



# Biotech Daily

Monday July 14, 2025

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH UP: COMPUMEDICS UP 17%; AMPLIA DOWN 9%**
- \* **IMUGENE 2 AZER-CEL COMPLETE RESPONSES; 6 CR, 3 PARTIAL of 11**
- \* **COMPUMEDICS RECORD UNAUDITED REVENUE UP 3% TO \$51m**
- \* **PACIFIC EDGE Q1 CXBLADDER TESTS PROCESSING DOWN 9% TO 6.9k**
- \* **VICTORIA \$1.5m WOMEN'S HEALTH RESEARCH GRANTS**
- \* **CLEVER CULTURE NOVO NORDISK APAS ORDER**
- \* **PROTEOMICS: 'OXIDX MEASURES MUSCLE DAMAGE, IN RACEHORSES'**
- \* **OSTEOPORE SWISS CRANIO-FACIAL IMPLANT APPROVAL**
- \* **NYRADA APPROVAL FOR FINAL PHASE I NYR-BI03 COHORT**
- \* **ALTERITY PLEADS 'SCHULTZ, DATA' TO 55.6% ASX PRICE QUERY**
- \* **LEGACY ORB HEALTH INCREASES, DILUTED TO 10% OF VITASORA**
- \* **OPYL EXECUTIVE CHAIR SAURABH JAIN TAKES 5%**
- \* **ONE MONTH TO GO FOR TAIWAN \$137k FOR MEDICAL, HEALTH GRANTS**

## MARKET REPORT

The Australian stock market fell 0.11 percent on Monday July 14, 2025, with the ASX200 down 9.7 points to 8,570.4 points. Twenty-one of the Biotech Daily Top 40 were up, 11 fell, seven traded unchanged and one was untraded.

Compumedics was the best, up 4.5 cents or 17.3 percent to 30.5 cents, with 258,110 shares traded. Universal Biosensors rose 16.7 percent; Clarity and Impedimed improved more than eight percent; Cynata, Micro-X and Nova Eye climbed more than six percent; Medadvisor was up 5.3 percent; 4D Medical, Immutep and Prescient rose more than two percent; Curvebeam, EBR, Emvision, Genetic Signatures, Medical Developments, Paradigm and Starpharma were up one percent or more; with CSL, Dimerix, Mesoblast and Polynovo up by less than one percent.

Friday's 9.4 percent best, Amplia, led the falls, down three cents or 8.6 percent to 32 cents, with 11.4 million shares traded. Botanix lost 6.45 percent; Nanosonics, Resonance and Syntara fell four percent or more; Cyclopharm, Orthocell and Telix shed two percent or more; Avita, Neuren and Resmed were down more than one percent; with Clinuvel, Cochlear and Pro Medicus down by less than one percent.

## IMUGENE

Imugene says two more complete responses takes the total to six, with three partial responses of 11 evaluable patients in its phase Ib trial of 'azer-cel' for blood cancer. Imugene said six of the 11 evaluable patients had reported a complete response at day-60, which was "defined as the disappearance of all signs of cancer in response to treatment" and that three patients had achieved a partial response.

Imugene managing-director Leslie Chong told Biotech Daily that the twelfth patient had a partial response at day-30 scans and had not reached the day-60 scan, yet.

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).

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

Today, Ms Chong said a partial response was a "significant reduction in tumor size, typically at least 50 percent, or disease burden" and for approved autologous CD19 CAR T products, "the average time to best response is two-to-three months with some patients taking up-to six months to achieve their best response".

The company said the trial included CAR-T-cell-naïve indications in other lymphomas.

Imugene said the first patient was cancer free at 15 months "with additional patients having durable responses at two, five and 11 months and durability data continuing".

The company said it expected to meet with the US Food and Drug Administration for a pivotal, registrational study for azer-cel; and the trial continued to "actively enrol patients" at 10 US sites with up-to six sites in Australia planned.

Separately, the company requested a trading halt "pending an announcement ...[on] capital raising", with trading to resume on July 16, 2025, or on an earlier announcement.

Imugene last traded at a post-34-to-one-consolidation 42.5 cents.

## COMPUMEDICS

Compumedics says it has record unaudited revenue for the year to June 30, 2025 up 2.6 percent to \$51.0 million, compared to the prior corresponding period.

Last year, Compumedics said revenue for the year to June 30, 2024 from sales of its Somfit and Nexus360 sleep diagnostics, Oktii wireless amplifier, ultrasonic bloodflow systems, supplies, technical service and support was \$49,719,000 (BD: Aug 30, 2024).

Today, the company said sleep and neurology revenue was up 16 percent to \$46.3 million, Somfit and Nexus360 sales rose 41 percent to \$6.0 million, with no revenue from its magneto-encephalography (MEG) brain monitoring business; with sales orders up 22 percent to \$63.4 million, including \$5.9 million in MEG orders, with three systems in progress and revenue of about \$15 million expected in the year to June 30, 2026.

The company said earnings before interest, taxation, depreciation and amortization (Ebitda) was about \$3 million, with "record sales orders, a return to profitability, and growing traction in the US and [software as a service] segments have set a strong foundation for 2025-'26"; and it expected revenue of at least \$70 million for the year to June 30, 2026, with Ebitda of about \$9 million.

Compumedics executive chair Dr David Burton said the result reflected "the step-change underway at Compumedics".

"2025-'26 will see us scale into a more focused, cash-generative global business underpinned by recurring revenues from Somfit and clinical innovation, with MEG deliveries and growing demand in China providing further upside," Dr Burton said.

Compumedics was up 4.5 cents or 17.3 percent to 30.5 cents.

## PACIFIC EDGE

Pacific Edge says total laboratory throughput of its Cxbladder urine tests for bladder cancer were down 8.9 percent to 6,900 tests in the three months to June 30, 2025.

In May, Pacific Edge said that operating revenue for the year to March 31, 2025 was down 8.6 percent to \$NZ21,846,000 (\$A19,914,000), with total laboratory throughput of tests down 11.5 percent to 28,894 tests (BD: May 30, 2025).

Today, the company reported “resilient demand for its tests in the three months to the end of June 2025, despite ... loss of Medicare coverage in April 2025 and the disruption caused from the transition of US customers from Detect to Triage”.

Earlier this year, Pacific Edge said local coverage determination changes by its US Medicare administrative contractor Novitas halted coverage of its Cxbladder urine test, effective from April 24, 2025 (BD: Apr 28, 2025).

At the time, the company said it generated 60 percent of US revenue from Medicare and would “focus on the paths available” including reconsideration requests for its Triage and Monitor products but would “not seek re-coverage of Cxbladder Detect”.

Later, Pacific Edge said the US Centers for Medicare and Medicaid Services proposed a draft ‘gap-fill’ price for its Cxbladder Triage of \$US1,018 (\$A1,551) (BD: Apr 29, 2025).

At that time, Pacific Edge chief executive officer Dr Peter Meintjes said the Triage Plus was “a multi-modal test that combines DNA and RNA workflows” analyzed by an algorithm ... to assist clinicians manage haematuria patients as high, intermediate or low risk.

Today, the company said US total laboratory throughput was down 11.9 percent to 5,717 tests in the three months to March 31, 2025, “largely due to the disruption of asking physicians to switch from Cxbladder Detect to Triage for haematuria evaluation”, with test volumes from contract US customers such as Kaiser Permanente “unaffected by the determination” and Asia Pacific volumes up 8.8 percent to 1,183 tests.

Pacific Edge said it had “positive discussions” with Novitas following the lodging of a Medicare reconsideration request based on evidence not considered in the review that led to the non-coverage decision, including additional evidence from a randomized control study of Cxbladder Triage and American Urology Association guidelines.

Pacific Edge fell 0.1 cents or one percent to 9.6 cents.

## VICTORIA GOVERNMENT

The Victoria Government says 15 researchers will share \$1.5 million in grants to help “advance the understanding of how disease and other health issues affect women”.

A media release from the Minister for Health and Ambulance Services Mary-Anne Thomas said the recipients would receive \$15,000 to \$150,000, each, under the Women’s Health Research Catalyst Grants program.

The Victoria Government said the funds were for research in sexual and reproductive health, cardiovascular health, oncology, orthopaedics and chronic pain.

The Government said recipients included Monash University’s Dr Lakshini Gunasekera trialling hormonal treatment for menstrual-related migraines, University of Melbourne researchers for a model of care for pelvic pain management in regional areas and the Baker Institute’s Dr Louise Segan for sex differences in atrial fibrillation.

The Government said all recipients were “undertaking research in a health or medical field, including discovery, pre-clinical, clinical or lived experience”.

Mary-Anne Thomas said that the grants would “help Victorian women get the care they deserve by focusing on medical conditions that affect women differently or disproportionately, and those that have not been given the attention they need in the past”.

### CLEVER CULTURE SYSTEMS (FORMERLY LBT INNOVATIONS)

Clever Culture says the Copenhagen, Denmark-based Novo Nordisk has ordered an automated plate assessment system (Apas) Independence.

Clever Culture said Novo Nordisk would assess the suitability of both Apas 90mm settle plates and 55mm contact plate modules for pharmaceutical environmental monitoring and microbiology analysis across its manufacturing network in Europe.

The company said the sale price was “consistent with pricing previously disclosed”.

A June Clever Culture presentation said the company expected to earn \$1.5 million over seven years for each sale of an APAS Independence with \$600,000 to be upfront.

Last year, Clever Culture said it had a \$3.1 million order from Astrazeneca for four Apas systems, with the contract value including annual maintenance and support fees for each instrument (BD: Dec 6, 2024).

Today, the company said Novo Nordisk’s evaluation of the system would “be completed by a centralized team based in Denmark who will assess the performance of the Apas Independence for the reading of microbiology culture plates collected during environmental monitoring and compare it to their existing manual processes”.

Clever Culture said it had generated sales and installations with five multinational pharmaceutical companies: Astrazeneca, Bristol Myers Squibb, Thermo Fisher, Novo Nordisk, and one which “recently completed a successful evaluation for settle plates”; and collectively, the five companies operated “a large number of manufacturing sites globally, representing an estimated sales opportunity of between 60 to 80 Apas instruments”.

Clever Culture said it expected “to announce evaluations and sales to additional ... customers over the course of the 2026 fiscal year”.

Clever Culture managing-director Brent Barnes said the company was pleased to receive the Novo Nordisk order for an Apas Independence, for an evaluation.

“This milestone aligns with our strategy of focusing on partnerships with major pharmaceutical manufacturers who are looking to identify new initiatives and technology that have the potential to improve their current practices globally,” Mr Barnes said.

“The evaluation will give Novo Nordisk the opportunity to experience the performance and potential of the Apas technology, as they consider broader implementation across their manufacturing network,” Mr Barnes said.

Clever Culture rose 0.4 cents or 23.5 percent to 2.1 cents with 6.3 million shares traded.

### PROTEOMICS INTERNATIONAL LABORATORIES

Proteomics says its Oxidx blood test for oxidative stress “can identify muscle damage and assess recovery in Australian thoroughbred racehorses”.

Proteomics said a 34-horse study with the University of Western Australia showed the test had “diagnostic sensitivity to muscle recovery” and offered horse trainers “a tool to objective tailor training and racing schedules for individual horses to optimize post-race recovery and enhance performance”.

The company said the study was a “milestone” with an Australian launch by 2026.

In 2022, Proteomics said it had a joint venture called Oxidx Pty Ltd with Perth’s University of Western Australia to develop diagnostic products using its ‘2-tag’ measure for oxidative stress, with target applications in “chronic fatigue, muscular dystrophy, high-performance athletes and the horse-racing industry” (BD: Aug 29, 2022).

Last year, the company said its Oxidx finger-prick, blood test for oxidative stress “can identify and assess recovery from exercise-induced muscle damage in elite marathon runners” (BD: Jan 19, 2025).

Proteomics was unchanged at 47 cents with 1.2 million shares traded.

### OSTEOPORE

Osteopore says it has Swiss approval for its biomimetic and bioresorbable craniofacial implants through bilateral treaties with the European Union (EU).

Osteopore said that in the absence of a renewed mutual recognition agreement between Switzerland and the European Union, its Conformité Européenne (CE) mark certified medical devices had received regulatory approval in Switzerland.

In 2024, the company said it moved to EU renewed medical device regulations in 2023, and appointed Singapore's Zimmer Biomet to distribute its craniofacial products in Europe, the Middle East and Africa, Asia Pacific, Australia and New Zealand (BD: Jul 16, 2024). Osteopore was up 0.7 cents or 70 percent to 1.7 cents with 57.3 million shares traded.

### NYRADA INC

Nyrada says it has safety review committee approval to dose the sixth and final cohort of its phase I trial of Xolatryp, or NYR-BI03, for traumatic brain injury and stroke.

Earlier this year, Nyrada said it had begun recruiting its 40-patient, phase I trial of NYRBI03 for traumatic brain injury and stroke (BD: Mar 17, 2025).

Today, the company said the safety review committee raised no issues and that final phase I trial readouts were expected by October 2025.

Nyrada was up one cent or 3.7 percent to 28 cents.

### ALTERITY THERAPEUTICS

Alterity has told the ASX that it is not aware of any information it has not announced which, if known, could explain the recent trading in its securities.

The ASX said that Alterity's share price rose 55.56 percent from a low of 0.9 cents on Thursday, July 10 to a high of 1.4 cents on Friday July 11, 2025, and noted a "significant increase" in the volume of shares traded.

Alterity said that it had "previously informed the market that it is expecting to release two sets of data in mid-year 2025, namely finalized phase II data from the 'ATH-201 study [and] open-label data from the ATH-202 study".

The company said it was scheduling investor meetings for a non-deal roadshow and had "reached out to institutional, wholesale and high-net-worth investors as well as analysts and brokers, to arrange one-on-one meetings and invite them to in-person presentations".

Alterity fell 0.3 cents or 20 percent to 1.2 cents with 66.0 million shares traded.

### VITASORA HEALTH (FORMERLY RESPIRI)

Legacy OH (Orb Health) Holdings Inc says it has increased its holding in Vitasora and been diluted from 168,153,993 shares (11.19%) to 173,520,610 shares (10.10%).

The Dallas, Texas-based Orb Health said it was issued 5,366,617 shares under a subscription on March 10, 2025 at 8.62 cents a share and between May 15 and July 8, 2025 was diluted due to a share issue.

Earlier this year, the then Respiri said it bought the Dallas, Texas-based Orb Health Inc for \$US9,000,000 (\$A14,409,000) in scrip and had raised \$US700,000 (\$A1,100,000) in a placement to Orb Health (BD: Jan 21, 2025).

Later, the company said it had "commitments" for a \$4.0 million placement at 4.0 cents a share, a 16.7 percent discount to the last closing price (BD: Mar 3, 2025).

Vitasora fell 0.1 cents or 3.3 percent to 2.9 cents.

## OPYL

Opyl executive chair Saurabh Jain says he has become a substantial shareholder in the company with 12,833,333 shares, or 5.22 percent.

The Sydney-based Mr Jain said that with Rishi Jain Investment Pty Ltd he acquired 12,833,333 shares in lieu of director fees and as a key performance indicator bonus on December 20, 2024 and July 8, 2025.

Opyl fell 0.2 cents or 8.7 percent to 2.1 cents with 1.8 million shares traded.

## TAIWAN EXTERNAL TRADE DEVELOPMENT COUNCIL

The Taiwan External Trade Development Council says submissions for its up-to \$US90,000 (\$A137,000) award for three medical or health projects closes on August 14. Last month, a media release said the Taiwan Ministry of Economic Affairs' International Trade Administration said the Taiwan External Trade Development Council (TAITRA) would award \$US90,000 to three medical companies and/or researchers with proposals using "Taiwan's high-quality health products and holistic solutions" (BD: Jun 16, 2025). A media release said researchers and organizations with "ideas that would benefit from the inclusion of a Taiwanese partner are encouraged to visit the website, identify a Taiwanese enterprise that fits their idea, make a submission and then be in the running for the prizes".

For more information and submissions go to: <http://bit.ly/44Mgmmr>.