Biotech Daily

Tuesday July 15, 2025

Daily news on ASX-listed biotechnology companies

*** ASX UP, BIOTECH EVEN: ATOMO UP 7%; AMPLIA DOWN 11%**

*** EBR PRELIMINARY US CMS PASS-THROUGH REIMBURSEMENT**

*** IMAGION TO FILE PHASE II MAGSENSE TRIAL IND TO FDA**

*** CLARIFICATION: IMUGENE**

*** CENTENARY: AAVR2 FOR SAFER, MORE EFFECTIVE GENE THERAPIES**

*** INVION 'LOYALTY OPTIONS' RAISE $1m**

*** SYNTARA BEGINS PHASE Ic SNT-6302 SCAR TRIAL**

*** LUMOS TAKES 'MATERIAL AGREEMENT' HALT TO SUSPENSION**

*** PENGANA TAKES 18% OF ONCOSIL**

*** AUSTRALIAN ETHICAL TAKES 7% OF ONCOSIL**

MARKET REPORT

The Australian stock market was up 0.7 percent on Tuesday July 15, 2025, with the ASX200 up 59.9 points to 8,630.3 points. Seventeen of the Biotech Daily Top 40 were up, 17 fell, four traded unchanged and two were untraded.

Atomo was the best, up 0.1 cents or 6.7 percent to 1.6 cents, with 802,414 shares traded. Clarity climbed 5.9 percent; 4D Medical, Actinogen, EBR and Paradigm were up more than four percent; CSL and Dimerix were up more than three percent; Aroa, Avita, Clinuvel, Genetic Signatures, Nanosonics, Pro Medicus and Syntara rose more than two percent; Mesoblast, Neuren, Polynovo and Telix were up more than one percent; with Resmed up by 0.7 percent.

Amplia led the falls for the second day in a row, following last week's 18.6 percent climb, down 3.5 cents or 10.9 percent to 28.5 cents, with 11.3 million shares traded. Cynata lost 6.25 percent; Alcidion, Compumedics and Resonance fell more than four percent; Medadvisor, Nova Eye and Proteomics were down more than three percent; Cyclopharm, Immutep, Impedimed, Micro-X, Prescient and Starpharma shed two percent or more; Emvision was down 1.1 percent; with Cochlear, Orthocell and SDI down by less than one percent.

EBR SYSTEMS

EBR says it has preliminary approval for US Centers for Medicare & Medicaid Services (CMS) transitional pass-through reimbursement (TPT) for its Wise CRT system.

In April, EBR said the US Food and Drug Administration approved its leadless Wise cardiac re-synchronization therapy (CRT) for left ventricular pacing (BD: Apr 14, 2025).

EBR managing-director John McCutcheon told Biotech Daily that the company "will be charging sites more than $US45,000 [$A68,700] per system and the transitional pass-through reimbursement "will cover the device cost for outpatient procedures".

EBR said preliminary approval was expected to be effective from October 2025 and would provide hospitals with Medicare reimbursement when treating patients in an outpatient setting with the Wise CRT system for a period of three years.

The company said the transitional reimbursement program was "designed to facilitate hospital adoption of breakthrough medical technologies that demonstrate substantial clinical improvement for patients, but whose costs are not yet fully incorporated in standard Medicare payment rates".

EBR said it would "continue to engage with CMS through the upcoming annual rule-making and public comment process, with a final determination to follow".

Mr McCutcheon said the company was "excited to receive preliminary approval of TPT reimbursement for EBR's Wise System".

"This major milestone along with CMS's previous proposal to approve [new-technology add-on payment] reimbursement will allow us to target broad patient access for Wise in the US," Mr McCutcheon said.

Earlier this year, EBR said the US CMS recommended its Wise system receive the maximum "new technology add-on payment" of 65 percent of cost (BD: Apr 15, 2025).

"Both these outpatient and inpatient reimbursement schemes are expected to become effective from October 2025," Mr McCutcheon said. "We look forward to continuing our engagement with the CMS to accelerate widespread adoption of Wise."

EBR was up 5.5 cents or 4.7 percent to $1.23 with 1.4 million shares traded.

IMAGION BIOSYSTEMS

Imagion says it expects to file a US Food and Drug Administration investigational new drug application (IND) for a phase II trial of Magsense for breast cancer by October.

Imagion said it met with the FDA and that "no issues were identified that could negatively impact the company's current plans and that the dialogue included input regarding future clinical and commercial development considerations".

In 2023, the company 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).

Today, Imagion said it would fast-track the manufacturing of Magsense for the phase II trial and had appointed the Norman, Oklahoma-based University of Oklahoma's Dr William Dooley as principal investigator for the multi-site, open-label study.

Imagion executive chair Bob Proulx said the company's "clinical team was pleased and very encouraged with the level of engagement we had with the reviewers".

"We view the fact that senior agency staff participated on the call as a sign that the agency is interested in what we are doing, our plans for the phase II trial in the US and the potential impact our technology may have on breast cancer diagnosis and staging," Mr Proulx said.

Imagion was up 0.3 cents or 21.4 percent to 1.7 cents with 45 million shares traded.

CLARIFICATION: IMUGENE

Last night's edition referred to Imugene's "129-patient, phase Ib trial of azer-cel with interleukin-2 cytokine for large B-cell lymphoma, with azer-cel safe and tolerable".
In fact, Imugene acquired Precision Biosciences for its azer-cel technology in which it had conducted an 84-patient trial.
The current phase I/Ib trial is expected to enrol a total of 42 patients.
No sub-editors were hurt in making this clarification, but they have been warned, sternly.
We apologise to Imugene for any confusion.
Imugene was in a trading halt and last traded at 42.5 cents.

CENTENARY INSTITUTE

The Centenary Institute says an alternate receptor for adeno-associated viruses (AAVR2) could be used to deliver safer and more effective gene therapies.
The Centenary Institute said that with the University of Sydney it found that the AAVR2 receptor "could allow lower doses of virus to be used in treatment, helping to reduce side effects and treatments costs, while improving patient outcomes" for genetic disorders including Duchenne muscular dystrophy, Pompe disease and haemophilia.
The Institute said the study, titled 'An alternate receptor for adeno-associated viruses' was published in the journal Cell, with the full article available at: http://bit.ly/44OhS7w.
The Centenary Institute said that gene therapies typically used "modified viruses, known as adeno-associated viruses (AAVs), to deliver healthy genes into the body".
The Institute said gene therapies could be life-changing for patients but "frequently require high vector doses to achieve therapeutic effects which in some cases can trigger severe immune responses, lead to serious complications, or even death".
The Centenary Institute said using genetic, biochemistry and molecular biology techniques its researchers showed "that AAVR2 plays a crucial role in helping several AAV types, including those widely used in patients, enter cells more efficiently".
The Institute said the study was supported by funding from New South Wales Health, the Federal Government's National Health and Medical Research Council, Therapeutic Innovation Australia, Tour de Cure, Cure the Future and Brandon Capital Cureator.
Co-senior author Dr Charles Bailey said the team "not only identified this new receptor AAVR2 but also discovered how it binds to the viruses that deliver the genes".
"This discovery uncovers a completely new pathway for delivering genes into cells. Modulating this pathway can potentially make gene therapies safer, cheaper and more precise," Dr Bailey said. "We then went a step further and engineered a miniature version of the receptor and demonstrated that this significantly enhances how efficiently the gene therapy is taken up in human cells and tissues".

INVION

Invion says it has raised $1 million, through the issue of "loyalty options" at 1.5 cents each, exercisable at 14 cents each by June 30, 2027.
Invion said eligible shareholders had applied for 19,225,155 loyalty options, raising about $288,377, with the shortfall taken up by underwriter Blue Ocean Equities Pty Ltd as well as sub-underwriters including executive chair Prof Thian Chew.
In June, Invion said it expected to raise between $1 million and $16 million through the issue of 77 loyalty options for every 100 shares owned, as well as one piggyback option for every two options exercised before December 31, 2025 (BD: Jun 13, 2025).
Invion was unchanged at 10.5 cents.

SYNTARA (FORMERLY PHARMAXIS)

Syntara says it has dosed the first of up-to 20 patients, in its phase Ic trial of topical SNT-6302, formerly PXS-6302, for keloid, or raised, scars.
In 2023, the then Pharmaxis said a 42-patient, phase I trial showed PXS-6302 topical cream reduced collagen in scars by 30 percent but not appearance at three months, which pointed to the need for a long study in established scars (BD: May 24, 2023).
In February, Syntara said a 14-patient subset showed “significant improvements” in scar vascularization and extra-cellular matrix remodeling (BD: Feb 18, 2025).
At that time, Syntara said SNT-6302 was developed as a topical treatment to modify scar composition and reduce fibrosis by inhibiting the enzyme lysyl oxidase (LOX).
Today, the company said the open-label, placebo-controlled, ‘Satellite’ study, would enrol up-to 20 participants aged 18 years and older with multiple, active keloids measuring between five and 25 square centimetres.
Syntara said participants would undergo a four-week placebo run-in period followed by application of topical SNT-6302 four days a week for a treatment period of three months.
The company said the trial would assess safety, tolerability, pharmaco-kinetics and preliminary efficacy, including changes in scar volume, collagen attenuation, tissue stiffness and patient-reported outcomes of itch and pain.
Syntara said keloid scars grew in area and depth, were “disfiguring and debilitating and often associated with chronic pain, itch and significant psychological distress”.
The company said Prof Fiona Wood was principal investigator with the trial to be conducted through the Fiona Wood Foundation and the University of Western Australia.
Syntara was up 0.1 cents or 2.1 percent to 4.9 cents with 1.8 million shares traded.

LUMOS DIAGNOSTICS HOLDINGS

Lumos has requested a voluntary suspension following Friday’s trading halt pending an announcement “in relation to strategic material agreements” (BD: July 11, 2025).
Trading will resume on July 16, 2025, or on an earlier announcement.
Lumos last traded at 2.9 cents.

ONCOSIL MEDICAL

Pengana Capital Group says it has increased its substantial shareholding in Oncosil from 2,349,702 shares (16.52%) to 3,422,619 shares (18.19%).
The Sydney-based Pengana said that on July 11, 2025 it bought 1,072,917 shares for $1,287,500, or $1.20 per post-400-to-one consolidation share.
Oncosil was up one cent or 0.9 percent to $1.11.

ONCOSIL MEDICAL

Sydney’s Australian Ethical says it has increased its substantial shareholding in Oncosil from 732,568 shares (5.15%) to 1,304,473 shares (6.93%).
Australian Ethical said that it bought 35,446 shares on June 25, 2025 for $35,445, or $1.00 a share, and a further 536,459 shares on July 11, 2025 for $643,751, or $1.20 a share (see above).