



# Biotech Daily

Monday July 24, 2023

*Daily news on ASX-listed biotechnology companies*

- \* ASX DOWN, BIOTECH UP: CYNATA UP 11%; MESOBLAST DOWN 7%
- \* MICRO-X US BAGGAGE SCANNER CONTRACT EXTENDED \$21m
- \* IMPEDIMED RECEIPTS UP 11% TO \$11.5m
- \* MTP CONNECT, FEDERAL \$6.2m FOR 6 DEVICE PROJECTS
- \* CORRECTION: CYNATA THERAPEUTICS
- \* CORRECTION: BOTANIX PHARMACEUTICALS
- \* DIMERIX DMX-200 FSGS TRIAL 1st COHORT RANDOMIZED
- \* CLARITY PROSTATE CANCER TRIAL HALF RECRUITED
- \* RECCE: SCIENTIA STARTS DOSING FASTER RATE R327 FOR UTIs
- \* CYNATA REVIEWS TRIAL PROGRAM
- \* ALTHEA: IRELAND TO PAY \$542 FOR 50ml MARIJUANA CBD12:THC10
- \* CANN GROUP MARIJUANA HARVEST 'TWICE PREVIOUS YEARS'
- \* MEDIBIO HEART DEPRESSION TEST: '71% SENSITIVITY, SPECIFICITY'
- \* BIONOMICS REQUESTS 'ASX REMOVAL' TRADING HALT
- \* ANTEOTECH REQUESTS 'CAPITAL RAISING' TRADING HALT
- \* AROVELLA 2.25m TOM DUTHY SHARES, 6.5m OPTIONS EGM
- \* AMPLIA 2.5m M-D DR CHRIS BURNS OPTIONS AGM
- \* VOLPARA 450k DIRECTOR MARK BOUW OPTIONS AGM
- \* GZ FAMILY DILUTED TO 5% OF LUMOS
- \* GRAHAM MCLEAN REPLACES FISHER PAYKEL DIRECTOR DONAL O'DWYER
- \* RADIOPHARM: DR SHERIN AL-SAFADI MEDICAL, CORPORATE HEAD

## MARKET REPORT

The Australian stock market fell 0.1 percent on Monday July 24, 2023, with the ASX200 down 7.5 points to 7,306.4 points.

Twenty-four of the Biotech Daily Top 40 stocks were up, eight fell, six traded unchanged and two were untraded.

Cynata was the best, up 1.5 cents or 11.1 percent to 15 cents, with 323,835 shares traded.

Patrys climbed 10 percent; Amplia and Micro-X were up nine percent or more; Telix improved 7.7 percent; Dimerix and Next Science were up more than five percent; 4D Medical, Avita, Cyclopharm, Genetic Signatures, Immutep, Nova Eye and Orthocell were up four percent or more; Proteomics was up 3.5 percent; Impedimed and Opthea rose more than two percent; Clinuvel, Emvision and Pharmaxis were up more than one percent; with Cochlear, Medical Developments, Polynovo, Pro Medicus, Resmed and Volpara up by less than one percent.

Mesoblast led the falls, down nine cents or 6.6 percent to \$1.275, with 4.7 million shares traded.

Starpharma lost 5.9 percent; Alcidion fell 4.55 percent; Imugene shed 2.1 percent; Neuren and Prescient were down more than one percent; with CSL, Nanosonics and Paradigm down by less than one percent.

## MICRO-X

Micro-X says the US Department of Homeland Security has extended its \$7.25 million, 18-month baggage scanner contract with a further \$21 million over 40-months.

In 2021, Micro-X said it had US Government contracts worth up to \$US4.1 million for its baggage screening scanner and self-screening portal (BD: Sep 29, 2021).

Today, the company said the extension would help it build and test fully-integrated, self-screening stations at US airports with travelling passengers, with the aim to have a self-screening security system operating at the 440 US airports.

Micro-X said the project had eight phases, with milestone payments between \$3 million to \$6 million.

Micro-X was up one cent or 9.5 percent to 11.5 cents with 13.25 million shares traded.

## IMPEDIMED

Impedimed says that receipts from customers for the year to June 30, 2023, was up 10.6 percent to \$11,487,000 compared to the previous corresponding period.

Impedimed said that receipts for the three months to June 30, 2023, slipped 1.9 percent to 2,700,000 and came primarily from sales and software as a service revenue from its Sozo and its L-Dex bio-impedance spectroscopy body fluid measuring devices.

The company said it had a cash burn of \$3,061,000 for the three months to June 30, with cash and cash equivalents of \$45,710,000 compared to \$40,730,000 last year.

Impedimed was up half a cent or 2.5 percent to 20.5 cents with 7.6 million shares traded.

### [MTP CONNECT, FEDERAL GOVERNMENT](#)

MTP Connect says that with the Federal Government it has provided \$6.2 million to six medical device programs.

MTP Connect said that with the Federal Minister for Health and Aged Care Mark Butler it made the grants through the Clinical Translation and Commercialisation Medical Technologies (CTCM) Program, a Medical Research Future Fund program.

The Federally-funded organization said that Medical Developments was awarded \$1,500,000 for the development of its “next generation” Pentrox methoxyflurane inhaler for analgesia and 4D Medical received \$1,100,000 for its XV-Perfusion contrast-free, four-dimensional lung scanner

MTP Connect said that Sydney’s Cathrx was granted \$1,500,000 for a “pulsed field ablation system” for atrial fibrillation, Melbourne’s Vivid White Pty Ltd received \$1,000,000 for a clinical study, manufacturing and registration of a device to treat glaucoma and prevent blindness, Perth’s Vital Trace Pty Ltd was awarded \$656,666 for a lactate biosensor for fetal monitoring and Melbourne’s Ventora Medical Pty Ltd won \$500,000 for the development and a feasibility study of a neonatal airway pressure monitor.

MTP Connect chief executive officer Stuart Dignam said the CTCM program “identifies and nurtures high quality medical device projects that have commercial potential and supports their translation through early clinical trials”.

Mr Butler said that the 4D Medical lung scanner was “nearing commercial development [and] ... could save thousands of Australian lives by detecting lung cancer early”.

“Turning a scientific discovery into a medical product that’s ready for clinical use is a long and expensive process,” Mr Butler said.

“The grants to the lung scanner and five other outstanding Australian innovations will allow these new treatments and devices to start helping people sooner,” Mr Butler said.

### [CORRECTION: CYNATA THERAPEUTICS](#)

Friday’s edition incorrectly reported that a phase III trial of Cynata’s Cymerus for moderate knee osteoarthritis at the University of Sydney expected recruitment by the end of 2024.

In fact, the trial is expected to be recruited by the end of this year, 2023.

The mistake was made by the Friday sub-editor who has been replaced.

Sincere apologies to Cynata.

Cynata was up 1.5 cents or 11.1 percent to 15 cents.

### [CORRECTION: BOTANIX PHARMACEUTICALS](#)

Friday’s edition inaccurately had the headline ‘Botanix raises \$12.5m to extinguish debts’.

In fact, Botanix raised \$12.5 to buy royalty streams.

The edited copy erroneously said that the company “was obliged to pay sales milestones of up to \$US160 million on reaching the first \$US75 million of net sales, as well as royalties ranging from 12 percent to 20 percent on net sales”.

This was a misreading of the detailed announcement to the ASX.

In fact, the company said it was obliged to pay sales milestones of up to \$US160 million on reaching milestones including the first \$US75 million of net sales and up to \$1.8 billion of sales, as well as royalties ranging from 12 percent to 20 percent on net sales.

Biotech Daily apologizes unreservedly to Botanix and has offered the remains of the Friday sub-editor for pre-clinical testing.

Botanix was up half a cent or 3.7 percent to 14 cents with 2.8 million shares traded.

### DIMERIX

Dimerix says it has completed randomization of the first 72-patient cohort of its phase III trial of DMX-200 for focal segmental glomerulosclerosis (FSGS) kidney disease.

In May, 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 it expected to report results on or around March 15, 2024, and that 133 patients had entered the screening and/or stabilization process.

Dimerix said the final data collection was scheduled on February 26, 2024, with part one of the interim outcome expected to be announced about March 15, 2024.

The company said it continued to recruit for the second part of the trial.

Dimerix was up 0.4 cents or 5.6 percent to 7.5 cents.

### CLARITY PHARMACEUTICALS

Clarity says it has recruited 25 of the 50 patients for its phase II trial of its 64-copper sarcophagine (SAR)-Bombesin prostate cancer imaging diagnostic.

Last year, Clarity said the trial would assess the safety of 64-copper SAR-Bombesin, as well the diagnostic potential for men with negative prostate specific membrane antigen (PSMA) positron emission tomography (PET) or low PSMA expression disease in patients with suspected biochemical recurrence of prostate cancer, and patients with metastatic castrate-resistant prostate cancer not eligible for PSMA therapy (BD: Aug 22, 2022).

Clarity was unchanged at 88 cents.

### RECCE PHARMACEUTICALS

Recce says Sydney's Scientia Clinical Research has begun dosing subjects in its phase I/II trial of R327 for urinary tract infection (UTI) at faster infusion rates.

Earlier this month Recce said that it had dosed the first cohort, including the first woman to receive R327, at Adelaide's CMax, at two "faster infusion rates" of 2,500mg over 30 minutes and 45 minutes, in its trial of intravenous R327 for urinary tract infections, with no serious adverse reactions (BD: Jul 10, 2023).

Recce was up two cents or 2.9 percent to 70 cents.

### CYNATA THERAPEUTICS

Cynata says it has reviewed its trial programs, with its graft versus host disease trial to begin by October 2023, and the diabetic foot ulcer trial to be recruited this year.

Cynata said recruitment for its phase II trial of CYP-004 for osteoarthritis was initially slower than expected but had increased "dramatically", with 300 patients enrolled and primary evaluation results expected by July 2026.

The company said enrolment for its phase I trial of CYP-006TK for diabetic foot ulcer were "lower than expected" due to an unexpectedly high screening failure rate but said it had updated the trial protocol and opened additional centres, with recruitment expected to be completed by the end of 2023 and results available in "mid-2024".

## ALTHEA GROUP HOLDINGS

Althea says Ireland will reimburse its CBD12:THC10 marijuana for spasticity associated with multiple sclerosis and chemotherapy-related nausea and vomiting.

In May, Althea said Ireland's Health Products Regulatory Authority has approved the sale and distribution of its THC20:CBD1 medical marijuana oil, and that it was one of two companies to have a tetrahydrocannabinol (THC) based oral product, as well as cannabidiol (CBD) products (BD: May 19, 2023).

Today, Althea said the agreed reimbursement price was EUR327.89 (\$A541.56).

Althea chief executive officer Joshua Fegan told Biotech Daily that the reimbursement was for a single 50ml bottle of the marijuana oil, which was expected to last about one month. Althea was unchanged at five cents.

## CANN GROUP

Cann Group says it has harvested 320 square metres (3,444 square feet) of marijuana crop, "twice the area of crop that had been harvested previously".

Cann Group said the amount equated to an "annualized" production level of eight tonnes, nearing its target of 12.5 tonnes at its Mildura good-manufacturing-practice facility and reaching earnings before interest, taxes, depreciation and amortization (Ebitda) profitability by June 30, 2025.

Cann Group chief executive officer Peter Koetsier said "this is a tremendous achievement by our production team at Mildura and gives us strong confidence that we are on track to reach our 12.5 tonne annualized volume target".

Cann Group was up half a cent or four percent to 13 cents.

## MEDIBIO

Medibio says a 313-subject trial shows its heart rate depression test has 71.65 percent sensitivity and, 71.43 percent specificity, but provided no statistical significance.

Medibio said the trial showed a 35.58 percent positive predictive value and a 92.11 percent negative predictive value.

Last year, the company said it had begun a 400-patient, 17-centre, US study of the relationship between sleep disturbance and depressive episodes, to detect the likelihood of a current major depressive episode in individuals referred to sleep clinics for polysomnography assessment (BD: Jul 21, 2022).

Today, Medibio said the trial "aimed to detect the likelihood of a current major depressive episode in individuals referred to sleep clinics for [polysomnography assessment] assessment".

The company said that "a robust bi-directional relationship exists between mental illness and sleep disturbances, and depression is highly prevalent in individuals with sleep disorders ... [but there was] insufficient depression screening in sleep clinics".

Medibio chief executive officer Dr Tom Young said that "to have achieved these results based on preliminary testing, in the first phase of our [sleep signal analysis of depression burden study] trial highlights the significant potential for the company's algorithmic offering when compared to the current standard of care."

"The preliminary results for the accuracy of our [artificial intelligence]-based algorithm for the sensitivity component exceeded our expectations, and the initial indications now provide the company with a strong framework for ongoing analysis of the phase I results through to the commencement of the phase II trial," Dr Young said.

Medibio fell 0.05 cents or 33.3 percent to 0.1 cents with 3.1 million shares traded.

### BIONOMICS

Bionomics has requested a trading halt, pending an announcement “in relation to an application to be removed from the official list of the ASX”.

At the end of 2021, Bionomics said it had raised about \$US20 million (\$A28 million) in an initial public offering of 1,622,000 ADSs on the Nasdaq (BD: Jan 16, 2022).

Trading will resume on July 26, 2023 or on an earlier announcement.

Bionomics last traded at 2.2 cents.

### ANTEOTECH

Anteotech has requested a trading halt “pending an announcement by the company concerning a capital raising”.

Trading will resume on July 26, 2023 or on an earlier announcement.

Anteotech last traded at 3.9 cents.

### AROVELLA THERAPEUTICS

Arovella says its extraordinary general meeting will vote to issue 2.25 million shares and 6.5 million options to chair Dr Thomas Duthy.

Arovella it would issue Dr Duthy 2,250,000 shares valued at \$90,000, 3,043,478 director options exercisable at 4.0 cents each within five years, valued at \$70,000 and 3,478,261 incentive options exercisable at 3.2 cents each within 48 months, valued at \$80,000.

The company said that if the resolutions were not passed it would pay Dr Duthy \$160,000 in cash.

Arovella said that 25 percent of both groups of options would vest on the later of shareholder approval or June 30, 2023, with the remainder vesting in equal tranches on September 30, 2023, December 31, 2023 and March 31, 2024.

The company said shareholders would vote to ratify the issue of placement shares and options and adviser options.

The meeting will be held at The CFO Solution, Level 3, 62 Lygon Street, Carlton, Victoria on August 23, 2023 at 11am (AEST).

Arovella was up 0.1 cents or two percent to five cents with 4.4 million shares traded.

### AMPLIA THERAPEUTICS

Amplia says its annual general meeting will vote to issue 2.5 million options to managing director Chris Burns, in addition to his \$350,000 salary.

Amplia said Mr Burns’ options would be exercisable at 13.5 cents, a 150 percent premium to the 10-day volume weighted average price “to the date at which Dr Burns agreed to enter into long-term employment” by June 5, 2028.

The company said shareholders would also vote to approve the remuneration report, re-elect director Dr Warwick Tong and approve the 10 percent placement facility.

The meeting will be held at Level 22, Tower 5, 727 Collins Street, Melbourne on August 24, 2023 at 11am (AEST).

Amplia was up 0.7 cents or nine percent to 8.5 cents.

### [VOLPARA HEALTH TECHNOLOGIES](#)

Volpara says its annual general meeting will vote to re-elect director Mark Bouw and issue him 450,000 options in addition to his \$70,000 salary.

Volpara said Mr Bouw's options would be exercisable at \$1.30 each by January 1, 2030. The company said shareholders would vote to re-elect directors Karin Lindgren and Roger Allen, approve the long-term incentive plan, ratify the issue of shares under the incentive plan, amend its constitution, issue restricted stock units to chief executive officer Teri Thomas equivalent to 40 percent of her \$NZ164,800 annual salary and approve its 10 percent placement capacity.

The meeting will be held virtually on August 17, 2023 at 10am (AEST).

Volpara was up half a cent or 0.55 percent to 91.5 cents.

### [LUMOS DIAGNOSTICS HOLDINGS](#)

GZ Family Holding says its 21,930,614 share-holding in Lumos has been diluted from 6.89 percent to 5.36 percent.

The Sydney-based GZ Family Holdings said it had been diluted by the conversion of a convertible note on July 11, 2023 and a placement on July 14, 2023.

Last year, Lumos said it had an \$8 million, two-year, convertible note with New York's Lind Partners and Melbourne's SBC Global Investment Fund (BD: Nov 21, 2022).

Last week, Lind said it had ceased its substantial holding in Lumos and Lumos said it had raised \$4.75 million through a placement at 7.0 cents a share and hoped to raise \$4.75 million through a share plan (BD: Jul 10, 14, 2023).

Lumos fell 0.1 cents or 1.45 percent to 6.8 cents with 22.5 million shares traded.

### [FISHER & PAYKEL HEALTHCARE CORP](#)

Fisher & Paykel Healthcare says it has appointed Graham McLean a director, effective on October 1, 2023, with director Donal O'Dwyer to retire on December 31, 2023.

Fisher & Paykel said Mr McLean was Clean Space Holdings chief executive officer and a director, and Universal Biosensors chair and was previously a Stryker Corp director.

According to his LinkedIn page, Mr McLean held a Bachelor of Science from England's Durham University.

Fisher & Paykel fell three cents or 0.1 percent to \$22.54 with 265,270 shares traded.

### [RADIOPHARM THERANOSTICS](#)

Radiopharm says it has appointed Dr Sherin Al-Safadi as its head of medical and corporate affairs, effective from today.

Radiopharm said Dr Al-Safadi was most recently Point Biopharma's head of medical affairs and a co-founder of Foundation Amal, and previously was an executive at Bayer.

The company said Dr Al-Safadi held a Bachelor and a Master of Science from Montreal's McGill University, a Master of Business Administration from Montreal's John Molson School of Business and a Doctor of Philosophy from Montreal's Concordia University.

Radiopharm was unchanged at 11 cents.