

# **Biotech Daily**

## Thursday June 19, 2025

## Daily news on ASX-listed biotechnology companies

- \* ASX FLAT, BIOTECH DOWN: AMPLIA UP 190%; EBR DOWN 8%
- \* AMPLIA UP 203% ON 2nd AMP945 COMPLETE PANCREATIC CANCER RESPONSE
- \* ORTHOCELL: 'REMPLIR BEATS STANDARD FOR NERVE FUNCTION, IN RATS'
- \* NEUROSCIENTIFIC: 2010 DATA BACKS STEMSMART FOR GvHD
- \* RACE DOSES 1st PHASE I RC220, DOXORUBICIN PATIENT
- \* TRIVARX RECRUITS 1st US VETERAN HEART-DEPRESSION PATIENT
- \* BIO-MELBOURNE 2025-'28 STRATEGY
- \* UNIVERSAL BIOSENSORS REQUESTS 'CAPITAL RAISING' TRADING HALT
- \* MICROBA REQUESTS 'CAPITAL RAISE' TRADING HALT
- \* AUSBIOTECH, ENDPOINTS: 1 WEEK TO VICTORIA BIO-BRIEFING
- \* PINNACLE TAKES 5% OF NANOSONICS
- \* ACORN TAKES 9% OF AMPLIA
- \* BLINKLAB CTO CORNELIS BOELE DILUTED BELOW 5%
- \* BLINKLAB CSO DR SEBASTIAAN KOEKKOEK DILUTED BELOW 5%

#### MARKET REPORT

The Australian stock market slipped 0.09 percent on Thursday June 19, 2025, with the ASX200 down 7.5 points to 8,523.7 points. Seven of the Biotech Daily Top 40 companies were up, 25 fell, seven traded unchanged and one was untraded.

Amplia was the best (see below), up 15.4 cents or 190.1 percent to 23.5 cents, with 88.1 million shares traded. Impedimed climbed 3.6 percent; Dimerix and Micro-X rose two percent or more; Cochlear was up 1.6 percent; with Clarity, Clinuvel and Medical Developments up by less than one percent.

EBR led the falls, down nine cents or 7.7 percent to \$1.08, with 1.5 million shares traded; followed by Syntara, down 7.0 percent to 5.3 cents with 131.6 million shares traded. Mesoblast lost 6.7 percent; Curvebeam was down 5.3 percent; Medadvisor, Optiscan and Prescient fell four percent or more; 4D Medical, Botanix, Compumedics, Neuren and Paradigm were down more than three percent; Aroa, Cyclopharm, Cynata, Emvision, Genetic Signatures, Immutep, Proteomics, Resonance and Telix shed more than two percent; CSL, Nanosonics, Pro Medicus and Starpharma were down one percent or more; with Avita, Polynovo and Resmed down less than one percent.

## **AMPLIA THERAPEUTICS**

Amplia was up as much as 202.5 percent on news that its AMP945, or narmafotinib, led to a second confirmed complete response in a pancreatic cancer patient.

On Monday, the company said narmafotinib, or AMP945, with chemotherapy, for pancreatic cancer led to one 'pathological complete response' (BD: Jun 16, 2025).

Today, Amplia said a confirmed complete response was "a formal designation of response where there is a complete disappearance of all tumor lesions that is maintained for more than two months".

The company said a confirmed complete response was "a rare outcome in advanced pancreatic cancer where the disease has spread to other parts of the body".

Last month, Amplia said its 55-patient, phase lb/lla 'Accent' trail showed narmafotinib with standard-of-care chemotherapies gemcitabine and Abraxane led to 15 metastatic pancreatic cancer partial responses (BD: May 15, 2025).

In May, Amplia managing-director Dr Chris Burns told Biotech Daily that 15 partial responses from 55 patients was better than the chemotherapy alone historical average. Amplia said a previous study had shown the chemotherapies gemcitabine and Abraxane efficacy in advanced pancreatic cancer reported one complete response of 431 patients. Dr Burns said a second complete response in the trial was "really wonderful news, particularly given how rare these are observed in advanced pancreatic cancer".

"Along with the pathological [complete response] announced earlier in the week, this outcome further demonstrates the promising activity narmafotinib, on top of standard-ofcare, is showing in pancreatic cancer," Dr Burns said.

Amplia climbed as much as 16.4 cents or 202.5 percent to 24.5 cents, before closing up 15.4 cents or 190.1 percent at 23.5 cents with 88.1 million shares traded.

## **ORTHOCELL**

Orthocell says Remplir for nerve repair leads to "superior regeneration of nerve tissue and earlier return of muscle function" compared to standard-of-care, in rats.

Orthocell said it commissioned a study of "the impact of sutures on nerve regeneration and functional recovery in surgical repair of severed peripheral nerves", conducted by its chief scientific officer and Perth's University of Western Australia.

The company said the study of 48 rats with sciatic nerve injury compared the use of one suture, three sutures, six sutures and one suture augmented with Remplir on nerve function and regeneration 12 weeks post-treatment.

Orthocell said interim results showed that Remplir led to an early return of function, higher quality nerve regeneration, restoration of nerve structure and no inflammatory response. The company said the study was commissioned to support US Remplir sales roll-out and its US representatives were "making significant progress towards imminent first sales and first US surgical use of Remplir".

Earlier this year, Orthocell said it had US Food and Drug Administration 510(k) clearance to begin commercial distribution of its Remplir collage wrap for the surgical repair of peripheral nerves in the US (BD: Apr 4, 2025).

Today, Orthocell managing-director Paul Anderson said the company was "delighted with the results from our suturing study, validating the superior Remplir clinical outcomes, previously published in a highly regarded, peer-reviewed journal".

"These study results provide key data to support the US product sales roll-out and rapid market adoption and will be a cornerstone of our US medical education efforts," Mr Anderson said.

Orthocell was unchanged at \$1.20 with 1.8 million shares traded.

## NEUROSCIENTIFIC BIOPHARMACEUTICALS

Neuroscientific says a historical 19-patient, phase I trial of target acquisition Stemsmart cells supports their use in steroid-refractory graft-versus-host disease (GvHD). Earlier this year, Neuroscientific said it would acquire Perth's Isopogen WA and its Stemsmart cells for indications including Crohn's disease; and later, said Isoposen was preparing to dose the first of up-to 12 special access program patients with the mesenchymal stromal cells for Crohn's disease (BD: Apr 16, May 23, 2025).

Today, the company said the September 2007 to April 2010 trial studed Stemsmart cells as a treatment for graft-versus-host disease in 12 adult patients with GvHD and seven adult patients with chronic GvHD, and showed that infusions were well tolerated with no acute infusion-related toxicities and no subsequent toxicities.

The company said that in patients with non-chronic disease, Stemsmart led to a complete response in seven of 12 patients (58.3%), a partial response in four of 12 patients (33.3%) and no response in one patient.

Neuroscientific said that in patients with chronic disease, two of seven patients (28.6%) had a complete response, two had a partial response, and no response in three patients. The company said three-year survival for patients with acute graft-versus-host disease was 55 percent, compared to the expected survival of 15 to 20 percent and median survival in chronic graft versus host disease patients was eight months.

Neuroscientific said the complete response to Stemsmart therapy was "a statistically significant predictor of survival for acute GvHD patients (p= 0.0008) but not for chronic GvHD (p= 0.100)".

The company said six children with acute GvHD and four children with chronic disease had been treated on compassionate grounds with Stemsmart, with all children surviving more than 12 months post-transplant, "an improvement on anticipated mortality". Neuroscientific chief technical officer Dr Marian Sturm said the "significant clinical responses in these studies demonstrate the potential for life changing outcomes with Stemsmart [mesenchymal stromal cell] therapy".

"Those patients who develop steroid-refractory GvHD are no longer responding to treatment, and with no other treatment options available, face a high rate of mortality," Dr Sturm said.

Neuroscientific was untraded at six cents.

## RACE ONCOLOGY

Race says it has dosed the first of up-to 53 patients in its phase I combination trial of RC220 bisantrene and doxorubicin for advanced solid tumors.

Last month, Race said it had dosed the first patient with RC220 monotherapy in the trial, with no vein inflammation or other adverse events reported (BD: May 1, 2025).

Today, the company said the first patient was dosed with the combination therapy at the Miranda, New South Wales' Southside Cancer Care Centre, with no treatment-related, dose-limiting, adverse side effects observed.

Race head of medical Dr Simon Fisher said beginning the trial and the early safety observations were encouraging.

"We are partnering well with our Australian sites and working diligently to activate additional sites in Hong Kong and South Korea," Dr Fisher said.

"We remain excited with the progress of RC220 in the clinic and its potential to offer an improved treatment option for the many patients at risk of cardio-toxicity related to doxorubicin therapy," Dr Fisher said.

Race was up seven cents or 5.5 percent to \$1.35.

### TRIVARX (FORMERLY MEDIBIO)

Trivarx says it has recruited the first of up-to 30 US veterans in a study of its electrocardiography (ECG) sleep scoring algorithm for a major depressive episode. In March, Trivarx said that with the US Department of Veterans Affairs it would conduct a 12-week trial of its algorithm for depression; and later, said it had opened the trial at the West Los Angeles Veterans Affairs Medical Center (BD: Mar 13, May 30, 2025). Today, the company said as well as using the single-channel ECG, veterans participating in the trial would wear a wrist-worn device during the night providing the company with additional data for further research, development and commercialization. Trivarx chair David Trimboli said the first patient recruitment was "a major achievement for the company and signals the commencement of our innovative clinical trial". Trivarx fell 0.1 cents or 10 percent to 0.9 cents with 1.6 million shares traded.

#### **BIO-MELBOURNE NETWORK**

The Bio-Melbourne Network says it has released its 2025-'28 strategy to "strengthen Victoria's [health technology] sector".

The Bio-Melbourne Network said the plan included "five key pillars [which were] catalyzing sector growth, strengthening Victoria's investment value, cultivating a culture of learning, leading advocacy and showcasing the sector's achievements".

The Network said the plan was announced by chief executive officer Karen Parr at an online launch event and reflected "the organization's role as a connector and advocate for Victoria's [medical technology], [biotechnology] and health innovation sectors".

"As Victoria's peak body for almost 25 years, representing more than 200 member organizations, we play a critical role in enabling collaboration, facilitating knowledgesharing, and advocating for an environment that fosters innovation, commercialization, and manufacturing to thrive," Ms Parr said.

"This plan sharpens our focus and reinforces our commitment to driving sector-wide outcomes that position Victoria as a global leader in health innovation," Ms Parr said. Bio-Melbourne Network chair Dr Emma Ball said the strategy arrived "at a critical time".

"The Victorian and global health technologies sector is evolving rapidly," Dr Ball said. "It's a practical, purposeful guide for how Bio-Melbourne Network will lead and amplify the impact of its members and the sector," Dr Ball said.

The Bio-Melbourne Network said that a document on the strategy was available at: <u>https://biomelbourne.org/biomelbourne-network-strategy-launch-2025-2028/</u>.

#### UNIVERSAL BIOSENSORS

Universal Biosensors has requested a trading halt "pending the release of an ASX announcement by the company in connection with a proposed capital raising". Trading will resume on June 23, 2025, or on an earlier announcement. Universal Biosensors last traded at 3.5 cents.

#### MICROBA LIFE SCIENCES

Microba has requested a trading halt pending an announcement "in relation to a proposed capital raise".

Trading will resume on June 23, 20245, or on an earlier announcement. Microba last traded at 11.5 cents.

#### **AUSBIOTECH**

Ausbiotech says its Victoria 'Bio-Briefing' event will be held at Level 33, 477 Collins Street, Melbourne on June 26, 2025 from 4.45pm to 6.30pm (AEST).

Ausbiotech said the event would provide "insights into non-dilutive capital and how it can transform biotech funding while navigating Australia's unique financing landscape during these uncertain times".

The industry organization said the event included panellists Endpoints Capital chief commercial officer Holly Stefl, Rhythm chief executive officer Dr David Atkins, Haines Consulting chief executive officer Stuart Haines and CFO Plus director Rohina Batra. Ausbiotech said the event was held in partnership with Sydney's Endpoints Capital and Sydney intellectual property law firm FB Rice.

The organization said tickets were free for members, \$100.00 for non-members and available at: <u>https://www.ausbiotech.org/events/event/vic-biobriefing-june-2025</u>.

#### NANOSONICS

Pinnacle Investment Management Group Ltd says it has become a substantial shareholder in Nanosonics with 15,812,969 shares, or 5.21 percent.

The Brisbane-based Pinnacle said that it bought and sold shares between February 26 and June 13, 2025, with the single largest purchase 1,323,484 shares on June 13 for \$5,839,769, or \$4.41 a share.

Nanosonics fell eight cents or 1.9 percent to \$4.10 with two million shares traded.

#### AMPLIA THERAPEUTICS

Acorn Capital Ltd says it has increased its substantial shareholding in Amplia from 27,583,089 shares (7.70%) to 34,573,696 shares (8.91%).

The Melbourne-based Acorn said that on June 16, 17 and 18, 2025 it bought 5,059,812 shares for \$363,239, or 7.2 cents a share.

#### **BLINKLAB**

Blinklab chief technical officer Cornelis Boele says his 5,775,000 share-holding has been diluted below the five percent substantial threshold.

Last month, Blinklab said it raised \$7.66 million at 30.0 cents a share, a 15.8 percent discount to the 15-day volume weighted average price, in a placement (BD: May 1, 2025). According to its most recent filing, Blinklab had 162,122,180 shares on issue, meaning Mr Boele retained 3.6 percent of the company.

Blinklab fell one cent or 2.2 percent to 44 cents.

#### **BLINKLAB**

Blinklab chief scientific officer Dr Sebastiaan Koekkoek says his 5,775,000 share-holding has been diluted below the five percent substantial threshold (see above).

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