



# Biotech Daily

Thursday September 28, 2023

*Daily news on ASX-listed biotechnology companies*

- \* **ASX FLAT, BIOTECH UP: PARADIGM UP 8%; PATRYS DOWN 12.5%**
- \* **ACADIA PARK ROLLS IMPEDIMED DIRECTORS**
- \* **MACH7 EXTENDS HONG KONG SOFTWARE DEAL FOR \$15m**
- \* **CARDIEX WITHDRAWS NASDAQ LISTING, LOSES DIRECTOR JARROD WHITE**
- \* **ALLEGRA TO RESPOND TO FDA SPINAL CAGE QUERY IN '2-to-3 MONTHS'**
- \* **COGSTATE JAPAN PARTNER ESAI DEMENTIA, NOUKNOW INSURANCE**
- \* **ANTISENSE FILES ATL1102 COVID-19 PATENT; TWO STUDIES PUBLISHED**
- \* **IMUGENE: 'PRECISION TRANSFERS AZER-CEL IND'**
- \* **NOXOPHARM: CRO-67 'REDUCES TUMOR GROWTH, IN MICE'**
- \* **GENETIC TECHNOLOGIES 50-PATIENT GOLD COAST GENETYPE STUDY**
- \* **ALGORAE 20m DIRECTOR 'PERFORMANCE' SHARES AGM**
- \* **4D MEDICAL 1.3m M-D PROF ANDREAS FOURAS OPTIONS AGM**
- \* **AUSTCO 677k CEO CLAYTON ASTLES PERFORMANCE RIGHTS AGM**
- \* **TDM TAKES 30% OF SOMNOMED**
- \* **JASON PETERSON TAKES 6% OF INVEX**
- \* **CICADA APPOINTS DR KATHERINE WOODTHORPE CHAIR**
- \* **LUMOS APPOINTS CHAIR SAM LANYON ADVISOR ON \$80k**

## MARKET REPORT

The Australian stock market slipped 0.08 percent on Thursday September 28, 2023 with the ASX200 down 5.5 points to 7,024.8 points. Eighteen of the Biotech Daily Top 40 stocks were up, 13 fell, five traded unchanged and four were untraded.

Paradigm was the best, up 4.5 cents or 8.2 percent to 59.5 cents, with 606,771 shares traded. Cynata climbed 7.4 percent; Resonance rose 6.7 percent; Impedimed and Prescient improved more than five percent; Genetic Signatures and Resmed were up four percent or more; Cyclopharm, Dimerix, Kazia, Neuren and Volpara were up more than three percent; SDI rose 2.5 percent; Avita, Emvision and Immutep were up more than one percent; with Medical Developments, Pro Medicus and Telix up by less than one percent.

PatrYS led the falls, down 0.1 cents or 12.5 percent to 0.7 cents, with one million shares traded. Imugene lost eight percent; Nova Eye was down five percent; 4D Medical, Actinogen, Antisense and Atomo fell four percent or more; Clinuvel, Mesoblast and Next Science lost more than three percent; Starpharma shed 2.9 percent; Nanosonics and Orthocell were down more than one percent; with Cochlear down by 0.3 percent.

## IMPEDIMED

All resolutions to replace Impedimed directors have passed by about 58 percent of votes in favor to 42 percent of votes against.

Impedimed said that the widest margin was for the resolution to elect McGregor Grant as a director, with 876,407,536 votes (59.84%) in favor and 588,121,884 votes (40.16%) against.

The company said that the narrowest margin was for the election of Janelle Delaney, with 55.06 percent of votes in favor and 44.94 percent against.

Impedimed said that the four former directors were removed with more than 57.5 percent of the votes in favor.

Three previous directors continue on the board.

In July, Impedimed said it had received a Corporations Act 2001 203D notice from Acadia Park Pty Ltd calling for the removal of chair Donald Williams and directors Amit Patel, David Anderson and Daniel Sharp (BD: Jul 31, 2023).

In August the company said it had received a notice under section 249D of the Corporations Act 2001 requesting the four directors be replaced by Nanosonics chief financial officer McGregor Grant, Christine Emmanuel-Donnelly, Andrew Grant and Janelle Delaney (BD: Aug 3, 2023).

Impedimed said that the notice cited “a perceived disconnect between the Australian shareholders and the present board relating to the company’s recent capital raising and perceived risks to shareholder wealth”.

In May and June, Impedimed said it had commitments to raise \$20 million in a placement at 13.0 cents a share, its \$5 million share plan had more than \$20 million in applications, and it had scaled it back to \$10 million (BD: May 19, Jun 21, 2023).

Impedimed was up one cent or 5.9 percent to 18 cents with 3.7 million shares traded.

## MACH7 TECHNOLOGIES

Mach7 says it has a five-year deal extension with the Hospital Authority of Hong Kong for its data management software, with a total value of \$15.26 million.

In 2020, Mach7 said it had a \$4.8 million software licence order from the Hospital Authority for its enterprise imaging data management software and had entered a five year \$HK81 million (\$A16.25 million) contract with the Authority in October 2018 to provide the software system, with \$HK41 million received to date (BD: May 14, 2020).

Today, the company said the deal with the Hong Kong authority, was for its vendor neutral archive administration tool and E-unity support and maintenance software, and included recurring revenue of \$12.36 million, or \$2.47 million annually.

Mach7 said the professional services component was \$2.9 million and would be delivered and recognized over the course of the extension on an “as needed” basis.

Mach7 chief executive officer Mike Lampron said the company was “pleased to see continued support from this very important and long-standing client.”

“This long-term commitment shows the value that Mach7 brings to our clients and the deep-rooted partnerships that develop over time,” Mr Lampron said.

“The inclusion of professional services in this extension further illustrates how our product can continue to add value through increased use cases beyond what was imaginable at contract inception,” Mr Lampron said.

Mach7 was up 4.5 cents or 6.3 percent to 75.5 cents.

## CARDIEX

Cardiex says it has withdrawn its registration with the US Securities and Exchange Commission and Nasdaq initial public offering, with director Jarrod White resigning. In July, Cardiex said it had filed a registration statement with the US SEC for an initial public offer on the Nasdaq; and in August, said it would offer 1,333,333 American depositary shares (ADSs), representing 100,000,000 Australian shares to list on the Nasdaq under the code CDEX (BD: Jul 26, Aug 31, 2023).

Today, the company said the Los Angeles-based Roth Capital Partners LLC, its lead book-running manager for the offer, was unable to execute the underwriting agreement required to make its registration statement with the US SEC, meaning no securities could be sold, nor offers to buy be accepted.

Cardiex said although it received “institutional investor interest” it was “not at a level to justify a dual listing in both Australia and the US”, with the associated costs being “far in excess of the benefits” to it and its shareholders.

The company said the withdrawal followed a “period of significantly decreased activity in the US [initial public offering] market which could not have been foreseen when the company commenced the process”.

Cardiex said it had invested time, resources and investment capital into the registration during the last 18-months and had received and cleared “all comments from the SEC and Nasdaq for a successful SEC registration and Nasdaq IPO”.

The company said it was reviewing and implementing alternative capital raising initiatives to fund sales, operational plans, the launch of its Pulse technology and its US FDA submission for its Conneqt band.

Cardiex said Jarrod White had resigned as an executive director, including as potential interim or outsourced chief financial officer.

Cardiex said Mr White had worked with the company since 2018, thanked him for his support and wished him well for future endeavours.

The company said following its withdrawal for quotation on the Nasdaq, it had requested a voluntary suspension from the ASX “pending the release of an announcement regarding its capital raising and annual report”.

Cardiex said due to the late notice of its withdrawal for quotation on the Nasdaq and the impact of that to “various disclosures and assumptions in the annual report”, the finalization and lodgment of the annual report was likely to be contingent on the release of the above announcements.

Trading is expected to resume October 3, 2023, or on an earlier announcement.

Cardiex last traded at 13.5 cents.

## ALLEGRA ORTHOPAEDICS

Allegra says it expects to respond to the US Food and Drug Administration (FDA) in two to three months regarding additional information for its spinal cage submission.

In August, Allegra said the US FDA has requested “more information” regarding its Sr–Ht–Gahnite spinal cage application for bone healing (BD: Aug 17, 2023).

The company previously said Sr–Ht–gahnite was composed of strontium, hardystonite (a calcium-zinc-silicate) and gahnite, a zinc-aluminium-oxide (BD: Jun 8, 2016).

Today, Allegra said it expected to receive feedback from the FDA following its informal response to the request for additional information and would “incorporate any relevant documents into the final submission which is due February 4, 2024”.

Allegra was untraded at 6.1 cents.

## COGSTATE

Cogstate says that Japan partner Eisai has announced a dementia care support insurance package including the co-developed Nouknow technology.

Cogstate said that earlier this week Eisai announced that its amyloid-beta monoclonal antibody Leqembi intravenous infusion had been approved in Japan for slowing progression of mild cognitive impairment and mild dementia due to Alzheimer's disease. The company said that yesterday, Eisai announced it had co-developed with Tokio Marine & Nichido Fire Insurance Co the 'Dementia Care Support Insurance' to financially support early detection and early treatment for dementia.

Cogstate said that since August 2019, Eisai and Tokio Marine had promoted initiatives to for a dementia inclusive society, including the provision since April 2021 of Nouknow for self-assessment of cognitive function.

The company said the insurance would provide patients with a lump sum payment of diagnosed with either mild cognitive impairment or Alzheimer's disease and the policy provided the opportunity for holders "to use Nowknow as an ancillary service, ensuring the support of early detection and early treatment by identifying cognitive decline"

Cogstate chief executive officer Brad O'Connor told Biotech Daily that his company had a 50-50 revenue and profit share agreement with Esai Co Ltd dating back to 2019 and in 2020 launched Nouknow for brain health (BD Aug 28, 2019; Mar 23, 2020).

"At this stage we don't have sufficient information to say whether the insurance program will lead to revenues being material or not," Mr O'Connor said.

"But they are unlikely to be material in the short term," Mr O'Connor said.

Cogstate fell seven cents or 4.4 percent to \$1.525.

## ANTISENSE THERAPEUTICS

Antisense says it has filed a patent application for ATL1102 for long Covid-19 following published data suggesting it might be a diagnostic and therapeutic for the disease.

Antisense told Biotech Daily that, if granted, the patent titled 'Biomarkers and uses thereof in diagnosis and treating neurological post acute sequelae of COVID 19 (NPASC)' would protect its intellectual property until 2043.

The company said the published research suggested ATL1102 might be able to modulate aberrant immune cytokine responses for patients with long Covid-19.

In 2022, Antisense said a potential therapeutic biomarker of long Covid-19 was 'significantly modulated' by ATL1102 (BD: Aug 19, 2022).

Today, the company said that two articles from Chicago's Northwestern Medicine Neuro-Covid Clinic's Dr Igor Koralnik had been published.

The first article, titled 'Neuro-Pasc is characterized by enhanced CD4+ and diminished CD8+ T cell responses to SARS-CoV-2 Nucleocapsid protein', is available at:

<https://www.frontiersin.org/articles/10.3389/fimmu.2023.1155770/full>.

The second article, titled 'Plasma proteomics show altered inflammatory and mitochondrial proteins in patients with neurologic symptoms of post-acute sequelae of SARS-CoV-2 infection', was published in Brain Behavior and Immunity and is available at:

<https://www.sciencedirect.com/science/article/pii/S0889159123002532#s0100>.

Antisense chief executive officer Dr Garner said "these satisfying milestones conclude our work in this disease area for the time being".

"However, the positive data, and the proprietary intellectual property that has been created, create some intriguing opportunities that we or a partner may return to at a future date," Dr Garner said.

Antisense fell 0.3 cents or 4.2 percent to 6.9 cents.

## IMUGENE

Imugene says the US Food and Drug Administration has transferred Precision's investigational new drug application for the allogeneic 'azer-cell' CD19 Car-T therapy. In August, Imugene said it would pay Precision Biosciences up to \$US227 million (\$A352 million) for its off-the-shelf "azer-cell", or azercabtagene zapreleucel, CD19 Car T-cell therapy for blood cancers (BD: Aug 16, 2023).

Today, Imugene chief executive officer Leslie Chong said "we are actively progressing the ongoing multi-centre phase Ib study using the recommended phase II regimen of azer-cel as we prepare for the start of a potential phase II registrational study at the earliest opportunity".

Imugene fell 0.4 cents or eight percent to 4.6 cents with 57.6 million shares traded.

## NOXOPHARM

Noxopharm says dual-cell drug candidate CRO-67 reduces pancreatic cancer tumor volume by 56.7 percent ( $p = 0.0013$ ) and slowed growth rate by 48 percent, in mice. Noxopharm said its study with the University of New South Wales used human pancreatic cancer cells implanted in mice, which were then treated with CRO-67 for 21 days.

The company said the results were presented at the American Association of Cancer Research conference on pancreatic cancer and showed CRO-67 was "bioavailable and biologically active" in mice and supported its confidence in the treatment as a high priority. Noxopharm chief executive officer Dr Gisela Mautner said the results were "encouraging because they demonstrate that CRO-67 is having a strong effect in different settings such as human cell lines and mice, as well as in patient explants".

Last year, Noxopharm said six pancreatic cancer tumor cell samples exposed to its CRO-67 decreased by 85 percent and barrier cells by 87 percent, in-vitro (BD: Sep 14, 2022).

"While we are also planning a further study to demonstrate efficacy in a different model, we are already moving ahead and developing the dosing and formulation for patients," Dr Mautner said.

Noxopharm was up 0.4 cents or 10.5 percent to 4.2 cents.

## GENETIC TECHNOLOGIES

Genetic Technologies says it will begin a 50-patient study for its Genetype multi-risk test through its Precision Medicine Clinic at the Gold Coast Private Hospital.

Genetic Technologies said the pilot study would use its Genetype test with pharmacogenomics tests to provide "comprehensive wellness" profiles for Gold Coast Private Hospital patients, with patient enrolment to begin immediately.

The company said the Gold Coast Private Hospital was a 336-bed, 22-theatre hospital and part of the Healthscope network, and that a positive outcome could help it rollout additional 'Precision Medicine Clinics' throughout the network of hospitals.

Genetic Technologies chief executive officer Simon Morriss said the company was "seeing a seismic shift in healthcare today, with acknowledgement of the important contribution that risk assessments tests such as Genetype and [pharmacogenomics] can make to 'precision medicine'".

"Being able to identify those people at higher risk of certain diseases and those who are more likely to respond to appropriate treatments is a major step forward in improving patient health outcomes," Mr Morriss said.

Genetic Technologies was unchanged at 0.2 cents with 9.7 million shares traded.



### ALGORAE PHARMACEUTICALS (FORMERLY LIVING CELL TECHNOLOGIES)

Algorae says its annual general meeting will vote to elect director Bradley Roland Latham and issue him 20,000,000 performance shares.

In July, the then Living Cell said it had appointed Mr Latham as a non-executive director (BD: Jul 3, 2023).

Today, the company said the 20,000,000 performance shares would vest in four equal tranches of 5,000,000 shares each, based on performance milestones.

Algorae said the hurdles included: collaboration with two or more companies on its prospective research and development projects; the filing of two or more patents; achieving a \$50 million market capitalization; and if it receives ethics approval to start two clinical trials.

The company said shareholders would vote to adopt the remuneration report and approve the 10 percent placement facility.

Earlier this month, Living Cell said it had formally changed its name to Algorae Pharmaceuticals with its ASX code to be changed to 1AI from September 11, 2023 (BD: Sep 8, 2023).

The meeting will be held at Level 23, Rialto South Tower, 525 Collins Street, Melbourne, on November 2, 2023 at 12pm (AEDT).

Algorae was up 0.2 cents or 15.4 percent to 1.5 cents with 1.2 million shares traded.

### 4D MEDICAL

4D Medical says its annual general meeting shareholders will vote to issue 1,306,100 options to managing director Dr Andreas Fouras.

4D Medical said the options were related to Dr Fouras' long-term incentive plan and would be exercisable at \$1.60 each, a 100 percent premium to the 30-day volume weighted average price and expiring four years after being granted.

The company said shareholders would vote to adopt the remuneration report, elect directors Dr Geraldine McGinty, Bruce Rathie and Lilian Bianchi, and approve amendments to its constitution to permit holding wholly virtual meetings.

The meeting will be held at The Woodward Conference Centre, Level 10, Melbourne Law School, The University of Melbourne, 186 Pelham Street, Carlton, on November 2, 2023 at 10am (AEDT).

4D Medical fell two cents or four percent to 48 cents.

### AUSTCO HEALTHCARE

Austco says its annual general meeting will vote to approve the issue of 677,486 performance rights to chief executive officer and director Clayton Astles.

Austco said the performance rights, in addition to Mr Astles \$914,993 annual salary, were exercisable at 1.5 cents each by September 30, 2026, and related to the period of July 1, 2023 to June 30, 2026, with a total value of \$118,560.

The company said 60 percent of the rights would vest on November 2, 2023 if the company's earnings per share increased by more than 12 percent and the other 40 percent if the company's total shareholder return index moved by more than 10 percent.

Austco said shareholders would vote to adopt the remuneration report, re-elect director Anthony Glenning and approve its additional 10 percent placement capacity.

Austco said the meeting would be held online on November 1, 2023 at 10am (AEDT) at: <https://meetnow.global/MVH2WFK>.

Austco was unchanged at 19 cents.

### SOMNOMED

Sydney's TDM Growth Partners says it has increased its substantial holding in Somonmed from 28,151,777 shares (28.41%) to 32,572,382 shares (30.00%).

TDM said it held the shares for Thomas and Rebecca Cowan, Madleowill Pty Ltd and Hamish Corlett and Zoolander Investments Pty Ltd and Benjamin Gisz.

TDM said it acquired 4,420,605 shares in the recent rights offer at 60 cents a share.

Earlier this week, Somnomed said that its fully-underwritten retail entitlement offer raised \$5.7 million, taking the total raised with the institutional offer and placement to \$15.45 million (BD: Sep 26, 2023).

Somnomed was up 3.5 cents or 5.2 percent to 70.5 cents.

### INVEX THERAPEUTICS

Jason Peterson says he has increased his substantial holding in Invex from 3,995,076 shares (5.3159%) to 4,792,883 shares (6.3774%).

The Perth-based Peterson said he bought the shares on behalf of Sunset Capital Management, Cityscape Asset Pty Ltd and Celtic Capital on-market with the single largest purchase 710,599 shares for \$142,120 or 20 cents a share on undisclosed dates.

Invex was unchanged at 19.5 cents.

### CICADA INNOVATIONS

Cicada says it has appointed Dr Katherine Woodthorpe as its chair, replacing Andrew Rothery.

Cicada said Dr Woodthorpe had more than 30 years' experience commercializing technologies, including healthcare, environmental, climate science and renewable energy. The company said Dr Woodthorpe had been a director of Sirtex, as well as advising on the development of the South Eveleigh Precinct, formerly the Australian Technology Park. Cicada chief executive officer Sally-Ann Williams said "having a female trailblazer join Cicada's board ... is a strong signal to everyone that there is a critical role for women to play in leadership in this crucial sector".

The company said it had "a 23-year track record of developing deep [technology] ventures" and its incubators, commercialization training and community brought together entrepreneurs, scientists, business leaders and policymakers.

### LUMOS DIAGNOSTICS

Lumos says non-executive chair Sam Lanyon will advise it on investor relations, capital raising and commercialization through a \$80,000-a-year consultancy deal.

Lumos said the appointment was due to its managing-director Doug Ward being located in the US and had recognized the importance to have an Australia-based advisor "to assist with its capital market activities and to interface with the market in a timely manner".

According to its annual report, Mr Lanyon received a \$US99,966 (\$A156,824) annual salary for his role as chair.

Lumos said the deal was additional to Mr Lanyon's salary, effective from July 1, 2023.

Lumos fell half a cent or 4.8 percent to 10 cents with 4.1 million shares traded.