



Biotech Daily

Wednesday January 22, 2025

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH UP: ORTHOCELL UP 16%; DIMERIX DOWN 6%**
- * **PACIFIC EDGE TEST VOLUMES 'STEADY'; MEDICARE UNCERTAINTY**
- * **LTR APPOINTS SYMBION AUSTRALIA SPONTAN DISTRIBUTOR**
- * **COMPUMEDICS \$3m PHILIPS SOMFIT SLEEP TESTING DEAL**
- * **AUDEARA, CLINICO LAUNCH EARBUDS IN TAIWAN**
- * **ORTHOCELL TO FILE 5 REMPLIR SUBMISSIONS IN 2025**
- * **IMMUTEP ENROLS PHASE II EFTI SOFT TISSUE SARCOMA TRIAL**
- * **ISLAND ENROLS PHASE IIa/IIb ISLA-101 DENGUE THERAPY PATIENTS**
- * **ARCHER US BIOCHIP PATENT**
- * **LANTHEUS TAKES 12% OF RADIOPHARM**
- * **ORB HEALTH TAKES 11% OF RESPIRI**
- * **EMYRIA CHAIR GREG HUTCHINSON EXEC; DR MICHAEL WINLO CSO**
- * **CORRECTION: AUSBIOTECH**

MARKET REPORT

The Australian stock market was up 0.33 percent on Wednesday January 22, 2025, with the ASX200 up 27.4 points to 8,429.8 points. Eighteen of the Biotech Daily Top 40 companies were up, 16 fell, five traded unchanged and one was unchanged.

Orthocell was the best, up 20.5 cents or 15.8 percent to \$1.505, with 4.6 million shares traded. Percheron climbed 12.5 percent; Compumedics and Micro-X were up six percent or more; EBR was up 5.4 percent; Nanosonics, Prescient and Starpharma improved four percent or more; Alcidion and Neuren were up three percent or more; Aroa, Clarity, Opthea and Pro Medicus rose two percent or more; Genetic Signatures, Immunetep, Impedimed, Polynovo, Resmed and Telix were up more than one percent; with Cochlear up by 0.9 percent.

Dimerix led the falls, down three cents or 6.25 percent to 45 cents, with 4.2 million shares traded. Paradigm lost 5.5 percent; Curvebeam, Cyclopharm, Mesoblast and Universal Biosensors fell four percent or more; Actinogen was down 3.85 percent; Avita, Imugene, Medadvisor, Nova Eye and Syntara shed more than two percent; Clinuvel, CSL and Medical Developments were down more than one percent; with Emvision and Proteomics down by less than one percent.

PACIFIC EDGE

Pacific Edge says Cxbladder tests processed for the three months to December 31, 2025 were “steady on the prior quarter ... [reflecting] the impact of Medicare uncertainty”.

Last week, Pacific Edge said its US Medicare administrative contractor Novitas would cease reimbursement of its Cxbladder urine tests for bladder cancer from February 23, 2025, following an extension to finalize or withdraw changes to coverage of the tests last year (BD: Jul 29, 2024; Jan 19, 2025).

Today, the company said total laboratory throughput for the three months to December 31, 2024 was up 0.7 percent to 7,092 tests compared to 7,042 tests in the prior period. Pacific Edge said “Novitas’ deliberations remained the overriding challenge to test volume growth, although the seasonal holiday slowdown also impacted volumes in the quarter”.

The company said that a “steady demand from our US customer Kaiser Permanente, the sustained benefits of our sales force efficiency gains and an uplift in demand from the US clinicians most supportive of our tests diluted the impact of these factors”.

Pacific Edge said it had hired an additional full-time equivalent US sales team member for the last month of the period.

The company said in an investor update, released on January 13, 2025, it might pursue “a preliminary injunction and legal challenge to the finalization of the [local coverage determination]”.

Today, Pacific Edge said its response included “the path the company has set to regaining reimbursement certainty and our confidence of achieving that goal”.

The company said Asia Pacific test volumes for the three months were down 5.6 percent to 1,284 tests, compared to the prior period, reflecting “the seasonal holiday slowdown in New Zealand”.

Pacific Edge was up 0.1 cents or 1.75 percent to 5.8 cents.

LTR PHARMA

LTR says Melbourne pharmaceutical wholesaler Symbion Pty Ltd will distribute its Spontan nasal spray for erectile dysfunction in Australia.

Last year, LTR said the first patients had been prescribed Spontan nasal spray formulation of vardenafil, marketed as Levitra, under an Australian Therapeutic Goods Administration’s special access scheme (BD: Aug 5, 8, 16, 2024).

Today, the company said the Ebos Group subsidiary Symbion would provide warehousing, inventory management and nationwide distribution services for Spontan through its network of distribution centres, which service more than 3,900 pharmacies in Australia.

The company said the non-exclusive agreement was effective from March 1, 2025 and gave it access to established, scalable pharmaceutical infrastructure, aligning with the company’s strategy to support the early access scheme and prepare for a full-scale commercial launch following regulatory approvals.

LTR chair Lee Rodne said the partnership was “a pivotal step in building our commercial infrastructure”.

“Symbion’s extensive distribution network and expertise will ensure seamless access to Spontan across Australia,” Mr Rodne said.

“This agreement underscores our commitment to collaboration with industry leaders to establish a reliable supply chain, support the TGA’s early access program, and prepare for Spontan’s anticipated commercial launch,” Mr Rodne said. “Together, we are ensuring the highest standards of pharmaceutical handling and service delivery.”

LTR was up 3.5 cents or five percent to 73.5 cents with two million shares traded.

COMPUMEDICS

Compumedics says it has a \$3 million, five-year contract to supply its Somfit device to Philips Australia for pharmacy-based sleep testing.

Compumedics said it had worked with Philips since August 2023 as a distributor to for Australian pharmacy-based sleep programs and the partnership was “key to our success in this fast-moving area”.

The company said the contract “underpins approximately \$3 million of software-as-a-service revenues for Somfit in Australia currently, and over the contract period through to 2028”.

Compumedics was up two cents or 6.6 percent to 32.5 cents.

AUDEARA

Audeara says its CS1 Clinico-branded earbuds are being sold in Taiwan, following the completion of its product development agreement with Taipei’s Clinico Inc.

Earlier this year, Audeara said Clinico had paid \$180,000 in cash to develop and distribute its hearing earbuds in China and Taiwan (BD: Aug 5, 2024).

Later, the company said it received a \$570,000 purchase order for Clinico-branded hearing earbuds (BD: Oct 8, 2024).

Today, Audeara said the launch was “an important milestone in Audeara’s stated strategy to scale its ... technology division into international markets through product integration and white-label partnerships”.

Audeara chief executive officer Dr James Fielding said the launch of Clinico Sound Earbuds in Taiwan is a proud moment for Audeara, showcasing the results of our ongoing dedication and innovation in healthy hearing solutions”.

“This milestone also demonstrates the strength of our partnerships and the global relevance of our expertise, which extends beyond the Taiwanese market to collaborations such as our work with Eastech for the Chinese market,” Dr Fielding said.

“We are committed to transforming hearing health worldwide, one innovative product at a time,” Dr Fielding said.

“As the largest hearing aid retailer in Taiwan, Clinico provides ... a unique distribution advantage which is expected to expand further now that the product is officially in-market,” Dr Fielding said.

“With this product launch, we have established a strong platform for growth in major Asian markets, further complementing our broader international momentum,” Dr Fielding said.

Audeara was unchanged at 3.6 cents.

ORTHOCELL

Orthocell says it expects to apply for approvals of its Remplir collagen wrap for nerve repair in Canada, Thailand, the UK, the European Union and Brazil this year.

Orthocell said that the applications were “on the back of outstanding early sales traction” and would be accelerated ahead of US Food and Drug Administration clearance, which was expected in March or April 2025.

Last month, the company said it had submitted a 510(k) application to the US Food and Drug Administration for Remplir for peripheral nerve repair (BD: Dec 19, 2024).

Today, Orthocell said Remplir was currently approved in Australia, New Zealand and Singapore and distributed by Device Technologies (BD: Nov 27, 2024).

Orthocell was up 20.5 cents or 15.8 percent to \$1.505 with 4.6 million shares traded.

IMMUTEP

Immutep says it has enrolled all 40 patients in its phase II trial of eftilagimod alpha, or efiti, with radio-therapy and Keytruda for soft tissue sarcoma.

In 2023, Immutep said it would provide efiti, previously called IMP321, to the Warsaw, Poland-based Maria Skłodowska-Curie National Research Institute of Oncology to conduct an up-to 40-patient, open-label phase II trial in combination with radio-therapy and pembrolizumab, or Keytruda, for soft tissue sarcoma (BD: Apr 17, 2023).

Last year, the company said four of six soft tissue sarcoma patients in the phase II trial had “near complete responses” (BD: May 2, 2024).

Today, Immutep said that in the 21 patients evaluable for primary endpoint assessment “the triple combination achieved a greater than three-fold increase in tumor hyalinization/fibrosis, median 50 percent, at the time of surgical resection as compared to a historical median 15 percent from radio-therapy alone”.

The company said treatment had been safe “with no grade three or more toxicities related to efiti and pembrolizumab” and further data updates were “expected in 2025”.

Immutep was up half a cent or 1.6 percent to 32.5 cents with 2.3 million shares traded.

ISLAND PHARMACEUTICALS

Island says it has enrolled all 10 patients in the therapeutic arm of its phase IIa/IIb trial of ISLA-101 for dengue fever, taking the total with the preventative arm to 14 patients.

Last year, Island said the four patients in the prophylactic arm of its 14-patient, phase IIa/b trial showed ISLA-101’s “safety and anti-dengue activity” (BD: Nov 27, 2024).

Today, the company said high-level results from the phase IIb study were expected “to be available around April 2025” with full results from both cohorts expected by 2026.

Island managing-director Dr David Foster said the company was “pleased to have reached this important milestone in our ... clinical trial”.

“The enrolment of the final six subjects in the phase IIb therapeutic arm is a significant advancement in our clinical trial, and towards better understanding the potential of ISLA-101 as a treatment for dengue fever,” Dr Foster said.

Island was unchanged at 16 cents.

ARCHER MATERIALS

Archer says it has been granted a US patent for its biochip technology.

According to the US Patent and Trademark Office website, the patent, titled ‘Graphene Complexes and Compositions Thereof’ protected the composition, methods and use of Archer’s intellectual property till graphene but did not state the duration of the patent.

The company said the patent covered the development of the biosensing chip for graphene complexes and their compositions that could be used in bio-molecular sensing.

At publication, Archer had not responded to inquiries regarding the patent duration.

Archer was up 3.5 cents or 8.1 percent to 46.5 cents with two million shares traded.

RADIOPHARM THERANOSTICS

Boston’s Lantheus Holdings Inc says it has increased its substantial shareholding in Radiopharm from 149,625,180 shares (6.82%) to 282,958,513 shares (12.12%).

Lantheus said it bought 133,333,333 shares on January 20, 2025 for six cents a share in an \$8 million share subscription agreement (BD: Jan 19, 2025).

Radiopharm was up 0.1 cents or 3.85 percent to 2.7 cents with 6.4 million shares traded.

RESPIRI

Orb Health Inc says it has become a substantial shareholder in Respire with 168,153,993 shares, or 11.19 percent.

Yesterday, Respire said that it had purchased the Dallas, Texas-based Orb Health Inc for \$US9,000,000 (\$A14,409,000) in scrip and raised \$US700,000 (\$A1,100,000) in a placement to Orb Health (BD: Jan 21, 2025).

Today, Orb Health said that on January 20, 2025 it received 160,998,504 shares through its agreement with Respire and bought 7,155,489 shares for \$US400,000.

Respire fell 0.2 cents or 2.7 percent to 7.2 cents.

EMYRIA

Emyria says chair Greg Hutchinson has been appointed executive chair with managing-director Dr Michael Winlo becoming chief scientific officer, effective from today.

Emyria said as executive chair, Mr Hutchinson would “drive Emyria’s expansion efforts as the company prepares for significant growth off the back of encouraging clinical results” from its trials of 3,4 methylene-dioxy-meth-amphetamine (MDMA) with therapy for post-traumatic stress disorder and psilocybin with therapy for depression.

The company said Dr Winlo would remain a director and would be paid \$260,000 a year, exclusive of superannuation, with Mr Hutchinson to be paid \$190,000 a year, inclusive of superannuation.

Today, the company said shareholders would vote to issue Dr Winlo 2,000,000 options, exercisable at 5.1 cents each within three years.

Emyria was up 0.2 cents or 6.25 percent to 3.4 cents.

CORRECTION: AUSBIOTECH

Last night’s edition reported an incorrect cost to non-members for the March 7, 2025 women in life sciences leadership summit, to be held in Sydney.

The correct prices are \$215 for members and \$265 for non-members, with luncheon tickets costing \$230 and \$280 for members and non-members, respectively, with registration to close on February 7, 2025.

To register go to: <https://bit.ly/3E1AMhs>.

The error was made by the Tuesday sub-editor who had been paying too much attention to US politics and has been deported to a small South American republic.