Biotech Daily

Thursday September 18, 2025

Daily news on ASX-listed biotechnology companies

*** ASX DOWN, BIOTECH UP: PROTEOMICS UP 15.5%; AVITA DOWN 6%**

*** NEURIZON PLACEMENT RAISES $5m**

*** NEURIZON: $5.6m R&D TAX INCENTIVE; ADVANCE, OVERSEAS FINDING**

*** MEMPHASYS: ITL TURKEY TAKES DEAL TO $390k; 'CAPITAL RAISING' HALT**

*** ONCOSIL: PANCOSIL PANCREATIC CANCER TRIAL 'SAFETY, EFFICACY'**

*** IMUGENE 7 COMPLETE, 6 PARTIAL RESPONSES IN 16 PATIENTS**

*** PROTEOMICS AWARDED ISO 15189 CERTIFICATION**

*** IMRICOR 'HUMAN FACTORS STUDY' FOR ALL FDA REVIEW DEVICES**

*** BCAL DISTRIBUTES CLEARNOTE'S PANCREATIC, OVARIAN CANCER TESTS**

*** BLINKLAB: VANDERBILT UNIVERSITY 7th TO DX1 AUTISM STUDY**

*** CELTIC CALLS TO REMOVE INVEX M-D DR TOM DUTHY, CHAIR DAVID MCAULIFFE**

*** REGAL TAKES 6.6% OF ARTRYA**

*** PHOENIX TAKES 21% OF CONTROL BIONICS**

*** NIGHTINGALE TAKES 20.5% OF CONTROL BIONICS**

*** PLATINUM DILUTED TO 5% OF ADALTA**

*** CSL APPOINTS DR STEPHEN PITT HEAD OF SEARCH**

MARKET REPORT

The Australian stock market fell 0.83 percent on Thursday September 18, 2025, with the ASX200 down 73.3 points to 8,745.2 points. Twenty of the Biotech Daily Top 40 companies were up, 13 fell and seven traded unchanged.

Proteomics was the best, up 4.5 cents or 15.5 percent to 33.5 cents, with 1.8 million shares traded. Resonance rose 11.8 percent; Imricor improved 8.9 percent; Actinogen was up 6.25 percent, Atomo and Emvision were up five percent or more; both Curvebeam and Syntara were up four percent; Aroa, Imugene and Polynovo were up more than three percent; Clarity, EBR, Immutep, Medadvisor, Mesoblast and Neuren rose two percent or more; Dimerix, Nanosonics and Pro Medicus were up one percent or more; with SDI up by 0.6 percent.

Avita led the falls, down 10.5 cents or 5.8 percent to $1.70, with 1.3 million shares traded. 4D Medical fell 5.05 percent; Amplia, Botanix, Nova Eye and Orthocell lost more than three percent; Clinuvel, Cyclopharm, Micro-X and Prescient shed more than two percent; Compumedics, CSL, Genetic Signatures and Telix fell more than one percent; with Cochlear and Resmed down by less than one percent.

NEURIZON THERAPEUTICS

Neurizon says it has raised $5 million through an institutional placement at 12.0 cents a share, with board and management subscribing for $200,000, subject to approval.
Neurizon said the share price was an 18.9 percent discount to the five-day volume-weighted average price; and $130,000 of the board and management's subscription was subject to approval at its annual meeting, which would be held on or about November 26.
Neurizon said the funds would support preparations for its planned Healey amyotrophic lateral sclerosis (ALS) platform trial this year, pending US Food and Drug Administration clearance of its investigational new drug application, along with manufacturing of registration batches, regulatory filings, and pre-clinical initiatives to expand NUZ-001 to other neuro-degenerative diseases, as well as general working capital.
Neurizon was up one cent or 7.1 percent to 15 cents.

NEURIZON THERAPEUTICS (FORMERLY PHARMAUST)

Neurizon says it expects a $5.6 million tax incentive for the year to June 30, 2025, with NUZ-001 overseas research expenditure eligible for a 43.5 percent cash rebate.
Neurizon said Ausindustry awarded it an 'Advance and Overseas Finding', which meant that, in addition to eligible Australian research and development expenditure, planned overseas research and development for NUZ-001 was claimable under the Federal Research and Development Tax Incentive program for the three years to June 30, 2027.
In July, the company said it had a $1.5 million loan from Sydney's Radium Capital at 17 percent interest a year, secured against its expected Federal Government Research and Development tax incentive for the year to June 30, 2025 (BD: Jul 30, 2025).
Today, Neurizon chief financial officer Dan O'Connell said the "Advance and Overseas Finding is a strong validation of Neurizon's development pathway for NUZ-001, our lead candidate in ALS and related neurodegenerative diseases".
"It directly supports our ability to execute pivotal clinical trials and enhances investor confidence by providing a substantial, non-dilutive funding stream," Mr O'Connell said.
"Importantly, it enables us to accelerate timelines while reducing risk, ensuring we can keep momentum in bringing NUZ-001 closer to patients who urgently need new treatment options," Mr O'Connell said.

MEMPHASYS

Memphasys says its International Technical Legacy agreement to sell Felix in the Middle East and North Africa includes Turkey, with its contract up to $390,000.
In September, Memphasys said it had a $325,000, five-year deal with the Doha, Qatar-based International Technical Legacy (ITL) to supply its Felix sperm separation device to 15 countries in the Middle East and North Africa, on it receiving Conformité Européenne (CE) mark approval (BD: Sep 8, 2025).
At the time, the company said the deal had an initial binding order for the first two years, with volume and pricing to be reviewed for the remaining years.
Today, Memphasys said Turkey was one of Europe's "most active and rapidly expanding [in vitro fertilization] markets".
Separately, the company requested a trading halt pending an announcement "regarding a proposed capital raising", with trading to resume on September 22, 2025 or on an earlier announcement.
Memphasys last traded at 0.45 cents.

ONCOSIL MEDICAL

Oncosil says its 20-patient ‘Pancosil’ pancreatic cancer trial met safety and efficacy primary endpoints, with three partial responses and improved median survival.

In July, Oncosil said 20 patients had been enrolled in the Amsterdam University Medical Center investigator-led, phase I/II study of its radio-therapy device, computed tomography (CT) guided and percutaneously administered for pancreatic cancer (BD: Jul 4,2025).

Today, the company said two patients had recovered from grade three serious adverse device effects, one was procedure-related and one was possibly device-related.

Oncosil said three patients had partial responses, comparing tumor size prior to implantation of the Oncosil device and in addition to responses from chemotherapy alone, with median overall survival of 20.6 months from diagnosis, compared to historical outcomes for locally advanced pancreatic cancer of about 13 months.

The company said that the “technical success rate was 90 percent, demonstrating reliable and reproducible delivery of Oncosil via the percutaneous approach” and investigators concluded that it was “feasible to perform implantation with patients’ conscious, thereby reducing the length of the procedure and post-procedure recovery.”

The company said it presented the results at the Cardiovascular and Interventional Radiological Society of Europe in Barcelona and would aim for approvals by July 2026.

Oncosil chief executive officer Nigel Lange said the company was “greatly encouraged by the preliminary results of the Pancosil trial, in which the investigators concluded that Oncosil can be safely and effectively delivered using a percutaneous [computed tomography]-guided approach”.

“Importantly, this enables interventional radiologists to administer the treatment with precision and consistency, significantly expanding the potential reach of Oncosil,” Mr Lange said.

Oncosil was up 26 cents or 15.85 percent to $1.90.

IMUGENE

Imugene says it has seven complete responses and six partial responses of 16 evaluable patients (81.25%) in its phase Ib azer-cel blood cancer trial.

In 2023, Imugene said it would acquire ‘azer-cel’, or azercabtagene zapreleucel, CD19 chimeric antigen receptor T-cell therapy for blood cancers (BD: Aug 16, 2023).

Last year, the company said it had three complete responses of 10 treated patients in cohort B of its up-to 42-patient, phase Ib trial of azer-cel with interleukin-2 cytokine for large B-cell lymphoma, with azer-cel safe and tolerable (BD: Sep 2, 2024; Feb 14, 2025).

Last month, Imugene said it had six complete responses and five partial responses of 14 evaluable patients (78.6%) in its phase Ib azer-cel blood cancer trial (BD: Aug 4, 2025).

Today, the company said two additional patients had partial responses, with another transitioning from partial to complete response following a scan evaluation at day-90.

Imugene said the average time to best response seen was one-to-three months, with durability of response “also deepening” in treated patients.

The company said it was enrolling patients at 10 sites in the US, with up-to six sites in Australia planned, after the first Australian patient resulted in a complete response.

Imugene said the trial had recently expanded to include and treat chimeric antigen receptor-T-cell (CAR T) naïve patients diagnosed with a broad range of non-Hodgkins lymphomas, including primary central nervous system lymphoma, chronic lymphocytic leukaemia or small lymphocytic lymphoma, marginal zone lymphoma, Waldenstrom macro-globulinemia and follicular lymphoma.

Imugene was up one cent or three percent to 34 cents with seven million shares traded.

PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says it has been awarded International Organization for Standardization ISO 15189 certification for its Australian laboratory operations.

Proteomics said the certification was a “a core milestone in the commercialization and clinical use of Proteomics International's suite of precision diagnostic tests” and affirmed its position as “one of the world's leading laboratories for proteomics and protein-based based testing services”.

Proteomics chief executive officer Dr Richard Lipscombe said “the certification supports our strategic growth trajectory as we advance the commercialization of our first-in-class diagnostic tests for diabetic kidney disease, oesophageal cancer and endometriosis”.

Proteomics was up 4.5 cents or 15.5 percent to 33.5 cents with 1.8 million shares traded.

IMRICOR MEDICAL SYSTEMS

Imricor says it has completed the human factors study for all its devices currently being reviewed by the US Food and Drug Administration.

Imricor said the study was a “critical step” in the US Food and Drug Administration (FDA) approval process, ensuring that nine of is devices, including its magnetic resonance ablation products, could be used safely and effectively by clinicians, with completion a “major milestone in advancing toward FDA market approval”.

The company said it completed a seven-month usability study involving 46 healthcare professionals, comprising 23 electrophysiologists and 23 electrophysiology nurses and technologists from hospitals in the US, with physicians from nearly 20 US hospitals participating in the study.

Imricor chief executive officer and chair Steve Wedan said “the scale of this study cannot be overstated, having taken our team over a year from planning through execution”.

“Completing human factors testing across our entire product portfolio is an extraordinary achievement and a clear demonstration of the strength and dedication of the Imricor team,” Mr Wedan said.

“It also marks a major milestone on our path to FDA approval and positions us strongly as we prepare to bring [magnetic resonance imaging]-guided ablation to the US,” he said.

Imricor was up 12.5 cents or 8.9 percent to $1.53.

BCAL DIAGNOSTICS

Bcal says it will distribute the San Diego, California-based Clearnote Health’s Avantect pancreatic cancer and ovarian cancer blood tests in Australia and New Zealand.

Bcal said the initial two-year deal would begin in January 2026, with an option to extend for a further six years.

The company said the pancreatic cancer tests had demonstrated sensitivity of 68 percent and specificity of 97 percent, while the ovarian cancer test had a sensitivity of 78 percent and specificity of 94 percent.

Bcal executive chair Jayne Shaw said the company was “excited to partner with Clearnote Health to bring advanced diagnostic technology for early detection of cancer to Australia”.

“Clearnote Health is a leader in epigenomic-based multi-cancer detection,” Ms Shaw said.

“Their expertise, data scale, and international validation will accelerate Bcal’s growth,” Ms Shaw said. “Our agreement with Clearnote is transformational ... it positions us as a leader in early pancreatic and ovarian cancer detection and significantly broadens our reach beyond early breast cancer detection.”

Bcal was up 0.4 cents or 6.15 percent to 6.9 cents.

BLINKLAB

Blinklab says the Nashville, Tennessee-based Vanderbilt University Medical Center will join its Dx1 autism test as the seventh trial site.
In June, Blinklab said it had ethics approval for the 1,000-patient, main study of its US diagnostic trial of its Dx1 smartphone application for autism (BD: Jun 30, 2025).
Yesterday, the company said the Columbia-based University of Missouri's Thompson Center for Autism and Neurodevelopment would join the trial, and was currently expanding its clinical sites, with the study would enrol a minimum of 260 children diagnosed with autism and 260 neurotypical children, with enrolment reaching up to a potential 900 children in total, with the study expected to be completed by July 2026 (BD: Sep 17, 2025).
Today, Blinklab said it expected final US Food and Drug Administration submission by October 2026.
Blinklab was unchanged at 55 cents.

INVEX THERAPEUTICS

Invex says Singapore's Celtic Capital Pte Ltd has called for a general meeting to remove managing director Dr Thomas Duthy and chair David McAuliffe.
In its Corporations Act 2001 Section 203D(2) and Section 249D notice to Invex, signed by Celtic Capital's Jason Peterson and William Anthony, Celtic Capital said it held more than five of Invex and it required Invex to call a general meeting to remove Dr Duthy, Mr McAuliffe and any directors appointed after September 15, 2025.
Invex said that "if the purported notices are deemed to be valid, the directors will be required to call a general meeting within 21 days after receipt of the valid request pursuant to section 249D of the Corporations Act, and the meeting is to be held no later than two months after the request is given to the company".
Invex fell 1.5 cents or 12.5 percent to 10.5 cents.

ARTRYA

Sydney's Regal Funds Management says it has become a substantial shareholder in Artrya with 9,670,354 shares or 6.58 percent.
Regal Funds said it bought shares between May 21 and September 15, 2025, with the single largest purchase on September 15 of 3,329,376 shares for $6,825,221 or $2.05 a share.
Artrya fell eight cents or 3.5 percent to $2.22 with 496,515 shares traded.

CONTROL BIONICS

Phoenix Development Fund says it has increased its substantial shareholding from 58,495,641 shares (19.85%) to 70,194,769 shares (20.87%).
The Sydney-based Pheonix said the shares were "beneficially held" and on September 17, 2025 it acquired 11,699,128 shares for $409,469 or 3.5 cents a share through the issue of underwriting shares.
Yesterday, Control Bionics said its non-renounceable rights issue raised $309,836, and was underwritten for $1,150,610, for a total of $1.46 million (BD: Sep 17, 2025).
In its substantial shareholder notice signed by company secretary David Falk, Phoenix said its address was Nightingale Partners Pty Ltd, Level 3, 22 Market Street, Sydney
Control Bionics was up 0.1 cents or 2.7 percent to 3.8 cents.

CONTROL BIONICS

Sydney's Nightingale Partners Pty Ltd says it has increased its substantial shareholding from 56,292,796 shares (19.10%) to 68,766,916 shares (20.45%).
Nightingale said that on September 17, 2025 it acquired 11,461,154 shares for $401,140.34 or 3.5 cents a share through the issue of underwriting shares (see above).
In its substantial shareholder notice signed by company secretary David Falk, Phoenix said its address was Nightingale Partners Pty Ltd, Level 3, 22 Market Street, Sydney

ADALTA

Platinum Investment Management says its 78,814,880 substantial share-holding in Adalta has been diluted from 6.83 percent to 5.40 percent.
The Sydney-based Platinum said it was diluted on September 16, 2025 due to the issue of new shares.
In June, Adalta said that it raised $1,090,452 of a hoped for $1,300,000 at 0.3 cents a share, a 50.8 percent discount to the 15-day volume weighted average price, in its 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 0.3 cents with 14.9 million shares traded.

CSL

CSL says it has appointed Dr Stephen Pitt as its head of Search "as it seeks to boost its pipeline of new therapies through partnerships".
CSL said that Dr Pitt would "work closely with the business development team and therapeutic area leads to find and assess external investment opportunities that support CSL's growth and ambition to deliver enduring patient impact".
The company said Dr Pitt would report to the head of research and development Dr Bill Mezzanotte and would join the research and development "leadership team".
CSL said that Dr Pitt was previously an executive at Johson & Johnson Innovative Medicine and "delivered more than 15 strategic deals focusing on localized, intra-tumoral therapies for lung and head and neck cancers".
The company said Dr Pitt held a Bachelor of Science from the Hartford, Connecticut-based Trinity College and a Doctor of Philosophy from New York's Weill Cornell Graduate School of Medical Sciences and Memorial Sloan Kettering Cancer Center.
CSL said that Dr Pitt held multiple patents and was published in scientific journals.
CSL fell $2.73 or 1.4 percent to $198.34 with 1.6 million shares traded.