholder structure, a significant number of small shareholders, cost and administrative burden, as well as strategic flexibility.

The meeting will be held at Level 5, Automic Group, 126 Phillip Street, Sydney on September 18, 2026 at 10am (AEST).

Tissue Repair fell half a cent or 5.9 percent to eight cents.

CONNEQT HEALTH (FORMERLY CARDIEX)

Conneqt says its extraordinary general meeting will vote to issue 40,000,000 long-term incentive performance rights to its managing-director, chair and three employees.
Conneqt said shareholders would vote to issue managing-director Craig Cooper, executive chair Niall Cairns and chief strategy officer Catherine Liao 10,000,000 performance rights, each, as well as 5,000,000 performance rights, each, to head of engineering Scott Finneran and chief digital officer Oliver Shay.
The company said the performance rights would vest on the company reaching a share price of 6.0 cents a share and expire on August 28, 2031, with Mr Cooper, Mr Cairns and Ms Liao's rights worth $141,000, each, and Mr Finnern and Mr Shay's $70,500, each.
Conneqt said investors would vote to ratify the issue of placement shares, the participation of the Mr Cairns and Mr Cooper-owned C2 Ventures in the capital raise and the issue of 1,636,364 shares to director Charlie Taylor in lieu of $36,000 of fees.
The meeting will be held at 24-26 Kent Street, Sydney, on September 15, 2026 at 10am (AEST).
Conneqt fell 0.1 cents or 5.3 percent to 1.8 cents.

BIOTRON

Biotron says two cell-based studies show its BIT-HBV001 shows "strong anti-viral activity" against hepatitis B virus, with first-in-human studies expected by 2028.
Earlier this year, Biotron said that studies with California's Scripps Institute San Diego showed that BIT-HBV001 inhibited hepatitis delta virus (HDV) production by about 85 percent compared to drug-free controls, in-vitro (BD: Mar 18, 2026).
Previously, Biotron managing-director Dr Michelle Miller told Biotech Daily the HBV drug was not BIT225 and the company had been working on "novel compounds for this indication", with the structure and name of the compounds "not in the public domain".
Today, the company Biotron said a first study compared BIT-HBV001 with the recently-approved Myrcludex-B, or Myr-B, marketed by Gilead Sciences as Hepcludex in the US, in cells infected with hepatitis B and hepatitis delta virus, and showed "both drugs showed strong anti-viral activity against both viruses".
Biotron said the study showed BIT-HBV001 reduced the hepatitis B surface antigen by 98.1 percent compared to 93.8 percent for Myr-B, with hepatitis B DNA reduced by 99.7 percent for BIT-HBV-001 compared to 93.0 percent for Myr-B.
The company said BIT-HBV001 led to an 81.0 percent reduction for hepatitis D antigen compared to 93.8 percent for Myr-B.
Biotron said the second study showed BIT-HBV-001 and Myr-B had "significant anti-viral synergy" in three hepatitis B virus and hepatitis delta virus replication endpoints, indicating lower amounts of each drug combined may be used to achieve the same level of viral inhibition.
The company said it planned to progress BIT-HBV001 through pre-clinical studies and manufacture with the aim of beginning first-in-human studies "in the second half of 2027".
Biotron managing-director Dr Michelle Miller said the ongoing positive results from its hepatitis B program supported "the progression … to human clinical trials".
"A functional cure for chronic [hepatitis B virus] infection remains one of the most important unmet needs in anti-viral medicine," Dr Miller said.
"These latest results underline the broad potential of BIT-HBV001, including in treatment of high-risk [hepatitis B virus and hepatitis delta virus] co-infections," Dr Miller said.
Biotron was unchanged at 0.2 cents with 20.5 million shares traded.

CHIMERIC THERAPEUTICS

Chimeric has requested a trading halt “pending an announcement in relation to results under the company’s CDH17 clinical trial”.
Trading will resume on August 19, 2026, or on an earlier announcement.
Chimeric last traded at 3.5 cents.

MACH7 TECHNOLOGIES

Melbourne’s JM Financial and No Plan B say they have increased their substantial shareholding in Mach7 from 28,372,672 shares (11.76%) to 30,624,200 shares (13.03%).
JM Financial and No Plan B said that it bought and sold shares in more than 200 transactions between January 11, 2024 and August 4, 2026, with the single largest purchase 538,565 shares on March 31, 2025 for $185,532, or 34.45 cents a share.
Mach7 was unchanged at 28 cents.

NEUROTECH INTERNATIONAL

Neurotech says it has promoted Mark Davies from non-executive to executive chair on a salary of $300,000 a year, effective from today.
Neurotech said as executive chair Mr Davies would “assume a more active role in the strategic and operational leadership of Neurotech”.
The company said Mr Davies’ responsibilities would include “corporate strategy, capital markets and funding initiatives, partnering and licencing activities, investor engagement, governance, and strategic oversight of the company’s clinical and regulatory programs”.
Neurotech said that the appointment reflected its “progression into its next stage of development, with an increased focus on the phase III program, funding strategy and potential partnering and licencing opportunities”.
Neurotech was unchanged at 1.4 cents with 1.6 million shares traded.