



# Biotech Daily

Wednesday August 25, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX, BIOTECH UP: ACTINOGEN UP 14%; OSPREY DOWN 8%**
- \* **CLARITY OPENS UP 18% FOR CANCER RADIO-PHARMACEUTICALS**
- \* **ALTHEA RAISES \$10.6m**
- \* **PROBIOTEC REVENUE UP 12% TO \$121m, PROFIT DOWN 21% TO \$5m**
- \* **TRAJAN REVENUE UP 7% TO \$77m, PROFIT DOWN 28% TO \$2m**
- \* **COGSTATE REVENUE UP 44% TO \$45m, LOSS TO \$7.2m PROFIT**
- \* **GENETIC SIGNATURES REVENUE UP 151% TO 28m, LOSS TO \$1.8m PROFIT**
- \* **MEDICAL DEVELOPMENTS REVENUE UP 9% TO \$26m, PROFIT TO \$13m LOSS**
- \* **IDT REVENUE UP 19.5% TO \$17m, LOSS TO \$2m PROFIT**
- \* **CRYOSITE REVENUE UP 12% TO \$10m, PROFIT DOWN 56% TO \$653k**
- \* **IMPEDIMED REVENUE UP 47% TO \$8m, LOSS DOWN 3% TO \$21m**
- \* **ACRUX REVENUE UP 7% TO \$1.3m, LOSS UP 33% TO \$13m**
- \* **MEDLAB: TGA OKAYS NANABIS MARIJUANA CANCER PAIN TRIAL**
- \* **DIMERIX FILES PHASE III DMX-200 FSGS STUDY ETHICS APPLICATION**
- \* **BAYER INCREASES CARDIEX TRIAL CONTRACT \$682k**
- \* **CHIMERIC RELEASES 19m SHARES FROM ESCROW**
- \* **CREDIT SUISSE TAKES 6% OF IDT**
- \* **PERENNIAL TAKES 15% OF MEDADVISOR**
- \* **DEBORAH AMBROSINI REPLACES CANN GROUP CFO GREG BULLOCK**

## MARKET REPORT

The Australian stock market was up 0.39 percent on Wednesday August 25, 2021, with the ASX200 up 28.9 points to 7,531.9 points.

Twenty-seven of the Biotech Daily Top 40 stocks were up, nine fell and four traded unchanged.

Actinogen was the best, up 1.3 cents or 14.1 percent to 10.5 cents, with 13.2 million shares traded. Amplia climbed 13.9 percent; Impedimed improved eight percent; Universal Biosensors was up 7.7 percent; Alterity was up 6.25 percent; Dimerix and Prescient were up five percent or more; Pharmaxis and Telix were up more than four percent; Mesoblast and Imugene climbed more than three percent; Oncosil, Optiscan and Paradigm rose two percent or more; Clinuvel, Compumedics, CSL, Cynata, Genetic Signatures, Immutep, Nova Eye, Orthocell, Polynovo, Pro Medicus and Starpharma climbed one percent or more; with Cyclopharm, Neuren and Opthea up by less than one percent.

Osprey the falls, down 0.1 cents or 8.3 percent to 1.1 cents, with 1.6 million shares traded. Antisense lost 5.6 percent; Resonance fell four percent; Cochlear and Medical Developments were down more than three percent; Nanosonics shed 2.5 percent; Avita was down 1.6 percent; with Kazia, Next Science, Proteomics and Resmed down by less than one percent.

## CLARITY PHARMACEUTICALS

Clarity opened on the ASX, up 17.9 percent above the \$92 million initial public offer price of \$1.40 a share to develop and commercialize its radio-pharmaceuticals for cancer. In July, Clarity said it would trade under the code CU6 and had an indicative market capitalization of \$358.6 million (BD: Jul 20, 2021).

The company said in its prospectus the indicative market capitalization did not include 25,543,912 China Grand options, exercisable at \$1.75 each, giving China Grand about 8.3 percent if exercised, but with several vesting conditions including listing on the ASX and completing an agreement.

Clarity executive chair Dr Alan Taylor said the company's SAR technology employed radioisotopes copper-64 for diagnosis and copper-67 for therapy, "with the aim of achieving superior imaging and highly precise and accurate therapy".

Dr Taylor said the diagnostic and therapeutic trials "paved the way for the clinical development of two additional products, SAR-Bombesin and SAR-bis-PSMA, for the management and treatment of breast and prostate cancers.

Clarity said that the joint lead managers were Jeffreys and Bell Potter.

Separately, Clarity said it had dosed the first US patient in its 'Secure' trial of 64-Cu SAR-bis-PSMA for metastatic castrate resistant prostate cancer at the Omaha, Nebraska-based Urology Cancer Center and GU Research Network.

In May, Clarity said the US Food and Drug Administration had cleared an investigational new drug application for the 44-patient, phase I/IIa, single arm, dose-escalation prostate cancer trial (BD: May 4, 2021).

The company said that 64-Cu-SAR-bis-PSMA was used to image and select patients for 67-Cu-SAR-bis-PSMA therapy.

Clarity climbed as much as 31 cents or 22.1 percent to \$1.71, before closing up 10 cents or 7.1 percent at \$1.50 with 8.75 million shares traded.

## ALTHEA GROUP

Althea says it has raised \$10.64 million in a placement at 24 cents a share for its marijuana products.

Althea said that the offer price was a 15.8 percent discount to the closing price prior to the trading halt on August 23, 2021.

The company said that the proceeds would fund “a range of growth initiatives across the company’s pharmaceutical business ... [and] support further expansion in Australia, Europe and other international markets and to fund general working capital”.

Althea said Canaccord Genuity Australia was the lead manager to the placement.

Althea fell three cents or 10.5 percent to 25.5 cents with 5.4 million shares traded.

## PROBIOTEC

Probiotec says revenue for the year to June 30, 2021 was up 12.4 percent to \$120,506,877 with net profit after tax down 21.3 percent to \$5,069,220.

Probiotec said sales revenue was from contract drug manufacturing and product development.

The company said it would pay a fully-franked dividend of 3.0 cents a share for holders at the record date of October 1, to be paid on October 8, 2021.

Probiotec said diluted earnings per share fell 29.7 percent to 6.4 cents, with cash and equivalents of \$28,426,756 at June 30, 2021 compared to \$6,305,680 at June 30, 2020.

Probiotec was up nine cents or 4.3 percent to \$2.19.

## TRAJAN

Trajan says revenue for the year to June 30, 2021 was up 6.6 percent to \$76,568,000 with net profit after tax down 27.9 percent to \$1,880,000.

Trajan said it was a “developer and manufacturer of analytical science instruments, devices, and solutions used in biological, food and environmental analysis”.

The company said the diluted earnings per share was five cents, net tangible asset backing per share was 50 cents, and it had cash and cash equivalents of \$51,717,000 at June 30, 2021 compared to \$4,786,000 at June 30, 2020.

Trajan was up 20 cents or 6.6 percent to \$3.25.

## COGSTATE

Cogstate says revenue for the year to June 30, 2021 was up 43.5 percent to \$US32,686,396 (\$A45,132,885) with last year’s \$US1,315,000 (\$A1,815,732) net loss after tax of turned to a profit of \$US5,233,283 (\$A7,226,039).

Cogstate said revenue from its cognition testing software included \$US28,667,707 in clinical trials, \$US3,758,790 in healthcare and \$US259,899 in research revenue.

The company said last year’s 1.23 US cents diluted loss per share was turned to a diluted earnings per share of 3.07 US cents, with net tangible asset backing per share up 295.7 percent to 3.68 US cents, and it had cash and cash equivalents of \$US23,640,789 at June 30, 2021 compared to \$US10,330,777 at June 30, 2020.

Cogstate fell three cents or 1.7 percent to \$1.715.

## GENETIC SIGNATURES

Genetic Signatures says revenue for the year to June 30, 2021 was up 151.1 percent to \$28,284,000 with last year's \$2,086,000 net loss after tax turned to a profit of \$1,756,000. Genetic Signatures said the revenue growth was driven by demand for the Easyscreen severe acute respiratory syndrome coronavirus-2 (Sars-Cov-2) detection kit in Europe and Australia and had "resulted in the quadrupling of instruments in use compared to pre-pandemic placements".

The company said it had five products registered for sale under Conformité Européenne (CE) mark; the Sars-Cov-2 test as well as respiratory, enteric, anti-microbial resistance and sexually transmitted infections diagnostics.

Genetic Signatures said that last year's 1.64 cents diluted loss per share was turned to a diluted earnings per share of 1.21 cents.

The company said that net tangible asset backing per share was up 7.3 percent to 34.0 cents.

Genetic Signatures said that it had cash and cash equivalents of \$30,121,000 at June 30, 2021 compared to \$31,176,000 at June 30, 2020.

Genetic Signatures was up two cents or 1.3 percent to \$1.51.

## MEDICAL DEVELOPMENTS INTERNATIONAL

Medical Developments says revenue for the year to June 30, 2021 was up 8.6 percent to \$25,672,000 with last year's \$379,000 net profit after tax turned to a loss of \$12,565,000.

Medical Developments said that sales were primarily from its Pentrox inhaled methoxyflurane analgesic and respiratory equipment, and while revenue was at record levels, the company paid \$9.5 million to take back the rights to European Union distribution of Pentrox and \$9.0 million in "impairments ... related to medical devices segment goodwill and the [Commonwealth Scientific and Industrial Research Organisation] technology project".

The company said that last year's 0.58 basic earnings per share turned to a basic loss per share of 18.35 cents.

Medical Developments said that net tangible asset backing per share was 38.2 cents compared to negative 5.6 cents for the previous corresponding period.

The company said it had cash and cash equivalents of \$36,277,000 at June 30, 2021, compared to \$15,544,000 at June 30, 2020.

Medical Developments fell 13 cents or 3.2 percent to \$3.90.

## IDT AUSTRALIA

IDT says revenue for the year to June 30, 2021 was up 19.5 percent to \$16,927,000 with last year's \$1,919,000 net loss after tax up turned profit of \$2,103,000.

IDT said revenue came primarily from drug and marijuana manufacturing, particularly the manufacture of active pharmaceutical ingredients.

The company said last year's 0.8 cents diluted loss per share turned to a diluted earnings per share of 0.9 cents.

IDT said that net tangible asset backing per share was up 10 percent to 11 cents.

The company said that it had cash and cash equivalents of \$6,928,000 at June 30, 2021 compared to \$6,860,000 at June 30, 2020.

IDT was up four cents or 6.35 percent to 67 cents with 3.6 million shares traded.

## CRYOSITE

Cryosite says revenue for the year to June 30, 2021 was up 11.8 percent to \$10,081,963, with net profit after tax down 55.9 percent to \$652,574.

Cryosite said revenue from its cord blood and tissue bank was down to \$2,519,000, with clinical trial logistics revenue up 20.4 percent to \$7.5 million.

Cryosite said diluted earnings per share fell 55.8 percent to 1.34 cents, net tangible asset backing per share was up from negative 0.7 cents to 0.8 cents, and it had cash and cash equivalents of \$3,881,126 at June 30, 2021 compared to \$4,061,832 at June 30, 2020.

Cryosite fell half a cent or 1.1 percent to 44 cents.

## IMPEDIMED

Impedimed says revenue for the year to June 30, 2021 was up 46.5 percent to \$8,409,000 with net loss after tax down 3.1 percent to \$20,706,000.

Impedimed said Sozo revenue was up 64.1 percent to \$7,639,000 with legacy revenue from L-Dex bio-impedance spectroscopy device down 31.2 percent to \$714,000 and \$56,000 in other revenue.

Impedimed managing director Richard Carreon said that Sozo annual recurring revenue was up by 67 percent to \$8.7 million and the company had sold more than 770 Sozo units, with an additional 375 units under contract or leased.

The company said diluted loss per share was down 50.0 percent to 2.0 cents, net tangible asset backing per share was down 50.0 percent to 1.0 cent, and it had cash and cash equivalents of \$19,681,000 at June 30, 2021 compared to \$19,663,000 at June 30, 2020. Impedimed was up one cent or eight percent to 13.5 cents with four million shares traded.

## ACRUX

Acrux says revenue for the year to June 30, 2021 fell 15.3 percent to \$1,371,000 with net loss after tax up 33.3 percent to \$12,629,000.

Acrux said its revenue was primarily from licencing agreements in development and commercialization of generic topical prescription pharmaceutical products.

Acrux said diluted loss per share was up 1.8 percent to 5.75 cents, net tangible asset backing per share was constant at 6.0 cents and it had cash and cash equivalents of \$15,270,000 at June 30, 2021 compared to \$9,206,000 at June 30, 2020. Acrux.

Acrux was unchanged at 12 cents.

## MEDLAB CLINICAL

Medlab says the Australian Therapeutic Goods Administration has approved its phase III trial of synthetic marijuana-based Nanabis for cancer bone pain.

Last month, Medlab said Adelaide's Bellberry had approved two sites for the phase III trial (BD: Jul 12, 2021).

According to its entry on [clinicaltrials.gov](https://clinicaltrials.gov), the company said it would conduct a 360-participant, randomized, blinded trial aimed at showing the analgesic efficacy of Nanabis as a monotherapy in cancer patients by proving that the analgesic was significantly better than the placebo and that the magnitude of improvement was clinically important.

Medlab was unchanged at 17.5 cents.

## DIMERIX

Dimerix says it has filed for ethics approval of its 250-patient, phase III trial of DMX-200 for focal segmental glomerulo-sclerosis.

Dimerix said it expected to recruit patients at 167 sites in up to 18 countries in North and South America, Europe, the UK and the Asia Pacific region.

The company said the trial was a multi-centre, randomized, double-blind, placebo-controlled study of the efficacy and safety of DMX-200 in patients with focal segmental glomerulo-sclerosis (FSGS) receiving a stable dose of an angiotensin II receptor blocker. Dimerix said the primary endpoint for potential accelerated market approval was the percent change in protein in the urine from baseline to week-35 following treatment with DMX-200 compared with placebo.

The company said that the primary endpoint for full approval was “the slope of [estimated glomerular filtration rate] from baseline to week-104 following treatment with DMX-200 compared with placebo”.

Dimerix said that the first part of the trial would assess 70 patients to confirm efficacy and study powering for statistical measures, based on the estimated patient recruitment rate, expected by the end of 2022.

The company said that if recommended to continue part two the study would enrol the remaining 180 patients.

Dimerix was up 1.5 cents or five percent to 31.5 cents with 3.5 million shares traded.

## CARDIEX

Cardiex says it has an amended agreement with Bayer AG for the lease of Atcor devices and expanded data management services for Bayer’s ‘Concord’ trial.

Cardiex said the Leverkusen, Germany-based Bayer originally contracted Atcor in December 2017 to provide clinical trial laboratory and data management services in the trial for patients with chronic kidney disease with diabetes and/or hypertension, with an initial contract value of \$US756,000 (\$A1,055,000).

Last year, Cardiex said it had an amended agreement with Bayer AG worth \$US420,000 to lease its devices and for expanded data services (BD: Aug 21, 2020).

Today, Cardiex said that Bayer increased the contract by \$US495,000 (\$A682,000).

The company said the contract covered the lease of services and devices, including Atcor’s Xcel system for monitoring critical haemodynamic data and the Concord trial remained on schedule to conclude by January 2022.

Cardiex managing-director Craig Cooper said the contract amendment and expansion with Bayer “continues to validate the unique capabilities of our [US Food and Drug Administration]-cleared Sphygmocor technology”.

“Importantly, it is this technology, that is trusted by the leading global pharmaceutical companies, that forms the basis of our competitive differentiation as we expand into wearables, smart home health devices and other new markets,” Mr Cooper said.

Cardiex was up 0.2 cents or 3.1 percent to 6.7 cents.

## CHIMERIC THERAPEUTICS

Chimeric says 18,800,065 fully paid ordinary shares would be released from voluntary escrow on September 1, 2021.

Chimeric said the shares were already quoted on the ASX and were included in the 330,859,716 shares on issue.

Chimeric fell half a cent or 1.6 percent to 31 cents.

### IDT AUSTRALIA

Credit Suisse says it has become a substantial shareholder in IDT Australia with 14,010,641 shares (5.84%).

The Sydney-based Credit Suisse said it bought shares between April 26 and August 23, 2021, with the single largest purchase of 1,817,637 shares for \$1,256,134 or 69.1 cents a share on August 23, 2021.

### MEDADVISOR

Perennial Value Management says it has increased its substantial shareholding in Medadvisor from 52,491,057 shares (13.91%) to 56,297,258 shares (14.92%).

The Sydney-based Perennial said it bought and sold shares between June 28 and August 20, 2021 with the single largest purchase on July 2 of 2,044,088 shares for \$615,271 or 30.1 cents a share and on the same day sold the same number of shares for the same price.

Medadvisor was unchanged at 35.5 cents.

### CANN GROUP

Cann Group says its chief financial officer Greg Bullock will be replaced by Deborah Ambrosini effective from September 1, 2021.

Cann Group said Ms Ambrosini was most recently the chief financial officer with Acrux. Ms Ambrosini was previously the company secretary and a director of BPH Energy, formerly Biopharmica, which held biotechnology assets.

Cann Group was unchanged at 29 cents with 1.8 million shares traded.