



# Biotech Daily

Tuesday August 3, 2021

*Daily news on ASX-listed biotechnology companies*

- \* **ASX DOWN, BIOTECH EVEN: ONCOSIL UP 8%; PATRYS DOWN 18%**
- \* **MACH7 UP-TO \$2.4m EUNITY IMAGING LICENCE TO IDAHO'S ST LUKE'S**
- \* **AROA: 'MYRIAD MATRIX'S EFFICACY FOR PILONIDAL SINUS DISEASE'**
- \* **ECOFIBRE REVENUE DOWN 43% TO \$29m, PROFIT TO \$7m LOSS**
- \* **TBG H1 RECEIPTS UP 2.7% TO \$3m**
- \* **MAYNE TO DEFEND 'MISLEADING, DECEPTIVE CONDUCT' CLASS ACTION**
- \* **PARADIGM: FDA REQUIRES FURTHER IND CLARIFICATION**
- \* **PATRYS: COVID-19 DELAYS PAT-DX1 MANUFACTURE, TRIAL 6 MONTHS**
- \* **PHARMAUST'S EPICHEM WASTE-TO-FUEL REACTOR 'OPERATIONAL'**
- \* **PERENNIAL TAKES 13.5% OF MICRO-X**
- \* **REGAL FUNDS REDUCES TO 9% OF MICRO-X**
- \* **RACE FOUNDER DR WILLIAM GARNER REDUCES TO 6%**
- \* **PERENNIAL TAKES 9% OF LUMOS**
- \* **ZOLTAN VARGA INCREASES, DILUTED TO 18.5% IN TOTAL BRAIN**
- \* **ANTEOTECH: CEO DEREK THOMSON EXTENDED ON \$395k**
- \* **MIKE TONROE REPLACES GENETIC TECH CO SEC JUSTYN STEDWELL**
- \* **ELIZABETH SPOONER REPLACES STEMCELL CO SEC CHOW YEE KOH**

## MARKET REPORT

The Australian stock market fell 0.23 percent on Tuesday August 3, 2021, with the ASX200 down 16.9 points to 7,474.5 points. Nineteen of the Biotech Daily Top 40 stocks were up, 18 fell and three traded unchanged.

Oncosil was best, up 0.4 cents or 8.3 percent to 5.2 cents, with 4.3 million shares traded. Compumedics, Cynata and LBT climbed five percent or more; Medical Developments and Optiscan improved more than four percent; Alterity, Imugene and Telix were up more than three percent; Amplia, Avita, Impedimed, Mesoblast, Opthea, Pharmaxis and Volpara rose more than two percent; Genetic Signatures and Universal Biosensors were up more than one percent; with Cochlear and Kazia up by less than one percent.

PatrYS led the falls, down 0.9 cents or 18.4 percent to four cents, with 87.7 million shares traded. Actinogen and Paradigm lost more than 11 percent; Resonance shed 9.7 percent; Prescient and Proteomics fell five percent or more; Dimerix fell 4.2 percent; Starpharma was down 3.3 percent; Polynovo shed 2.1 percent; with Clinuvel, Cyclopharm, Immutep, Nova Eye and Orthocell down by more than one percent.

## MACH7 TECHNOLOGIES

Mach7 says it has licenced its Eunity universal viewing product to the Boise, Idaho-based St Luke's Health System for up-to \$2.4 million.

Mach7 said the contract for the first year was valued at \$443,000 and included a software licence fee, professional services and one year of annual support.

The company said the contract had the option for annual renewals of \$389,000 per year for an additional five years, taking the total contract value to \$2.4 million.

Mach7 said that St Luke's had to solve "complex workflow challenges" and chose the Eunity Enterprise Viewer as having "the most flexible capabilities" for its needs.

Mach7 was up three cents or three percent to \$1.02.

## AROA BIOSURGERY

Aroa says a six-patient study of its treated sheep stomach-based Myriad Matrix has validated efficacy for chronic pilonidal sinus disease.

Aroa said the Myriad Matrix was used as an implant in the surgical reconstruction of under an advanced soft tissue flap.

The company said that one minor post-operative complication resolved without requiring additional surgery and "all patients healed well with no major complications reported, even when used in contaminated fields".

Aroa said that pilonidal sinus disease was a chronic inflammatory disease affecting the soft tissue of the buttock cleft resulting in long-term, non-healing wounds that were hard to heal and challenging for clinicians to treat, and when lesions became infected, standard wound care might not be effective, with surgical reconstruction a last resort.

The company said the study, titled 'Surgical Reconstruction of Pilonidal Sinus Disease with Concomitant Extracellular Matrix Graft Placement' was led by the New Orleans-based Tulane University's plastic surgeon Dr Abigail Chaffin and was available at:

<https://www.magonlinelibrary.com/doi/full/10.12968/jowc.2021.30.Sup7.S28>.

Aroa head of research and clinical development Dr Barnaby May said that the "study findings build on a growing number of publications that shows Myriad Matrix can be used successfully under a tissue flap to reduce surgical complications in the reconstruction of challenging inflammatory wounds."

"Simple incision and drainage procedures have a recurrence rate of up to 40 percent for this condition which affects around 70,000 patients in the United States each year," Dr May said.

Aroa was unchanged at \$1.145.

## ECOFIBRE

Ecofibre says revenue for the year to June 30, 2021 was down 43.2 percent to \$28,793,000, with last year's \$13,156,000 profit turned to a loss of \$6,986,000.

Ecofibre said revenue from sales of its marijuana and hemp-based food additives were impacted by business disruptions in pharmacies, underperforming distributor model and price and product competition.

The company said that last year's 4.43 cents diluted earnings per share turned to a 2.16 cents diluted loss per share, net tangible assets per share fell 8.3 percent to 17.64 cents, with cash and cash equivalents of \$8,620,000 at June 30, 2021, compared to \$18,252,000 at June 30, 2020.

Ecofibre was up 1.5 cents or two percent to 76.5 cents.

## TBG DIAGNOSTICS

TBG says receipts from customers for the six months to June 30, 2021 was up 2.7 percent to \$2,893,000 compared to the previous corresponding period.

TBG said that receipts from customers for its molecular diagnostics products for the three months to June 30, 2021 fell 70.0 percent to \$568,000.

The company said it had 3.28 quarters of funding available.

TBG was in an ASX suspension and last traded at 27 cents.

## MAYNE PHARMA GROUP

Mayne Pharma says it has been served with a class action on behalf of shareholders to be held at the Supreme Court of Victoria.

Mayne said that the proceeding was brought by Phi Finney McDonald for the plaintiff and on behalf of all persons who acquired an interest in shares and/or American depository receipts between November 24, 2014 and December 15, 2016.

The company said the plaintiff alleges misleading or deceptive conduct and breaches of continuous disclosure obligations in respect of alleged anti-competitive conduct in the US that was the subject of investigations by the US Department of Justice and the Office of the Attorney-General in the State of Connecticut.

Mayne Pharma said it would “vigorously defend the proceeding ... and emphatically denies any and all allegations of wrongdoing”.

Mayne fell two cents or six percent to 31.5 cents with 3.1 million shares traded.

## PARADIGM BIOPHARMACEUTICALS

Paradigm says the US Food and Drug Administration has accepted five of six responses to questions on its trial approval application, but wants more information.

In March, Paradigm said it has filed its investigational new drug submission for a 930-patient, randomized, phase III trial of pentosan polysulfate sodium (PPS), marketed as Zilosul, for knee osteoarthritis (BD: Mar 26, 2021).

In May, the company said the FDA had six questions “principally in relation to recently completed non-clinical studies” but did not detail the questions, its answers, nor the FDA “feedback” triggering another 30-day review period (BD: May 25, 2021).

Today, Paradigm said the one remaining question was “directed at the non-clinical interpretation and clinical mitigation relating to one of Paradigm’s recently completed [good laboratory practice] non-clinical toxicology studies”.

The company said that it conducted 26 non-clinical studies in 2020 at the request of the FDA, to provide a non-clinical portfolio of injectable PPS, and of the 26 non-clinical studies, the FDA wanted clarification on one rat study.

Paradigm said it would respond to the FDA within the month, while continuing its phase III trial start-up activities in Europe and Australia.

The company said it was “on-schedule to commence screening participants in Australia” by the end of 2021, with site selection activities underway in Europe.

Paradigm chief medical officer Dr Donna Skerrett said that “for new indications that impact large populations, such as osteoarthritis, a thorough and iterative process with the FDA for initiating the pivotal registration studies is common practice”.

“Even though the pace of progressing the clearance process has been slowed due to Covid-19, resulting in all communications being written, we are confident that we can address the FDA’s one remaining question,” Dr Skerrett said.

Paradigm fell 25 cents or 11.3 percent to \$1.97 with 4.2 million shares traded.

## PATRYS

PatrYS says that Covid-19 delays in the PAT-DX1 manufacturing process will stall by six months, its first-in-human trials for cancer, originally due to begin by July 2022.

In February, PatrYS said it had selected a stable, high-yielding cell-line suitable for the commercial production of clinical-grade PAT-DX1 (BD: Feb 10, 2021).

Today, the company said it ordered the required materials six months in advance of their planned use, but the manufacturer advised that there were “delays in procuring certain key components required for the fermentation media” which were “entirely due to the impact of the Covid-19 pandemic on global reagent production and supply chains and ... outside the control of either PatrYS or its contract manufacturer”.

PatrYS said that the proprietary nature of the reagents meant it was not able to source materials from alternative suppliers.

The company said the engineering run for PAT-DX1 was expected to be delayed until late this year, with toxicology studies rescheduled to early next year, pending the availability of PAT-DX1, and it expected to apply for ethics approval for the phase I trial by July 2022.

PatrYS managing-director Dr James Campbell said the expected delay “by up to six months is disappointing for the PatrYS team and our loyal shareholders”.

“This delay is based solely on global supply chains, not technical obstacles, and highlights the many ways that the Covid-19 pandemic is impacting on our lives, including disrupting the production of critical medical products and services,” Dr Campbell said.

Dr Campbell said the company was preparing for the trial to begin “in late 2022”.

PatrYS fell 0.9 cents or 18.4 percent to four cents with 87.7 million shares traded.

## PHARMAUST

Pharmaust says its subsidiary EpicChem has completed its benchtop oxidative hydro-thermal dissolution flow reactor to develop waste to fuels technology.

Pharmaust said the benchtop flow reactor located at EpicChem’s Bentley, Western Australia-based Technology Park would advance the biomass and feedstock flow reactor’s material science and had the potential to convert plastics into renewable fuels, coal into diesel or agricultural bio-simulants, rubber tyres into liquid fuels or chemical products, trees into cellulosic ethanol or fine chemicals, and leftover stock or crops into liquid fuel or cellulosic ethanol and agricultural bio-stimulants.

Pharmaust said the flow reactor would be carbon neutral, environmentally sustainable and would use oxygen and water at high temperature and pressure to break down input materials to form useful end products.

EpicChem chief executive officer Colin La Galia said the establishment of the operational benchtop reactor was a “milestone”.

“Now we move to the next stage of evaluating its potential,” Mr La Galia said. “The flow reactor has the potential to help deal with converting and re-purposing waste.”

Pharmaust was unchanged at 9.2 cents.

## MICRO-X

Sydney’s Perennial Value Management says it has increased its substantial shareholding in Micro-X from 54,997,171 shares (12.24%) to 62,041,316 shares (13.50%).

Perennial said that between February 8 and July 29, 2021 it bought and sold shares, with the single largest purchase on July 29, of 5,000,000 shares for \$1,528,355 or 30.6 cents a share.

Micro-X was up 1.5 cents or 4.9 percent to 32 cents.

### MICRO-X

Sydney's Regal Funds Management says it has decreased its substantial holding in Micro-X from 48,974,294 shares (10.90%) to 41,062,795 shares (8.93%).

Regal Funds said that between February 24 and July 29, 2021 it bought and sold shares, with the single largest sale on July 29, of 5,000,000 shares for \$1,525,000 or 30.5 cents a share.

### RACE ONCOLOGY

Race founder Dr William Garner says he has decreased his substantial shareholding in Race from 10,445,089 shares (7.40%) to 9,230,000 shares (6.39%).

The San Juan, Puerto Rico-based Dr Garner said that between May 7 and July 29, 2021 he sold 1,215,089 shares for \$4,318,441 or \$3.55 a share.

Race was up four cents or 1.2 percent to \$3.36.

### LUMOS DIAGNOSTICS

Sydney's Perennial Value Management says it has increased its substantial shareholding in Lumos from 11,733,971 shares (7.81%) to 13,722,761 shares (9.14%).

Perennial said between July 5 and 30, 2021 it bought 1,988,790 shares on-market for \$2,578,273 or \$1.30 a share.

Lumos was up three cents or 2.4 percent to \$1.27.

### TOTAL BRAIN

Zoltan Varga says he has increased his shareholding in Total Brain and been diluted in a placement from 21,660,179 shares (19.99%) to 21,842,679 shares (18.52%).

The Hong Kong-based Mr Varga said that on July 30, 2020 he bought 182,500 shares for \$56,285 or 30.84 cents a share.

Last month, Total Brain said it had commitments to raise \$6.5 million in a placement and a fully-underwritten rights offer at 26 cents a share (BD: Jul 21, 2021).

Total Brain was unchanged at 24 cents.

### ANTEOTECH

Anteo says it has extended chief executive officer Derek Thomson's contract, on a base salary of \$395,000 a year, not including superannuation, effective from July 1, 2022.

In 2019, Anteo said Mr Thomson's base salary was \$280,000 a year (BD: Apr 29, 2019).

Today, the company said that Mr Thomson's short-term and long-term incentives would be combined and he would be able to earn up to 50 percent of the fixed pay depending on his performance against annually determined performance indicators.

Anteotech fell one cent or 4.65 percent to 20.5 cents with 10.7 million shares traded.

### GENETIC TECHNOLOGIES

Genetic Technologies says it has appointed chief financial officer Michael Tonroe as its company secretary following the resignation of Justyn Stedwell, effective immediately.

Genetic Technologies was unchanged at 0.8 cents with 33.3 million shares traded.

## STEMCELL UNITED

Stemcell says it has appointed Automic Group's Elizabeth Spooner as its company secretary replacing Chow Yee Koh, effective immediately.

Stemcell said Mr Koh will continue as a director and chief financial officer.

Stemcell was up 0.1 cents or 6.25 percent to 1.7 cents with 9.9 million shares traded.