



Biotech Daily

Wednesday April 19, 2023

Daily news on ASX-listed biotechnology companies

- * **ASX FLAT, BIOTECH UP: KAZIA UP 18%; CYCLOPHARM DOWN 8%**
- * **CONTROL BIONICS: 'WORLD'S 1st AUTONOMOUS DRIVING WHEELCHAIR'**
- * **IMAGION RIGHTS RAISE \$413k OF HOPED FOR \$2.4m; \$1.97m SHORTFALL**
- * **AMPLIA STARTS AMP945 PANCREATIC CANCER COHORT 3**
- * **ANTERIS, V2V MEDTECH WORK ON LEAKY HEART VALVE REPAIR**
- * **HYDRIX: 'GYDER TGA OKAY TRIGGERS \$330k MILESTONE'**
- * **PCI UPGRADES MELBOURNE FILL-FINISH OFFICE**
- * **GENETIC TECHNOLOGIES GENETYPE PROSTATE CANCER DATA**
- * **NUHEARA: CVS DISTRIBUTES HP HEARING PRO IN THE US**
- * **INSIGNIA TAKES 8.6% OF BOTANIX**
- * **RHYTHM LOSES CEO GLENN GILBERT; CHAIR OTTO BUTTULA MORE EXEC**

MARKET REPORT

The Australian stock market edged up 0.07 percent on Wednesday April 19, 2023, with the ASX200 up 5.3 points to 7,365.5 points. Twenty-one of the Biotech Daily Top 40 stocks were up, 15 fell, three traded unchanged and one was untraded.

Kazia was the best, up 3.5 cents or 17.95 percent to 23 cents, with 701,634 shares traded. Paradigm climbed 11.2 percent; Cynata and Prescient rose more than 10 percent; Impedimed improved 9.1 percent; Amplia, Atomo, Oncosil, Telix and Universal Biosensors were up five percent or more; Opthea and Volpara were up four percent or more; Patrys was up 3.3 percent; Emvision and Starpharma rose more than two percent; Clinuvel, Next Science, Nova Eye and Pharmaxis were up more than one percent; with Cochlear, Genetic Signatures and Mesoblast up by less than one percent.

Cyclopharm led the falls, down 17 cents or 7.8 percent to \$2.02, with 13,578 shares traded. Antisense lost 7.0 percent; Actinogen and Resonance fell four percent or more; Compumedics and Orthocell were down more than three percent; Avita, Dimerix, Immutep and Proteomics shed two percent or more; Medical Developments, Micro-X, Polynovo and Resmed were down more than one percent; with CSL, Nanosonics and Neuren down by less than one percent.

CONTROL BIONICS

Control Bionics says it has formally launched “the world’s first autonomous driving wheelchair module” using its Neuronode thought-to-computer technology.

Control Bionics said that its Drove module could be retro-fitted to powered wheelchairs, allowing users “to move their chair autonomously and precisely without a joystick, to specific locations within the home - a world first”.

The company said that it developed the Drove module with Deakin University’s Applied Artificial Intelligence Institute, using a digital camera system with Control Bionics’ tracking software and Neuronode technology to allow users to control an interface using only neural, or thought, signals.

Control Bionics said that using electro-myography (EMG) it could capture and process bio-electric signals into electronic commands “to allow users to do everything they would normally do with a keyboard, mouse, joystick or touchscreen”.

The company said the launch of the wheelchair module was held at Melbourne’s Deakin University Burwood campus.

Control Bionics said that Deakin University’s Applied Artificial Intelligence Institute co-director Prof Kon Mouzakis and the Federal House of Representatives Member for Kooyong Dr Monique Ryan launched the wheelchair module, with Control Bionics chief executive officer Jeremy Steele and Control Bionics product executive Lester Lo, as well as Drove case study Brodie Shaw and her parents Jeremy and Donna Shaw.

The company said that the Drove module was the latest application of its Neuronode technology which enabled people living with severe disabilities to communicate despite being “locked in”.

Mr Steele said the technology made “a huge difference” to those who tested it during development, allowing them to do simple things able bodied people often took for granted.

“Our Neuronode technology allows people who are completely locked in to communicate and now Drove will enable them to safely move around their home,” Mr Steele said.

“It’s a level of independence they’d never considered possible,” Mr Steele said.

“Being able to move so the sun isn’t in your eyes or leave a room on your terms are things most of us don’t think twice about, but [when] you have to rely on someone else for them, having a device that gives this control is amazing,” Mr Steele said.

Control Bionics said that the Drove system would be available under the Australian Government National Disability Insurance Scheme.

Mr Steele said the hope was that Drove would give independence to users and take some basic tasks from carers.

“Giving independence, security and control to those living with restricted movement from diseases such as sclerosis, cerebral palsy and motor neurone disease (MND) as well as spinal cord injuries, was the driving reason behind Control Bionics’ inception and Drove goes a long way toward that,” Mr Steele said.

Deakin University research project lead Dr Srikanth Thudumu said the challenge was to overcome the limitations of traditional joystick-controlled models of electric wheelchairs, offering a more user-friendly and autonomous navigation experience.

“We developed a state-of-the-art digital twin with a user interface that displays a virtual representation of a user’s home,” Dr Thudumu said.

“This interface has enabled users to select a destination, while our advanced control system ensures safe navigation within the home environment,” Dr Thudumu said.

“Additionally, we have incorporated an override mechanism that allows users to regain manual control at any time,” Dr Thudumu said.

A demonstration video is at: <https://www.youtube.com/watch?v=lxuKXM9VI-Q>.

Control Bionics was untraded at 14 cents.

IMAGION BIOSYSTEMS

Imagion says its rights issue at 1.7 cents a share raised \$412,903 of a hoped-for \$2.4 million, leaving a \$1,970,000 shortfall to be placed by July 14, 2023.

Last month, Imagion said it would undertake a one-for-eight, non-underwritten, non-renounceable entitlement offer to raise up-to \$2.4 million at 1.7 cents a share, a 22.7 percent discount to the price on March 6, with funds to be used for its Magsense HER2 breast cancer imaging agent (BD: Mar 7, 2023).

Today, Imagion said the shortfall would be placed at the board's discretion at a price equal to or more than the original offer's issue price.

Imagion fell 0.1 cents or 5.9 percent to 1.6 cents with 11.3 million shares traded.

AMPLIA THERAPEUTICS

Amplia says it has recruited the first of three patients in cohort 3 of its oral dose ranging phase Ib/IIa trial of AMP945 for pancreatic cancer.

Last year, Amplia said it had dosed the first of 12 patients in the open-label, 'Accent' trial studying the pharmaco-kinetics, safety and efficacy of AMP945 for advanced pancreatic cancer (BD: Nov 29, 2022).

Today, the company said cohort 3 would receive an increased oral dose of AMP945 after safety committee assessed the dose used in cohort 2 was safe and well-tolerated.

Amplia said AMP945 was dosed orally as a capsule before and between standard-of-care weekly doses of gemcitabine and nab-paclitaxel chemotherapy.

Amplia managing director Dr Chris Burns said that making progress in the trial was the "next step in identifying a safe and effective dose to take forward to the phase II stage of the trial".

Amplia was up half a cent or 5.9 percent to nine cents.

ANTERIS TECHNOLOGIES

Anteris says it will work with the Delaware-based V2V Medtech to develop a heart valve repair device for treating mitral and tricuspid valve regurgitation, or leaky valves.

Anteris said devices had been developed by physicians at New York Presbyterian, also known as Columbia University Hospital, and used a transcatheter edge-to-edge repair method for mitral and tricuspid valve regurgitation.

The company said the terms of the agreement included acquiring 30 percent of V2V Medtech, up-to \$US8 million in cash and in-kind contributions provided over five stages of device development milestones, with contributions expected to range from \$US700,000 to \$US1.6 million in stage one.

Anteris said following the agreement the V2V Medtech board would have three members with two appointed by Anteris.

The company said that break-fees ranged from \$US200,000 at the end of stage one in increments up to \$US1 million at the end of stage five.

Anteris said it had an option to buy the shares of all the initial shareholders if V2V Medtech achieved "first-in-human" with the device, exercisable at the higher of fair market value and \$US150 million.

Anteris chief executive officer Wayne Paterson said the agreement was a "strategic partnership" that broadened the company's portfolio and allowed it to enter "additional market segments where [it] can expect significant long-term growth".

Anteris was up fell six cents or 0.25 percent to \$23.76.

HYDRIX

Hydrix says it will invest a further \$330,000 in Gyder Surgical after its Hip Navigation System was approved for sale by the Australian Therapeutic Goods Administration. Hydrix said it had an equity-in-kind milestone agreement with client and investee company Gyder Surgical, a hip replacement device development company based in Mulgrave, Victoria and the increased investment took the total amount invested to \$1.76 million. Gyder chief executive officer Sujit Dike said the Hip Navigation System was “a non-invasive, pin-less, and image-less smart navigation system for total hip replacement using the anterior approach”.

Mr Dike said the TGA approval was “a major milestone” and believed there was “a strong appetite for intuitive, efficient, easy-to-use, and cost-effective enabling technologies that improve surgical accuracy during hip arthroplasty”.

Hydrix executive chair Gavin Coote said it was “very rewarding to have developed this world first product and technology innovation for Gyder Surgical and to have successfully managed the TGA regulatory application process”.

Hydrix was up half a cent or 13.9 percent to 4.1 cents.

PCI PHARMA SERVICES

Contract development manufacturing organization PCI Pharma Services says it has opened three automated, sterile, fill-finish machines at its Melbourne facility.

The San Diego, US-based PCI said the machinery was from Cytiva, formerly known as General Electric Life Sciences, and could be used to fill various sterile medications into vials and syringes for small-to-mid scale client needs.

The company said the services would help Australian biotechnology and pharmaceutical companies to accelerate their drugs’ proof-of-concept studies and expedite the early-stage drug development process.

PCI chief commercial officer Tim Robert said, “with Melbourne being an especially popular place to conduct phase I trials we knew we needed to bring this capability and added capacity to the local market”.

GENETIC TECHNOLOGIES

Genetic Technologies says its Genetype prostate cancer risk assessment test identifies 23 percent more men at risk of prostate cancer than family history alone.

Genetic Technologies said that the study, titled ‘Development and validation of a simple prostate cancer risk prediction model based on age, family history and polygenic risk’ was co-authored by its staff and published in the journal The Prostate.

The full article is available at: <https://onlinelibrary.wiley.com/doi/10.1002/pros.24537>.

The research paper said the Genetype test assessed a UK Biobank population-based cohort of 198,334 unaffected Caucasian men aged 40-to-69 and predicted five-year risk of prostate cancer.

The paper said that of eligible participants, 8,996 (4.5%) were diagnosed with incident prostate cancer in a follow-up, and that the best-fitting testing model included a polygenic risk score, family history, a 10-year age group and interactions between these factors.

The study concluded “men at increased risk of prostate cancer could benefit from informed discussions around the risks and benefits of available options for screening for prostate cancer”.

Genetic Technologies was up 0.05 cents or 14.3 percent to 0.4 cents with 9.7 million shares traded.

[NUHEARA](#)

Nuheara says its Hewitt Packard Hearing Pro self-fitting, over-the-counter hearing aid will be available through CVS Health's online distribution network in the US.

Nuheara managing director Justin Miller said CVS Health Corp distributing its hearing aids would "benefit the over 40 million Americans who experience mild-moderate hearing loss". Nuheara was unchanged at 16 cents.

[BOTANIX PHARMACEUTICALS](#)

Insignia Financial Ltd says it has increased its substantial shareholding in Botanix from 70,717,484 shares (6.117%) to 112,295,811 shares (8.601%).

The Sydney-based Insignia said that between November 11, 2022 and February 14, 2023 it bought and sold shares in 12 separate transactions, with the largest purchase on February 13, 2023 of 64,388,960 shares for \$4,120,893, or 6.4 cents a share.

Insignia said that on April 13, 2023 it bought 32,444,444 shares for \$2,920,000 or 9.0 cents a share.

Earlier this month, Botanix said it had "firm commitments" for a placement to raise \$10.0 million at nine cents a share, for the commercial launch of its sofpironium bromide for excessive sweating (BD: Apr 3, 2023).

Botanix was up 0.1 cents or 1.1 percent to 9.3 cents with 4.65 million shares traded.

[RHYTHM BIOSCIENCES](#)

Rhythm says its chief executive officer and managing-director Glenn Gilbert has resigned, effective from April 21, 2023.

Rhythm said executive chair Otto Buttula would "assume additional executive duties, spending more time in the company's Melbourne offices, alongside [its] expanded executive team".

The company said it was grateful to Mr Gilbert for his contribution since his appointment as chief executive officer in 2018 and wished him well for the future.

Rhythm fell eight cents or 14.3 percent to 48 cents.