



# Biotech Daily

Tuesday February 27, 2024

*Daily news on ASX-listed biotechnology companies*

- \* **ASX UP, BIOTECH DOWN: CLARITY UP 8%; ACTINOGEN DOWN 13.5%**
- \* **TRAJAN H1 REVENUE DOWN 5% TO \$76m; PROFIT TO \$378k LOSS**
- \* **POLYNOVO RECORD H1 REVENUE UP 66% TO \$49m; \$2.7m PROFIT**
- \* **IMPEDIMED H1 REVENUE DOWN 15% TO \$5m; LOSS DOWN 10% TO \$10m**
- \* **IMRICOR RETAIL RIGHTS RAISE \$684k; TOTAL \$8.6m**
- \* **TELIX TO BUY MANUFACTURER ISOTHERAPEUTICS FOR \$21m**
- \* **AUDEARA MAIDEN \$2.1m ZILDJIAN MASS PRODUCTION ORDER**
- \* **4D MEDICAL, IMBIO VETERANS AFFAIRS RESEARCH DEAL**
- \* **RECCE CONTINUES MCRI PARTNERSHIP**
- \* **DIMERIX COLLECTS INTERIM PHASE III DMX-200 FSGS TRIAL DATA**
- \* **RACE RECEIVES \$4m FEDERAL R&D TAX INCENTIVE**
- \* **PERENNIAL TAKES 5% OF IMMUTEP**
- \* **PERENNIAL TAKES 15% OF MICROBA**

## MARKET REPORT

The Australian stock market was up 0.13 percent on Tuesday February 27, 2024, with the ASX200 up 10.2 points to 7,663.0 points. Thirteen of the Biotech Daily Top 40 stocks were up, 17 fell, nine traded unchanged and one was untraded. All three Big Caps fell.

Clarity was the best, up 20 cents or 7.8 percent to \$2.76, with 468,095 shares traded. Immutep, Opthea and Telex climbed more than six percent; Avita, Nanosonics, Percheron (Antisense) and Starpharma improved four percent or more; Nova Eye rose 2.4 percent; Amplia and Proteomics were up more than one percent; with 4D Medical and Pro Medicus up by less than one percent.

Actinogen led the falls, down 0.5 cents or 13.5 percent to 3.2 cents, with 6.6 million shares traded. Cynata and Prescient lost eight percent or more; Atomo and Impedimed shed seven percent or more; Universal Biosensors was down 6.45 percent; Alcidion, Cyclopharm, Dimerix, Imugene and Micro-X fell more than four percent; Clinuvel and Medical Developments were down more than three percent; Cochlear, Genetic Signatures, Neuren, Next Science, Polynovo and Resmed shed one percent or more; with CSL down by 0.6 percent.

## TRAJAN GROUP HOLDINGS

Trajan says revenue for the six months to December 31, 2023 was down 4.6 percent to \$76,410,000, with last year's \$3,186,000 net profit after tax turned to a loss of \$378,000. Trajan said revenue came from sales of its products and devices for the analysis of biological, food, and environmental samples and fell due to "ongoing destocking activity in the downstream supply chain into [the six months to December 31, 2023]".

The company said profit margins were "impacted by lower sales volume and production volume creating lower scale benefits to cover overhead costs".

Trajan said "in response to global macroeconomic challenges" it was implementing a number of initiatives to reduce the operating cost base, which was expected to be realized by the full year to June 30, 2024.

The company said last year's diluted earnings per share of 2.1 cents turned to a diluted loss per share of 0.25 cents, with net tangible assets per ordinary security down 33.3 percent to six cents, and it had cash and equivalents of \$11,194,000 at December 31, 2023 compared to \$21,121,000 at December 31, 2022.

Trajan said that guidance for the full year was \$163.0 million to \$167.0 million.

Trajan fell 28 cents or 21.5 percent to \$1.02.

## POLYNOVO

Polynovo says revenue for the six months to December 31, 2023 was up 65.6 percent to \$48,765,000, with last year's loss tax turned to a record net profit after tax of \$2,694,000.

In 2022, Polynovo said revenue from Novosorb burn wound treatment sales and contracts with the US Biomedical Advanced Research and Development Authority for the six months to December 31, 2021 led to a maiden profit of \$1,618,550 (BD: Feb 25, 2022).

Today, the company said the increased revenue for the six months to December 31, 2023 was due to increasing sales as it "gained market penetration in the US through an expanded sales force and customer base and effective marketing".

Polynovo said its US Biomedical Advanced Research and Development Authority contract revenue was up 133.1 percent to \$4,912,000 compared to the prior corresponding period due to "the increase in recruitment of patients for the pivotal trial".

The company said last year's diluted loss per share of 0.58 cents turned to earnings per share of 0.39 cents, net tangible assets rose 11.1 percent to 10.0 cents, with cash of \$45,580,000 at December 31, 2023 compared to \$50,479,164 at December 31, 2022.

Polynovo fell 3.5 cents or 1.7 percent to \$1.985 with 2.3 million shares traded.

## IMPEDIMED

Impedimed says revenue for the six months to December 31, 2023 was down 15.4 percent to \$4,784,000, with net loss after tax down 10.1 percent to \$9,718,000.

Impedimed said revenue came from sales of its bio-impedance spectroscopy systems and software services, including Sozo for lymphoedema, heart failure and calorie malnutrition.

The company said revenue fell due to the "the completion of clinical trials conducted by Astrazeneca, which was \$100,000 in the current period compared with \$1.2 million in the prior corresponding period" and the decreased loss was "primarily related to the Sozo Pro development nearing completion".

Impedimed said diluted loss per share was up 16.7 percent to 0.05 cents, with net tangible assets up 50.0 percent to three cents, and it had cash and cash equivalents of \$36,905,000 at December 31, 2023 compared to \$26,197,000 at December 31, 2022.

Impedimed fell 0.6 cents or seven percent to eight cents with 6.2 million shares traded.

## IMRICOR MEDICAL SYSTEMS

Imricor says its retail rights offer at 45.0 cents a share has raised \$638,581 at 45.0 cents per Chess depository interests (CDIs), taking the total raised to \$8.639 million.

Earlier this month, Imricor said it had "commitments" for \$8.0 million through placements and an institutional rights offer, with a \$7.1 million retail offer to follow (BD: Feb 5, 2024).

Today, the company said it might issue the shortfall CDIs to third parties.

Imricor fell three cents or six percent to 47 cents.

## TELIX PHARMACEUTICALS

Telix says it will acquire radiochemistry and bio-conjugation manufacturer Angleton, Texas-based Isotherapeutics Group for up-to \$US13.6 million (\$A20.7 million)

Telix said Isotherapeutics was a radio-pharmaceutical company that offered technologies for developing therapeutic and diagnostic agents as well as contract manufacturing services to companies in the industry, including Telix.

The company said the acquisition would increase its in-house drug development capabilities, reduce costs and time to achieve technical milestones and expand its US manufacturing footprint with a site that includes a good manufacturing practice clean room and production infrastructure suitable for clinical use.

Telix said following the transaction, Isotherapeutics would continue to provide development and manufacturing services to its existing customers and continue to provide services to the company's strategic partners and collaborators.

The company said the purchase price included an up-front cash payment of \$US2 million, \$US6 million in shares, cash of \$US5 million in performance-related milestone payments as well as up-to an estimated \$900,000 in two-year revenue share from existing Isotherapeutics customers.

Telix managing-director Dr Chris Behrenbruch said the acquisition would "further expand our manufacturing footprint in the US".

"This acquisition enhances our business with highly-sought-after skills, capabilities and facilities that are very much central to our development activities," Dr Behrenbruch said.

Telix was up 74 cents or 6.75 percent to \$11.70 with 1.3 million shares traded.

## AUDEARA

Audera says it has received a \$2.1 million maiden mass production order from the Norwell, Massachusetts-based Avedis Zildjian for its hearing impairment devices.

Audera said the order marked the "transition from development phase to contract manufacturing and licensing phase with its music instrument customer".

In an Appendix 4C, on January 31, 2023, the company said it was working with an unnamed "leading musical instrument company to licence, develop and integrate Audera technology into a new product line specifically targeting musicians and music-lovers".

At that time, Audera said "this will be the first time that [its] proprietary personalization technology will be incorporated into third-party products under the go-to market strength of a well-established brand outside of the audiology industry".

Today, the company said the Zildjian project had reached a "crucial phase of preparation for mass production ahead of the commercial launch of the product to the market", expected by January, 2025.

Audera the order was its largest single order to date and was expected to have a positive impact on cashflows and push toward breakeven and profitability.

Audera was up 2.7 cents or 81.8 percent to six cents with two million shares traded.

## 4D MEDICAL

4D Medical says with the US Department of Veterans Affairs will conduct a 2,000-veteran study of its Imbio lung texture analysis for assessing pulmonary fibrosis.

Last year, 4D Medical said it had acquired the Minneapolis, Minnesota-based Imbio for \$US25 million (\$A38.6 million), and that Imbio was a “medical imaging artificial intelligence company transforming how patients with lung and cardiothoracic conditions are detected, diagnosed and treated” (BD: Dec 11, 18, 2023).

Today, the company said its wholly-owned subsidiary Imbio had a research agreement with the Department of Veterans Affairs Center for Innovations in Quality, Effectiveness and Safety, to study its device for detecting the prevalence, diagnostic delay, and mortality associated with interstitial lung abnormalities and interstitial lung disease in military veterans.

4D Medical said the project would “quantify the delay between acquisition of the lung cancer screening [computer tomography] and diagnosis of pulmonary fibrosis”.

The company said that the project would quantify the degree of radiographic progression, [or] change in percentage of fibrosis, between lung cancer [computer tomography] with evidence of fibrosis and a five-year follow-up scan”.

The company said because lung cancer screening was often led by primary care, under-reporting of radiographic abnormalities on computer tomography may lead to delays in pulmonary subspecialty referral, and subsequent initiation of appropriate therapy.

4D Medical managing-director Prof Andreas Fouras said the company’s “acquisition of Imbio is already yielding results with an additional pathway to supporting lung health in the veteran community”.

“This research agreement is a major milestone in adding value to lung cancer screening programs in the [Department of Veterans Affairs] and elsewhere, as we progress our [lung texture analysis] product to [US Food and Drug Administration] approval later this year,” Prof Fouras said.

“4D Medical’s demonstrated work to date with veterans has been focused on exposures to airborne hazards during deployment and I look forward to sharing further progress on this over the coming weeks and months,” Prof Fouras said.

4D Medical was up half a cent or 0.8 percent to 65 cents.

## RECCE PHARMACEUTICALS, MURDOCH CHILDREN’S RESEARCH INSTITUTE

Recce says it has a continuation of its anti-infective research partnership with the Melbourne-based Murdoch Royal Children’s Research Institute (MCRI).

In 2022, Recce said it had established an ‘anti-infective research unit’ with the MCRI at Melbourne’s Royal Children’s Hospital but did not disclose the commercial terms of the agreement (BD: Dec 15, 2022).

Today, the company said the agreement streamlined its ongoing pre-clinical programs while investigation further indications for future clinical trials, including its R327 pre-clinical programs for Escherichia coli, or urinary tract infections and urosepsis, Mycobacterium abscessus, Streptococcus pneumoniae and Neisseria gonorrhoeae.

Recce chief executive officer James Graham said the company’s “continued work at the [anti-infective research] unit aligns with Murdoch Children’s mission to address the global health threat of anti-microbial resistance through innovative research”.

“The synergy between our organizations will undoubtedly lead to ground-breaking discoveries that have the potential to transform the landscape of infectious disease treatment,” Mr Graham said.

Recce fell half a cent or 1.1 percent to 45.5 cents.

## [DIMERIX](#)

Dimerix says it has collected interim data from the first 72 patients in its randomized, up-to 286-patient, phase III trial of its DMX-200 for focal segmental glomerulo-sclerosis (FSGS). In 2022, Dimerix said it had recruited the first of 286 patients in its phase III trial of DMX-200 for FSGS kidney disease (BD: May 31, 2022).

Today, the company said the data had been collected ahead of the first interim safety and efficacy analysis for review by the data safety monitoring committee in March, 2024.

Dimerix said it was expected to report the interim results by March 15, 2024, following a meeting with the monitoring committee, and a second interim analysis was planned after 144 patients had completed about 35 weeks of treatment.

The company said the relevant regulatory authorities and trial investigators were blinded to treatment allocations, grouped safety and efficacy data for the ongoing trial as well as data inputs for any interim analyses.

Dimerix managing-director Dr Nina Webster said the company was “only a matter of days away from our part one analysis outcome and, on the presumption of success, are continuing to prepare for part two of the phase III study”.

“Success in part one would signal that DMX-200 is performing better than placebo in reducing proteinuria, an important marker of kidney disease progression, in a larger cohort of patients than our prior phase II study and validates our strategy,” Dr Webster said.

Dimerix fell one cent or 4.55 percent to 21 cents with 6.6 million shares traded.

## [RACE ONCOLOGY](#)

Race says it has received \$4.0 million from the Australian Taxation Office under the Federal Government’s Research and Development Tax Incentive program.

Race said the rebated related to expenditure for the year to June 30, 2023.

Race fell 1.5 cents or 1.9 percent to 77.5 cents.

## [IMMUTEP](#)

The Sydney-based Perennial Value Management says it has become substantial in Immutep with 59,458,280 shares, or 5.00 percent.

Perennial said that between October 24, 2023 and February 21, 2024 it bought shares in more than 50 transactions, with the single largest purchase 1,962,161 shares on October 24 for \$609,608, or 31.1 cents a share.

Immutep was up two cents or 6.15 percent to 34.5 cents.

## [MICROBA LIFE SCIENCES](#)

Sydney’s Perennial Value Management says it has increased its substantial shareholding in Microba from 55,075,162 shares (13.73%) to 66,271,358 shares (14.80%).

Perennial said that between November 10, 2023 and February 22, 2024, it bought and sold shares in more than 60 transactions, with the single largest purchase 7,773,301 shares on November 23 for \$1,640,943, or 21.1 cents a share.

Microba