



# Biotech Daily

Tuesday August 22, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH EVEN: IMPEDIMED UP 10.5%; ATOMO DOWN 12%**
- \* **CLEO UP 15%, ON \$12m IPO FOR OVARIAN CANCER TESTS**
- \* **NANOSONICS REVENUE UP 38% TO \$166m, PROFIT UP 431% TO \$20m**
- \* **COGSTATE REVENUE DOWN 10% TO \$63m, PROFIT DOWN 52.5% TO \$6m**
- \* **CYCLOPHARM H1 REVENUE UP 44% TO \$16.5m, LOSS UP 13% TO \$3m**
- \* **RECCE DOSES R327 PHASE I/II DIABETIC FOOT INFECTION TRIAL**
- \* **EMVISION 9.2 MINUTE BRAIN SCAN**
- \* **FDA APPROVES INCANNEX PHASE II/III IHL-42X SLEEP APNOEA TRIAL**
- \* **ASX SUSPENDS ANALYTICA, CANN GLOBAL, MEDLAB ON FEES**
- \* **PHARMAUST: 11 OF 12 MONEPANTEL FOR MND PATIENTS 'STABLE'**
- \* **IMPEDIMED HOPES TO BREAK-EVEN BY 2026**
- \* **CLEO WINS CXCL10 US PATENT**
- \* **RACE: DR SMITH, DR TILLET IN; Mr CLARKE-BRUCE, DR CULLITY OUT**
- \* **PINNACLE INVESTMENT BELOW 5% OF NANOSONICS**
- \* **BIO NSW TO LAUNCH ON THURSDAY**

## MARKET REPORT

The Australian stock market edged up 0.09 percent on Tuesday August 22, 2023, with the ASX200 up 6.1 points to 7,121.6 points. Fifteen of the Biotech Daily Top 40 stocks were up, 16 fell, six traded unchanged and three were untraded.

Impedimed was the best, up two cents or 10.5 percent to 21 cents, with 2.5 million shares traded. Mesoblast climbed 6.8 percent; Compumedics, Emvision and Prescient improved more than five percent; Cyclopharm and Medical Developments were up four percent or more; Antisense, Opthea, Polynovo and Proteomics were up more than three percent; Pro Medicus rose 2.2 percent; with Avita, Cochlear, Neuren and Telix up by less than one percent.

Atomo led the falls, down 0.4 cents or 11.8 percent to three cents, with 10.6 million shares traded. Imugene lost eight percent; Actinogen shed 7.4 percent; Resonance and SDI were down more than six percent; Nanosonics, Nova Eye and Paradigm fell four percent or more; Starpharma was down 3.3 percent; Pharmaxis shed 2.5 percent; CSL, Dimerix, Immutep and Resmed were down one percent or more; with 4D Medical, Clinuvel, Next Science and Volpara down by less than one percent.

## CLEO DIAGNOSTICS

Cleo opened up 15 percent at 23 cents following its initial public offer to raise \$12 million at 20 cents a share to list on the ASX to commercialize its blood tests for ovarian cancer. Last month, Cleo said it hoped to raise \$12 million to list on the ASX under the code COV to commercialize its blood test to detect early stages of ovarian cancer, by measuring the CXCL10 biomarker, with technology licenced from Melbourne's Hudson Institute of Medical Technology (BD: Jul 17, 2023).

In its prospectus, Cleo said Hudson researchers had first identified the small inflammatory molecule CXCL10 in ovarian cancer tissue in 2010.

Cleo said the Hudson team then developed a novel assay prototype for measuring CXCL10 proteo-forms in biological samples called the 'Multiplex Active Ratio Test', which showed 90.0 percent sensitivity and 91.7 percent specificity in a study of 275 patients.

"Whilst initial analyses indicated greater than 90 percent sensitivity and specificity for the identification of early-stage epithelial ovarian cancers within the cohort, the company cautions that the results remain subject to further analysis, peer review and validation and should not be relied upon in making an investment decision," the prospectus said.

The prospectus said that Adrien Wing was the chair, with directors chief executive officer Dr Richard Allman, chief scientific officer Dr Andrew Stephens, lead medical adviser Prof Tom Jobling and Lucinda Nolan, and company secretary Pauline Moffatt.

Separately, substantial shareholder notices were filed by Adrien Michele Wing (11.09%), Richard Vom/Loumea Investment (7.10%) and the Hudson Institute (5.84%).

Cleo slipped to 19.5 cents in afternoon trading, closing up one cent or five percent at 21 cents with 4.3 million shares traded.

## NANOSONICS

Nanosonics says revenue for the year to June 30, 2023 was up 38.0 percent to \$165,993,000 with net profit after tax up 431.35 percent to \$19,883,000.

Nanosonics said revenue was from sales of its Trophon ultrasound probe cleaning systems, with the profit increase due to strong revenue growth, higher gross profit margins and improved operating leverage, as well as operating expenses reducing from 75.2 percent to 68.8 percent of total revenue.

The company said research and development spending was up 32.0 percent to \$29,514,000, or 17.8 percent of revenue.

Nanosonics said sales of Trophon in North America were up 40.6 percent to \$150,352,000, up 8.4 percent to \$8,148,000 in Europe and the Middle East, and up 27.5 percent to \$7,493,000 in the Asia Pacific.

Nanosonics chief executive officer Michael Kavanagh said that the financial year was "another year of significant achievement".

"The Trophon business continued to expand globally, delivering excellent sales growth and profitability," Mr Kavanagh said.

Nanosonics said it had its "first full year operating under the new largely direct sales model in North America" and had made progress with expansion plans to Japan and China.

The company said that the development of its Coris endoscope cleaner was continuing with a US Food and Drug Administration submission expected by April 2024.

Nanosonics said that diluted earnings per share was up 431.97 percent to 6.49 cents, with net tangible asset backing per share was up 19.2 percent to 49.53 cents.

The company said it had cash and cash equivalents of \$112,159,000 at June 30, 2023, compared to \$94,512,000 at June 30, 2022.

Nanosonics fell 23 cents or 4.9 percent to \$4.50 with 3.4 million shares traded.

## COGSTATE

Cogstate says revenue for the year to June 30, 2023 was down 10.07 percent to \$US40,451,123 (\$A63,188,258) with net profit after tax down 52.55 percent to \$US3,567,733 (\$A5,573,117).

Cogstate said revenue from its cognition testing software included \$US35,729,909 in clinical trials, \$US4,400,970 from healthcare and \$US320,244 from research revenue. The company said clinical trial sales decreased by about 59 percent on the previous year and that 2023 was a “challenging year... with revenue delays associated with ongoing clinical trials and a significant decline in clinical trials sales contracts”.

Cogstate said it “made the difficult decision to restructure the business” and had fired about 13 percent of full-time employees, reducing annual costs by \$US2.6 million, which would not produce cost savings in 2022-'23 but “positioned the group well”.

The company said diluted earnings per share was down 52.5 percent to 2.02 US cents, net tangible asset backing per share was up 30.95 percent to 13.54 US cents, with cash of \$US28,675,988 at June 30, 2023 compared to \$US30,597,170 at June 30, 2022.

Cogstate fell one cent or 0.7 percent to \$1.41.

## CYCLOPHARM

Cyclopharm says total revenue for the six months to June 30, 2023 was up 44.3 percent to \$16,487,618, with net loss after tax up 12.9 percent to \$2,895,275.

Cyclopharm said sales of Technegas for lung imaging remained stable at \$7.65 million, with sales of patient administration sets up 6.7 percent to \$5.61 million, with third party sales up 120 percent to \$7.27 million; with Europe accounting for about half its revenue followed by the Asia-Pacific region and Canada.

Cyclopharm said that it was “confident that the extension of Technegas into new applications will create substantive opportunities to exponentially expand Technegas beyond its traditional pulmonary embolism market”.

The company said that the Canadian Association of Nuclear Medicine Guidelines and the updated European Association of Nuclear Medicine Guidelines identified Technegas as “the recognized functional ventilation imaging agent for diagnosing pulmonary embolism and reinforce the superior use of Technegas, particularly in patients with [chronic obstructive pulmonary disease]”.

Cyclopharm said it would pay an unfranked interim dividend of 0.5 cents, for a record date of September 4 and payable on September 11, 2023.

The company said that its diluted loss per share was up 13.3 percent to 3.15 cents and its net tangible asset backing per share was down 18.4 percent to 31 cents.

Cyclopharm said it had cash and cash equivalents of \$18,077,806 on June 30, 2023 compared to \$26,517,893 in June 30, 2022.

Cyclopharm was up nine cents or four percent to \$2.36.

## RECCE PHARMACEUTICALS

Recce says it has begun dosing up-to 32 patients in its 14-day, phase I/II trial of R327 for diabetic foot infection at Sydney’s Liverpool Hospital.

Recce said the trial was supported by at-home nurses trained in R327 diabetic foot infection (DFI) treatment protocols, who would ensure daily dosing and wound health, while capturing a broad patient population.

The company said interim data was expected by October 2023.

Recce fell two cents or 2.8 percent to 69.5 cents.

## [EMVISION MEDICAL DEVICES](#)

Emvision says a 30-participant trial of its first-generation portable brain scanner device showed an average 9.2 minutes to complete a full workflow and brain scan.

In May, Emvision it had begun an up-to 150-patient, stage two, multi-site trial of its portable brain scanner for stroke and stroke mimic patients at emergency departments and in February said that it had scanned all 30 participants in its stage one, healthy volunteer trial of the scanner at Sydney's Liverpool hospital (BD: Feb 1; May 29, 2023). Today, the company said there were no adverse events nor any adverse device effects occurred, "while the hardware had a 100 percent scan success rate in terms of production of processable signals, with data and learnings obtained used to further advance [artificial intelligence]-based algorithm techniques".

Emvision chief executive officer Scott Kirkland said the company was "achieving significant breakthroughs" with the first-generation scanner over the last 12 months.

"As we progress through our studies, we are excited to learn about the full potential and capabilities of our world first technology," Mr Kirkland said.

Emvision was up 7.5 cents or 5.5 percent to \$1.43.

## [INCANNEX HEALTHCARE](#)

Incannex says the US Food and Drug Administration has approved its 116-patient, investigational new drug phase II/III trial of IHL-42X for obstructive sleep apnoea.

Incannex said IHL-42X was a composite of the marijuana tetrahydrocannabinol (THC), the carbonic anhydrase inhibitor acetazolamide and a synthetic marijuana dronabinol.

The company said patients would receive one dose of IHL-42X, dronabinol, acetazolamide or placebo for the entirety of the trial and complete daily surveys on sleep quality and attend monthly clinic visits to assess functional outcomes of sleep, cognitive function and other measures of safety and efficacy.

Incannex said that every three months, overnight polysomnography would be conducted to determine the effect of treatment on the patients' Apnoea Hypopnoea Index (AHI) along with a range of other sleep parameters.

The company said it would finalize institutional review board applications for trial sites.

Incannex was up 0.3 cents or 3.1 percent to 10 cents with 3.6 million shares traded.

## [ASX, ANALYTICA, CANN GROUP, MEDLAB CLINICAL](#)

The ASX says that Analytica, Cann Global and Medlab Clinical have been suspended for failing to pay their annual listing fees by close of business on Monday, August 21, 2023.

The ASX said that any entity that had not paid its annual listing fees by 5pm (AEST) on August 28, 2023 would be removed from the Official List.

Analytica was in a suspension and last traded at 0.1 cents.

Cann Global was in a suspension and last traded at 2.1 cents.

Medlab was suspended and last traded at \$6.60 (following a 150-to-one consolidation).

## [PHARMAUST](#)

Pharmaust says 11 of 12 patients in its phase I trial of monepantel for motor neuron disease were "stable", with no change in neurofilament light chain protein concentration. Pharmaust said protein concentrations in blood plasma provided an indication of neuron damage.

Pharmaust fell 0.3 cents or 4.1 percent to seven cents with 1.5 million shares traded.

## IMPEDIMED

Impedimed says it hopes for “break-even” cash flow in six to 10 quarters, with \$15 million to \$60 million in net cash and target revenue of \$50 million to \$100 million.

Impedimed said the US National Comprehensive Cancer Network (NCCN) updated its guidelines in March 2023, effectively doubling the company’s market in the US.

The company said the renewed forecast had a “significantly higher” revenue at profitability compared to its previous break-even plan, thanks to accelerating timelines from private payor policies and funding from its recent capital raise.

Impedimed was up two cents or 10.5 percent to 21 cents with 2.5 million shares traded.

## CLEO DIAGNOSTICS

Cleo says it has been granted a US patent covering its C-X-C motif chemokine ligand 10 (CXCL10) binding proteins and methods for diagnosing cancer.

Cleo said the US Patent and Trademark Office granted the patent, titled ‘CXCL10 Binding Proteins and Compositions Thereof’ which would provide protection until 2042.

The company said that patent covered its biomarkers and antibody formulations, which comprised the core technology of its ovarian cancer diagnostic blood test.

Cleo said that the determination of the level of CXCL10 might be used “to monitor tumor burden, malignancy progression or likelihood of tumor recurrence in a subject”. The company said the patent was granted in Australia earlier this year with applications pending in Europe, China, India, Japan, Korea, Israel, New Zealand and Singapore.

## RACE ONCOLOGY

Race says that director Dr Peter Smith has been appointed an executive director, on \$190,000 a year, replacing chief executive officer Damian Clarke-Bruce.

Race said non-executive director Dr John Cullity would retire, with former chief scientific officer Dr Daniel Tillet appointed a consultant on its bisantrene technology.

In June, Dr Smith was appointed a director replacing Daniel Sharp (BD: Jun 29, 2023).

In April, Mary Harney was appointed as the company’s chair with then chair Dr Cullity continuing as a non-executive director (BD: Apr 20, 2023).

In March, Dr Tillet resigned as an executive director to be replaced as chief scientific officer by Prof Tim Hammond from June 2023 (BD: March 24, 2023).

Last year, Race appointed Mr Clarke-Bruce as its managing-director on a base salary of \$475,000 a year effective from February 1, 2023 (BD: Dec 14, 2022).

Today, Ms Harney said that “part of the board’s role is to focus on delivering best value to shareholders”.

“In today’s news, we have moved quickly to rebalance the team in a manner which we believe both fits with shareholder expectations and enables us to move forward, making appropriate adjustments to and ultimately delivering on our primary focus of getting bisantrene into the hands of partners and patients,” Ms Harney said.

Race said that Dr Smith would be paid \$190,000 a year, excluding superannuation and would work 40 percent of his time.

The company said Dr Smith had more than 30 years’ experience in the industry, focused on therapeutics and oncology, and was currently Myrio Therapeutics chief executive officer and previously Alchemia and Amrad chief executive officer.

The company said that Dr Smith held a Bachelor of Arts and a Doctor of Philosophy from England’s University of Cambridge.

Race was up two cents or 2.4 percent to 85 cents with 1.5 million shares traded.

## [NANOSONICS](#)

Pinnacle Investment Management Group says it has ceased its substantial shareholding in Nanosonics.

The Brisbane-based Pinnacle Investment said that between March 27 and August 16, 2023 it bought and sold shares, with the single largest sale 464,532 shares for \$2,178,477 or \$4.69 a share.

## [BIO NEW SOUTH WALES](#)

Bio NSW says it will formally launch in Sydney on Thursday, modelled on similar organizations, such as the Bio-Melbourne Network and Life Sciences Queensland.

Bio NSW said it would be headquartered in Sydney, would have a “focus on innovation and commercialization in Newcastle and Wollongong”.

Bio NSW co-founder Anthony Murray told Biotech Daily that he worked for health research company Opyl, which was founded by former Bio-Melbourne chief executive officer Michelle Gallaher.

Bio NSW said it would “provide a platform for life sciences businesses, researchers and investors to connect, share ideas and collaborate”.

“New South Wales is home to a thriving life sciences industry, with world-leading research institutions, innovative businesses and a supportive ecosystem,” Mr Murray, said.

“We believe that Bio NSW can play a vital role in helping this industry grow and thrive,” Mr Murray said.

Bio NSW said it would offer services to its members, including networking events, education meetings, highlighting funding opportunities and digital resources.

The non-for-profit organization said it would “work to promote the [New South Wales] life sciences industry to policymakers and further afield”.

Bio NSW said that Mr Murray and co-founder Brad Walsh would formally launch the organization on Thursday, August 24, 2023 at an event supported by intellectual property firm, Spruson & Ferguson.

For more information, go to: <https://www.bionsw.org/>.