



# Biotech Daily

Wednesday July 19, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: IMPEDIMED UP 24%; ATOMO, PROTEOMICS DOWN 6%**
- \* **IMPEDIMED: CIGNA NATIONAL SOZO FOR LYMPHOEDEMA COVER**
- \* **ECHO IQ LAUNCHES ECHOSOLVE MITRAL REGURGITATION MODULE**
- \* **BIOCURATE, NLC DEAL TO SHARE EXPERTISE**
- \* **RECCE: I-V SYNTHETIC ANTI-INFECTIVE R327 'SAFE, WELL TOLERATED'**
- \* **TELIX DOSES 1st TLX250, PEPOSERTIB SOLID TUMOR PATIENT**
- \* **AUDEARA RECEIPTS UP 50% TO \$3.05m**
- \* **ALLEGRA RIGHTS FOR \$3m; \$3m ORTHOPEDICS SALES**
- \* **IMRICOR \$1.5m NORTH DAKOTA LOAN**
- \* **BOTANIX REQUESTS 'ROYALTY, CAPITAL RAISING' TRADING HALT**
- \* **ARGENICA APPLIES FOR ST VINCENT'S ARG-007 STROKE TRIAL**
- \* **IMUGENE: US PATENT FOR CF33 CANCER VIROTHERAPY**
- \* **PERENNIAL TAKES 15% OF MEDADVISOR**
- \* **NANOSONICS APPOINTS DR TRACEY BATTEN DIRECTOR**
- \* **DR RON WEITZMAN REPLACES IMUGENE CMO DR GIOVANNI SELVAGGI**

## MARKET REPORT

The Australian stock market was up 0.55 percent on Wednesday July 19, 2023, with the ASX200 up 39.9 points to 7,323.7 points. Sixteen of the Biotech Daily Top 40 stocks were up, 12 fell, 11 traded unchanged and one was untraded.

Impedimed was the best, up 4.5 cents or 24.3 percent to 23 cents, with 30.6 million shares traded. Medical Developments climbed 13.8 percent; Imugene improved 12.9 percent; Patrys was up 9.1 percent; Alcidion and Antisense climbed five percent or more; Micro-X and Paradigm improved more than four percent; 4D Medical and Cynata were up more than three percent; Polynovo, Resonance and Telix rose more than two percent; Cochlear, Genetic Signatures and Mesoblast were up more than one percent; with Avita and CSL up by less than one percent.

Atomo led the falls, down 0.2 cents or 5.71 percent to 3.3 cents, with 2.8 million shares traded, followed by Proteomics down 5.68 percent to 83 cents with 49,515 shares traded. Universal Biosensors fell four percent; Next Science lost 3.5 percent; Cyclopharm, SDI and Neuren shed more than two percent; Emvision, Opthea and Orthocell fell more than one percent; with Clinuvel, Pro Medicus and Resmed down by less than one percent.

## IMPEDIMED

Impedimed says Cigna Healthcare has published a nationwide US medical policy covering its Sozo test for limb lymphoedema.

Impedimed said Cigna provided coverage for more than 16 million people in all states of the US and was the “first top five national payor to publish a medical policy for covering testing using Sozo for individuals at risk for limb lymphoedema”.

The company said Cigna was a top five payor in 38 states.

Impedimed said the policy named Impedimed, Sozo and L-Dex and identified bio-impedance spectroscopy as “medically necessary” for the measurement of extracellular fluid volume in an individual at risk for developing limb lymphoedema.

The company said the policy provided access to coverage beyond breast cancer-related lymphoedema to all individuals at risk of developing limb lymphoedema.

Impedimed chief executive officer Richard Valencia said “the first national payor is a major milestone for our reimbursement strategy to achieve broad reimbursement coverage for Sozo testing for lymphoedema.”

“Cigna’s policy provides access to coverage for all individuals at risk of developing limb lymphoedema without prior authorization and impacts all 50 states,” Mr Valencia said.

“Each new policy adds to the already growing momentum of our expanding commercial effort,” Mr Valencia said.

Impedimed was up 4.5 cents or 24.3 percent to 23 cents with 30.6 million shares traded.

## ECHO IQ

Echo IQ says it has launched the Echosolve module to identify progression of mitral regurgitation, the most common heart valve abnormality, available from August 2023.

Echo IQ said without treatment, the prognosis for patients with severe mitral regurgitation was a one-year mortality rate of 20 percent and five-year rate of 50 percent.

Echo IQ chief medical advisor Prof David Playford said “the significant amount of data produced in an echocardiogram is distilled simply and clearly by the Echosolv technology and provides an evidence-based output that assists us to make decisions for our patients with mitral regurgitation”.

Echo IQ was unchanged at 16 cents.

## BIOCURATE

Biocurate says it has a deal with the Amsterdam-based NLC (Next Level Challenge) to share scientific and commercial expertise and collaborate to bring therapies to market.

Biocurate said both companies targeted early-stage projects and the partnership sought to improve the chances of success for projects in each organization’s portfolio by improving their access to skills and resources required to turn scientific discoveries into commercially viable therapies.

The company did not disclose commercial terms of the deal.

Biocurate director of partnerships Dr Eric Hayes said NLC was “an obvious choice of partner for Biocurate because of the quality and breadth of its complementary expertise, as well as its presence in, and access to the European pharmaceutical market”.

Biocurate chair John Brumby said the partnership “helps to ensure the fantastic research taking place in Victoria’s leading academic laboratories has a better chance of becoming medicines that improve people’s lives”.

“It also means NLC has access to the incredible talent we have in Victoria to support the success of the projects in their portfolio,” Mr Brumby said.

## RECCE PHARMACEUTICALS

Recce says that data from its 80-subject, phase I, safety and pharmaco-kinetics evaluation trial of R327 has shown no serious adverse effects.

Recce said R327 was well tolerated, with a “good” safety profile in all dose groups from 50mg to 6,000mg when administered intravenously during a one-hour infusion.

The company said the successful phase I safety and tolerability study paved the way for the next stage of R327’s development as a treatment of sepsis and urinary tract infections.

Recce said that the results showed “a significant dose-dependent concentration of R327 in both the urine and the plasma, highlighting the potential of R327 as a potential treatment of sepsis and complicated/uncomplicated [urinary tract infections]”.

The company said it was conducting a phase I/II urinary tract infection clinical trial evaluating intra-venous R327 at faster infusion rates.

Recce was up 7.5 cents or 11.2 percent to 74.5 cents.

## TELIX PHARMACEUTICALS

Telix says the first of up-to 80 patients has been dosed in a phase Ib combination study of TLX250 with Merck KGaA’s peposertib for solid tumors.

In an announcement emailed to investors but not released to the ASX, Telix said the phase Ib, open label, single-arm, multi-centre, dose escalation and expansion study would evaluate safety, dosing and activity of TLX250 in combination with the DNA damage response inhibitor peposertib for patients with solid tumors expressing carbonic-anhydrase IX, making it a potential pan-cancer target.

The company said that radiation induced DNA damage in targeted cancer cells and the Darmstadt, Germany-based Merck KGaA DNA-PK inhibitor peposertib “may act to prevent the cell from repairing this damage, resulting in higher potency at lower doses”.

Telix said that in part 1 of the trial up to 36 patients would receive three different activities of lutetium-177-TLX250 and three different dose levels of peposertib.

The company said that in the dose expansion part 2 of the trial patients would be enrolled in two cohorts, with the first treating 40 patients with metastatic or non-resectable clear cell renal cell carcinoma and the second of 20 patients with carbonic-anhydrase IX positive solid tumors, excluding renal cell carcinoma.

Telix said pre-clinical studies provided evidence that the combined effects of peposertib with TLX250 had the potential to “significantly improve” efficacy and reduce the required radiation dose for tumor reduction and remission, compared to targeted radiation alone, and it would continue its collaboration with Merck KGaA to “explore and optimize the combination of TLX250 or other next-generation targeted radiation therapy candidates with Merck’s [DNA damage response inhibitor] compounds in pre-clinical studies”.

Telix was up 33 cents or 2.8 percent to \$12.16 with 1.4 million shares traded.

## AUDEARA

Audeara says that receipts from customers for the year to June 30, 2023 were up 50.0 percent to \$3.05 million compared to the previous corresponding period.

Audeara said that receipts for the three months to June 30, 2023, primarily from its hearing devices, were down 13.5 percent to \$590,000.

The company said it had a cash burn of \$688,000 for the three months to June 30, with cash and cash equivalents of \$2,623,000, providing 3.8 quarters of funding, compared to \$2870,000 at June 30, 2022.

Audeara was up half a cent or 14.3 percent to four cents.

### ALLEGRA ORTHOPAEDICS

Allegra says it hopes to raise \$3,133,776 through a rights offer at nine cents a share, and expects to sell its orthopaedic division to related-party Robinwood by September.

Allegra said funds from the non-renounceable rights offer would go to commercialization of its cervical spinal cage, general and administration costs and working capital.

The company said the record date would be July 28, the offer would open on August 2 and close on August 22, 2023.

Allegra said it expected to sell its orthopaedic division to Robinwood Investments by August 31, 2023 and on completion must ensure the minimum cost value of the inventory transferred to be \$3 million, lower than the previously stated \$3.3 million.

In May, Allegra said it would sell its orthopaedics division for \$1 million cash and more than \$3.3 million for the cost value of inventory to shareholder Robinwood Investments Pty Ltd, associated with director Nicholas Hartnell (BD: May 3, 2023).

Allegra was up 0.2 cents or 3.6 percent to 5.7 cents.

### IMRICOR MEDICAL SYSTEMS

Imricor says it has a "commitment letter" from the North Dakota Development Fund for a \$US1 million (\$A1.47 million) loan for manufacturing and design capabilities.

Imricor said the terms were not yet agreed and that it may decide not to accept the loan, and would announce material terms should the loan be accepted.

Last year, the company said it had a \$US1.5 million loan from the North Dakota Innovation Technology Loan Fund for "financial flexibility" (BD: Dec 22, 2022).

Imricor was unchanged at 40 cents.

### BOTANIX PHARMACEUTICALS

Botanix has requested a trading halt, "pending [the] release of an announcement regarding a royalty acquisition and capital raising".

Trading will resume on July 21, 2023 or on an earlier announcement.

Botanix last traded at 14.5 cents.

### ARGENICA THERAPEUTICS

Argenica says it has filed an ethics application to Melbourne's St Vincent's Hospital for a 92-patient, phase II trial of ARG-007 in patients with acute ischemic stroke.

Argenica said ARG-007 aimed to reduce brain tissue death after stroke and, pending ethics approval, would conduct the double-blind, randomized, placebo-controlled, single-dose study in 10 hospital trial sites throughout Australia.

The company said the study would determine the safety, preliminary efficacy and pharmacokinetics of ARG-007 in acute ischemic stroke patients.

Argenica said that following treatment patients would be assessed for key safety outcomes as well as infarct volume and functional outcomes.

The company said it had appointed Prof Graeme Hankey as the trial's national coordinating principal investigator, Alithia Life Science as a clinical research consultant and Propharma as its clinical research organization.

Argenica said St Vincent's Hospital would make a decision in September 2023.

The company said the ARG-007 used in the trial would arrive at trial sites by mid-December, with recruitment expected to begin in the first three months of 2024.

Argenica was up half a cent or 1.3 percent to 38 cents.

## IMUGENE

Imugene says the US Patent and Trademark Office has allowed a patent for its oncolytic virotherapy CF33, including Vaxina (CF33-Hnis) and Checkvacc.

Imugene said the patent, titled 'Chimeric Poxvirus Composition and Uses Thereof', protected the composition and method of use of its oncolytic virotherapy until 2037.

The company said oncolytic viruses were designed to both selectively kill tumor cells and activate the immune system against cancer cells, with the potential to improve clinical response and survival.

Imugene was up 1.2 cents or 12.9 percent to 10.5 cents with 57.9 million shares traded.

## MEDADVISOR

Perennial Value Management says it has increased its substantial shareholding in Medadvisor from 76,208,867 shares (14.00%) to 81,825,163 shares (15.01%).

The Sydney-based Perennial said that between May 16 and July 18, 2023 it bought and sold shares, with the single largest purchase 3,278,460 shares for \$780,273 or 23.8 cents a share on June 26.

Medadvisor fell half a cent or 2.1 percent to 23 cents.

## NANOSONICS

Nanosonics says it has appointed Dr Tracey Batten as a non-executive director, effective from September 26, 2023.

Nanosonics said Dr Batten has been the chief executive officer of the UK's Imperial College Healthcare National Health Service Trust, St Vincent's Health Australia, Eastern Health and Dental Health Services Victoria and had held "various other clinical and medical leadership roles".

The company said Dr Batten was currently a director of Medibank Private, the Ebos Group, New Zealand's Accident Compensation Corporation and National Institute of Water and Atmospheric Research.

Nanosonics said Dr Batten held a Bachelor of Medicine and Bachelor of Surgery from the University of Melbourne, a Master's of Health Administration from the University of New South Wales and a Master's of Business Administration from Harvard Business School.

Nanosonics was unchanged at \$4.82 with 427,943 shares traded.

## IMUGENE

Imugene says Dr Ron Weitzman will replace Dr Giovanni Selvaggi as its interim chief medical officer.

Imugene said Dr Weitzman had worked as chief medical officer at Tango Therapeutics, overseeing development of oncological drugs including three investigational new drug applications, as well as head of clinical development at Exelixis for nearly seven years.

The company said Dr Weitzman had also worked at Genentech and Novartis.

Imugene said the California-based Dr Weitzman held a Doctor of Medicine from the University of Western Ontario.