Biotech Daily

Monday May 22, 2023

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: UNIVERSAL BIO UP 15%; PATRYS DOWN 17%**

*** EBR 'STATISTICALLY SIGNIFICANT' WISE PIVOTAL HEART TRIAL DATA**

*** AND HEALTH $1.4m LAUNCH VIC FOR ACTIVATE PROGRAM**

*** ANTERIS 'PROMISING DURAVR RESULTS, NO MORTALITY'**

*** AMPLIA, CSIRO $94k FOR TOPICAL FAK INHIBITOR RESEARCH**

*** ZELIRA RECEIVES $4.9m FOR HOPE MARIJUANA AUTISM TRIAL FUND**

*** AUSTCO $3.9m MAPLE VIEW TACERA NURSE CALL SYSTEM**

*** ONCOSIL TREATS 1st PANCREATIC CANCER PATIENT IN ITALY**

*** BIOXYNE COMPLETES BREATHE ACQUISITION**

*** AVECHO LICENCES TPM FOR CANCER TO ARTHUR GROUP**

*** PHARMAUST READY FOR 3rd MND MONEPANTEL DOSE**

*** PHARMAXIS REQUESTS 'SCARRING TRIAL RESULTS' TRADING HALT**

*** MERCHANT TAKES 11.4% OF AROVELLA**

*** VITURA DIRECTOR GUY HEADLEY SELLS 18.75m SHARES TO 19.8%**

MARKET REPORT

The Australian stock market fell 0.22 percent on Monday May 22, 2023, with the ASX200 down 16.2 points to 7,263.3 points. Fourteen of the Biotech Daily Top 40 stocks were up, 18 fell, seven traded unchanged and one was untraded.

Universal Biosensors was the best on its annual general meeting, up 3.5 cents or 15.2 percent to 26.5 cents, with 121,449 shares traded. Amplia climbed 10.6 percent; Nova Eye was up 6.8 percent; Impedimed improved 3.7 percent; Nanosonics, Neuren and Uscom rose more than two percent; Genetic Signatures and Micro-X were up more than one percent; with Clinuvel, CSL, Next Science, Paradigm, Proteomics, Resmed and Telix up by less than one percent.

Patrys led the falls, down 0.2 cents or 16.7 percent to one cent, with 12.7 million shares traded. Actinogen lost 8.3 percent; Kazia, Oncosil and Prescient fell more than seven percent; Alcidion shed 5.7 percent; Immutep and Volpara fell four percent or more; Antisense and Starpharma were down more than three percent; Cyclopharm, Emvision and Medical Developments shed more than two percent; Cochlear, Dimerix and Opthea were down more than one percent; with Avita, Mesoblast and Pro Medicus down by less than one percent.

EBR SYSTEMS INC

EBR says that its 183-patient Wise device pivotal trial met both the primary efficacy and safety endpoints with statistically significant improvement against pre-set benchmarks.
EBR said the 'Solve-CRT' (cardiac re-synchronization therapy) trial's efficacy endpoint for the wireless stimulation endocardially, or Wise device, was the improvement in heart function measured by reduction in left ventricular end systolic volume (LVESV) and showed a reduction of 16.4 percent using its Wise system compared to a performance goal of a reduction of 9.3 percent ($p = 0.003$).
The company said safety, measured by freedom from a device, or procedure-related complications, was 80.9 percent compared to a goal of 70 percent ($p < 0.001$).
EBR said it planned to file a pre-market approval submission to the US Food and Drug Administration by April 2024.
In a webinar, EBR chief executive officer John McCutcheon said the trial data was "the most successful milestone in the company's history".
He said that the trial population was that group of heart patients who had already failed cardiac re-synchronization therapy (CRT).
"Wise is complementary. There is no competition," Mr McCutcheon said.
"We are in a free space. These are patients that don't have any other options," Mr McCutcheon said.
Mr McCutcheon said the binary risk was the study data and "we have crossed that binary risk", there was nothing controversial in the data and with breakthrough device status, he expected an FDA response on Wise in six to nine-months from filing the final module.
The webinar slides said that all the data analyzed to date had shown "consistent, positive results in reversing heart failure symptoms and physiology".
Mr McCutcheon said that with heart failure patients the QRS section of their electro-cardio-gram widened showed a slowing of the electrical signal, and the trial showed a 39 milli-second shortening of that time, which was an improvement.
Mr McCutcheon said that following the positive trial results the company would be able to draw a further $US20 million ($A30.1 million) from Runway Growth Finance, next month
Last year, EBR said the loan, financed by Chicago's Runway Growth Finance Corp, had a term of five years, and a floating rate with a floor of 4.9 percent (BD: Jul 1, 2022).
"We drew $US20 million at that time and the $US20 million second tranche was contingent upon meeting the primary endpoints," Mr McCutcheon said.
"The last $US10 million is contingent on FDA approval, but expires June 2024," Mr McCutcheon said. "We may not be able to draw that final tranche," he said.
EBR was up 9.5 cents or 10.5 percent to $1.00 with 2.65 million shares traded.

AND HEALTH (AUSTRALIAN NATIONAL DIGITAL HEALTH INITIATIVE)

AND Health says it has received $1.4 million from the State Government's Launch Vic start-up agency for a 45-company digital and connected health accelerator program.
The organization said the six-month Activate program and would run in three cohorts of 15 companies over three years to provide support for scaling business, commercialization, raising capital and securing customers.
AND Health managing director Bronwyn Le Grice said Activate provided a "six-month program which provided hands-on support and mentorship, pre-vetted and curated industry experts and access to global industry leaders, focused on supporting companies to become investment and enterprise customer-ready".
AND Health said the first cohort of 15 companies had been selected through a competitive screening process.

ANTERIS TECHNOLOGIES

Anteris says its 13-patient first-in-human study of its Duravr transcatheter heart valve showed promising performance at one year with “no mortality”.

Anteris said the study showed “promising haemodynamic performance sustained to one year and restoration of near normal blood flow dynamics”.

The company said that the study reported no implant failures or device-related complications.

Anteris said that there were “no deaths, stroke, bleeding, reinterventions or myocardial infarction” but said there was one access site complication, one permanent pacemaker implantation and one case of moderate aortic regurgitation.

The company said the research, titled ‘Early safety and feasibility of a first-in-class biomimetic transcatheter aortic valve (Duravr)’ was published in the journal Eurointervention with an abstract available at: https://links.anteristech.com/3Os1pz7.

Anteris said the publication reported interim results from the Duravr in-human study designed to evaluate the safety and efficacy of the biomimetic valve as a treatment for symptomatic severe aortic stenosis.

The company said data for an additional seven recently enrolled patients was presented by Dr Susheel Kodali at the European Association of Percutaneous Cardiovascular Interventions annual meeting in Paris.

The Columbia University Irving Medical Centre, New York-based Dr Kodali said the short-term results showed “the haemodynamics are amazing and that’s one of the things I’m excited about”.

Dr Kodali said that when looking at a three-dimensional echocardiogram “the leaflets really open to the frame edge, and that’s different than what we see with other valves”.

Anteris was up 31 cents or 1.35 percent to $23.31.

AMPLIA THERAPEUTICS
COMMONWEALTH SCIENTIFIC AND INDUSTRIAL RESEARCH ORGANISATION

Amplia says it a $47,000 Federal Government matched grant to develop topical formulations of focal adhesion kinase inhibitor with the CSIRO.

Amplia said it would work with the Commonwealth Scientific and Industrial Research Organisation to develop formulations of its small molecule focal adhesion kinase (FAK) inhibitor that could be applied topically, or directly, to wounds to aid healing and reduce scarring.

The company said the Innovation Connections program was an up to $50,000 grant matched by the company managed by the CSIRO under the Federal Government’s Entrepreneur’s Programme that provided advice and funds to businesses to engage with researchers with specific capabilities.

Amplia chief executive officer and managing director Dr Chris Burns said there was “growing evidence in the scientific literature that inhibition of focal adhesion kinase in the skin may accelerate wound healing and limit scar formation”.

“We are looking forward to working with CSIRO to develop a formulation of our [focal adhesion kinase] inhibitors so we can determine their suitability for use in wound healing,” Dr Burns said.

“It is highly encouraging to secure this funding and have an opportunity to work with the world-class research team at CSIRO to explore the potential of our [focal adhesion kinase] inhibitors in topical applications,” Dr Burns said.

Amplia was up 0.9 cents or 10.6 percent to 9.4 cents.

ZELIRA THERAPEUTICS

Zelira says it has received $US3.25 million ($A4.88 million) from the Forman Family Foundation to fund clinical trials for its Hope marijuana product for autism.

Earlier this year, Zelira said the Dallas, Texas-based Cantheon Capital LLC would provide $US8.6 million ($A12.4 million) for phase II and III trials of Hope under a special purpose vehicle (SPV), or joint venture subsidiary (BD: Feb 15, 2023).

At that time, the company said "cash investors" would contribute $36 million to fund the special purpose vehicle in exchange for a cumulative 45 percent equity interest, with Cantheon's initial interest to be a maximum of 12.93 percent.

Today, Zelira said the Philadelphia, Pennsylvania-based Forman Family Foundation founded by Michael Forman and Jennifer Rice would contribute $US3 million and Philadelphia-based chief executive officer of PRWT Services Companies Malik Majeed would invest $US250,000.

Zelira said this contribution brought the total funds secured to $US11.85 million which was about 34 percent of the total $35 million to be raised for the special purpose vehicle.

The company said with this investment it expected to start Hope clinical trials once the definitive agreements from the transaction were completed and executed.

Zelira chair Osagie Imasogie said those involved had a "shared vision to complete formal clinical trials and gain [US Food and Drug Administration] regulatory approval to launch an approved Hope into a multi-billion-dollar market, paving the way for transformative healthcare solutions".

Zelira managing-director Dr Oludare Odumosu said the Forman Family Foundation and Mr Majeed's investment was a testament to their confidence in the company's "innovative launch, learn and develop strategy for validating cannabinoid medicines".

"Their strategic investment will further propel our efforts to revolutionise the field of cannabinoid medicines and bring much needed relief to patients worldwide," Dr Odumosu said.

Zelira was up four cents or 4.4 percent to 95 cents.

AUSTCO HEALTHCARE

Austco says it has a $3.9 million agreement to supply and install its Tacera nurse call system platform to the 192-bed Athens, Ontario-based Maple View aged-care facility.

Austco said that Maple View was wholly owned by the United Counties of Leeds and Grenville, Ontario, and was expected to open in late 2025 and the company expected revenue recognition by June 30, 2023.

The company said the contract was a "significant contract win" and included its Tacera system with built-in, real-time locating system functionality, pulse mobile and enterprise reporting.

Austco said the contract also included its low-voltage package which consisted of Wanderguard resident wandering system, access control, audio-visual systems and closed-circuit television monitoring.

Austco chief executive officer Clayton Astles said the company was "excited to partner with the staff and leaders of Maple View to deliver the industry's leading clinical care communications and staff workflow solutions".

"This partnership comes at a critical time, as the government of Ontario is committed to strengthening long-term care across the province, and Maple View will play a significant role in providing support and palliative care," Mr Astles said.

Austco was up 1.5 cents or 13.0 percent to 13 cents.

ONCOSIL MEDICAL

Oncosil says it has treated its first patient with its phosphorous-32 radiation device with chemotherapy for pancreatic cancer, at Rome's San Camillo-Forlanini Hospital.

The company said the treatment was expected to enhance the recognition of its device as "a treatment option in Italy as well as continuing to raise the profile across Europe".

Oncosil chief executive officer and managing director Nigel Lange said the treatment of its first patient in Italy was "a significant milestone" and that the company looked "forward to providing hope to patients in this country with a poor prognosis from cancer of the pancreas".

"Every year in Italy, more than 12,000 patients do not survive their cancer diagnosis and we are pleased to commence treatments to improve the recognition of the Oncosil device as an option for patients with pancreatic cancer," Mr Lange said.

Oncosil fell 0.1 cents or 7.1 percent to 1.3 cents with 16.5 million shares traded.

BIOXYNE

Bioxyne says it has completed the acquisition of Breathe Life Sciences and appointed chief executive officer Sam Watson and chief operating officer Jason Hine as directors.

Earlier this year, Bioxyne said it would buy 83 percent of the Gold Coast, Queensland-based Breathe Life Sciences, issue it 1,230,000,000 shares to its shareholders, 576,268,527 shares to Breathe International and up-to 37,732,857 shares to subsidiary Zonetech Wellness, providing Breathe International and Mr Watson a maximum voting power of 32.39 percent in Bioxyne, following the acquisition (BD: Mar 20, April 6, 2023).

In its most recent filing, Bioxyne said it had 665,645,398 shares on issue on the ASX.

Today, the company said its extraordinary general meeting voted in favor of the Breathe acquisition on May 5, 2023 and all conditions for the agreement had been met.

Bioxyne said it expected aggregated pro forma revenue for the year ending June 30, 2023 to be $7.3 million, with the company contributing $2.4 million and Breathe making up the remaining $4.9 million.

Bioxyne was unchanged at 2.5 cents.

AVECHO BIOTECHNOLOGY (FORMERLY PHOSPHAGENICS)

Avecho says it will licence its tocopheryl phosphate mixture (TPM) to Arthur Group LLC to develop a series of five TPM solubilized cancer drugs.

Avecho said it had shown TPM could dissolve poorly-water soluble injectable drugs in safer, clinical preferred dosage forms that would otherwise require adverse solvents that risked a range of adverse side effects.

The company said the Monmouth Junction, New Jersey-based Arthur Group focused on the research and development, manufacturing and marketing of pharmaceutical products and could develop tablets, capsules, injections, semi-solid and other dosage forms.

Avecho did not disclose the material terms, but said it would receive 30 percent of licencing revenue and 30 percent of the net profit from commercialization of the products.

Avecho chief executive officer Dr Paul Gavin said Arthur Group would start with "initial formulation screening of its licenced drugs to determine which [were] most compatible with TPM [with] the most receptive drugs to be prioritized first".

The company said Arthur Group would pay for all formulation and development, non-clinical testing, clinical trials and registration, and it expected the initial formulation step to take 12-to-18 months.

Avecho was up 0.1 cents or 20 percent to 0.6 cents with 37.8 million shares traded.

PHARMAUST

Pharmaust says the trial safety committee has no reported safety issues or serious adverse events in its phase I/II trial of monepantel for motor neuron disease.
Pharmaust said subject to pharmacokinetic data confirming absorption in cohort 2 as it did for cohort 1, all six cohort 1 patients would be elevated to cohort 3 and receive an increased dosage.
Pharmaust director Sam Wright told Biotech Daily that cohort 1 received 2mg/kg once daily with planned dose escalations to 4mg/kg, 6mg/kg and 10mg/kg but that actual dose escalations might differ based on safety monitoring committee reviews following 28 days of treatment at each dose level.
The company said it had collected and submitted blood samples from all 12 patients for an interim analysis of the trial.
Pharmaust fell 0.3 cents or 3.6 percent to eight cents with 2.1 million shares traded.

PHARMAXIS

Pharmaxis says it has requested a trading halt pending the analysis of “top-line results of an investigator-initiated phase Ic clinical trial in established scars”.
Trading will resume May 24, 2023, or on an earlier announcement.
Pharmaxis last traded at 5.5 cents.

AROVELLA THERAPEUTICS

Merchant Funds Management Pty Ltd says it has increased its substantial holding in Arovella from 77,604,246 shares (10.27%) to 86,210,282 shares (11.36%).
The Sydney-based Merchant Funds said that in April 2023 it bought 6,270,079 shares for $424,862, or 6.78 cents a share and sold 914,043 shares for $82,215, or 8.995 cents a share and in May, 2023 it bought 3,125,000 shares for $205,275, or an average of 6.32 cents a share.
Arovella fell 0.1 cents or 1.7 percent to 5.9 cents with 1.8 million shares traded.

VITURA HEALTH (FORMERLY CRONOS AUSTRALIA)

Vitura says director Guy Headley has sold 18,750,000 shares at 32 cents a share in a block trade share to two unnamed institutional investors.
In 2021, following the merger of Cannabis Doctors Australia with the then Cronos, Mr Headley said that he held 128,952,151 shares or 23.51 percent of the merged company (BD: Dec 16, 2021).
Biotech Daily calculates that Mr Headley continues to hold 110,202,151 shares or 19.8 percent of the company.
Vitura said Mr Headley had written to the company saying he had “no present intention to sell any further shares in the company in the near future and will consult with the company if that intention changes”.
Vitura was up 1.5 cents or 4.4 percent to 35.5 cents.