

Biotech Daily

Wednesday November 8, 2023

Daily news on ASX-listed biotechnology companies

- * ASX, BIOTECH UP: KAZIA UP 37.5%; UNIVERSAL BIOSENSORS DOWN 10%
- * MONASH, SYDNEY, WEHI \$15m MEDCHEM DRUG DISCOVERY PROGRAM
- * BOD 'COMMITMENTS' FOR \$2m, CUTS COSTS
- * ALTERITY ENROLS PHASE II ATH434 MSA TRIAL
- * HERAMED BEGINS HERACARE, HERABEAT TRIAL
- * VITURA IMPORTS MDMA FOR PATIENTS, TRIALS
- * NEXT SCIENCE TELLS ASX: 'AWARE IN LESS THAN 24 HOURS'
- * INOVIQ PRESENTS 2 EXONET DATA POSTERS
- * RECCE AGM 58% REMUNERATION REPORT 1st STRIKE
- * INCANNEX: 99% BACK MOVE FROM ASX TO NASDAQ
- * ACRUX RECEIVES \$2.9m FEDERAL R&D TAX INCENTIVE
- * PATRYS RECEIVES \$2.7m FEDERAL R&D TAX INCENTIVE
- * JASON PETERSON TAKES 10.3% OF INVEX
- * WILLIAM SOUTER REPLACES ACTINOGEN CFO JEFF CARTER
- * HERAMED M-D TO ADVISER; CFO TO BUSINESS DEVELOPMENT

MARKET REPORT

The Australian stock market was up 0.26 percent on Wednesday November 8, 2023, with the ASX200 up 18.3 points to 6,995.4 points. Twenty-six of the Biotech Daily Top 40 stocks were up, seven fell, five traded unchanged and two were untraded.

Kazia was the best, up three cents or 37.5 percent to 11 cents, with 1.2 million shares traded. Patrys climbed 25 percent; Imugene improved 22.7 percent; Next Science was up 20 percent; Actinogen was up 16.7 percent; Dimerix rose 9.7 percent; Impedimed was up 7.7 percent; Nova Eye climbed 5.9 percent; Genetic Signatures was up 4.4 percent; Clinuvel, Micro-X, Polynovo and Starpharma were up more than three percent; 4D Medical, Avita, Orthocell and Proteomics rose more than two percent; Alcidion, Amplia, Emvision, Mesoblast, Neuren, Pro Medicus and Telix were up more than one percent; with Cochlear, Nanosonics, Resmed and SDI up by less than one percent.

Universal Biosensors led the falls, down 2.5 cents or 10 percent to 22.5 cents, with 293,909 shares traded. Medical Developments and Opthea lost more than three percent; Cyclopharm and Volpara shed two percent or more; Antisense and Immutep were down more than one percent; with CSL down by 0.1 percent.

MONASH UNIVERSITY, THE UNIVERSITY OF SYDNEY THE WALTER AND ELIZA HALL INSTITUTE OF MEDICAL RESEARCH

Monash University says it has \$14.75 million in funding over five years for the Medchem Australia collaborative drug discovery initiative at its Parkville campus.

Monash University said the initiative, in collaboration with the Walter and Eliza Hall Institute and the University of Sydney, would "accelerate promising early-stage drug discovery projects towards clinical trials and, ultimately, create new medicines for a broad range of diseases".

The University said the project was established with \$9.75 million from the Federal Government's Medical Research Future Fund and more than \$5 million from Therapeutic Innovation Australia, itself, WEHI and the University of Sydney.

Monash University said the Federal Assistant Minister for Health and Aged Care Ged Kearney was at the Parkville campus today to meet the scientists involved in the initiative and to mark the launch.

Monash said Australia had "an enviable reputation in biomedical research, but a poor record in translating these discoveries into new homegrown medicines for patients who need them".

The University said the initiative would use the medicinal chemistry expertise of the three partners "to guide projects through the critical early stages of the drug discovery pipeline to translate 'hits' into drug candidates with enhanced commercial value".

Monash University said Medchem Australia would "plug a critical gap in Australia's drug discovery pipeline by ensuring promising projects addressing unmet medical needs are supported with additional resources and expertise to aid progression and enhance value". Monash University said the initiative would comprise have nodes of activity at the

Parkville-based Monash Institute of Pharmaceutical Sciences (MIPS), WEHI and the University of Sydney, with each maintaining facilities for drug design and synthesis. The University said Medchem Australia would fund "skilled medicinal chemists and project consumables for teams to progress projects that are selected on a competitive basis" and make its first call for project applications in early December.

Medchem Australia director Prof Brendon Monahan said the drug candidates would be "significantly more attractive to industry and ... catalyze investment to develop home grown, high value medicines, jobs and exports".

"Medchem Australia will provide promising Australian drug discovery projects with medicinal chemistry expertise and capability, at subsidized cost, to accelerate progression, enhance success, and maximize value and impact," Prof Monahan said. "Australia has innovative projects and world-class scientists working to develop new medicines to treat human disease, Prof Monahan said.

"However, at the moment a large proportion of these projects don't progress beyond the early stages because of resources or funding constraints," Prof Monahan said.

Medchem Australia offers a new path forward and, by building relationships and providing actual capability and expertise, will help drive projects to success, Prof Monahan said. WEHI's Prof Guillaume Lessene, Medchem Australia's chief investigator, said the initiative would accelerate drug discovery and development in Australia.

"This initiative will expedite drug discovery from compound to medicine significantly here in Australia, allowing researchers to take their ideas from the lab to the clinic quicker than ever before," Prof Lessene said.

"Medchem Australia will help advance the research discoveries made by our nation's talented scientists and will create a highly skilled workforce locally, allowing us to attract and retain the best talent," Prof Lessene said.

BOD AUSTRALIA

Bod says it has "firm commitments" to raise \$2.05 million in a placement at 3.0 cents a share, and will pay its directors shares, in lieu of cash, subject to shareholder approval. Bod said the placement price was a 49.5 percent discount to the 15-day volume weighted average price of 5.93 cents.

The company said the funds would increase its tetrahydrocannabinol (THC) flower inventory, support the manufacture of its Medicabilis marijuana soft gel capsules, as well as research and development of its Aqua Phase product and provide working capital. Bod said its Malaysia partner Antah Healthcare had committed \$1.1 million to the raise, and after the placement would hold 14.9 percent of the company.

Bod said it had undertaken a cost reduction program, including directors accepting shares in lieu of cash for their fees and chief executive officer Jo Patterson and chief technical officer Craig Weller reducing their yearly salaries to \$125,000 each.

The company said the cost reductions were due to a reported cash loss of \$1.9 million for the three months to September 30, 2023.

Bod fell 2.5 cents or 44.6 percent to 3.1 cents with 4.85 million shares traded.

ALTERITY THERAPEUTICS

Alterity says it has enrolled all 77 patients in its randomized, double-blind, placebocontrolled, phase II trial of ATH434 for early-stage multiple system atrophy (MSA). In 2021, Alterity said it had New Zealand approval for the trial; and earlier this year, said that the independent data monitoring committee had recommended the trial continued unchanged (BD: Dec 14, 2021, Jul 26, 2023).

Today, the company said the trial was conducted in the US, Europe, Australia and New Zealand in 77 adult multiple system atrophy patients randomly assigned to receive one of two dose levels of ATH434 or placebo.

Alterity said patients would receive treatment for 12 months, and that the trial would "provide an opportunity to detect changes in efficacy endpoints to optimize design of a definitive phase III study".

Alterity managing-director Dr David Stamler said "completing enrolment in our ATH424-201 clinical trial in MSA is a significant milestone for Alterity as we look to bring a new oral therapy to people living with this devastating disease".

"Due to the great clinical need and physician interest in our novel approach to address the underlying pathology of MSA, we exceeded our enrolment target," Dr Stamler said.

"With our trial now fully enrolled, study treatment will conclude in the fourth quarter of 2024 and the results from the trial will clarify the path forward for potential approval of ATH343," Dr Stamler said.

Alterity was unchanged at 0.7 cents with 2.3 million shares traded.

HERAMED

Heramed says it has begun an up-to 90 pregnancy clinical trial of its Heracare platform for six-to-nine-months at Queensland's Gold Coast Hospital.

In March, Heramed said the Gold Coast Hospital and Health Service would trial its Heracare platform, including the Herabeat foetal heart-rate monitor, as a standard-of-care for its Women Newborn and Children services (BD: Mar 21, 2023).

Today, the company said the trial was "an important step ... after such a rigorous and extensive process undertaken prior to the clinical trial beginning".

Heramed was up half a cent or 12.5 percent to 4.5 cents.

VITURA HEALTH

Vitura says the first 3,4-methylene-dioxy-meth-amphetamine (MDMA) capsules from its Cortexa joint venture with Pharmala Biotech have been imported into Australia. In May, Vitura said it had the joint venture with Toronto's Pharmala Biotech to produce and supply psychedelics for Australian research and clinical use (BD: May 2, 2023). Today, Vitura said that "bulk and patient ready" MDMA capsules were available for prescription and trials, and that the majority of the shipment was to "satisfy demand under existing supply agreements including leading University clinical trials".

Vitura said it had imported MDMA active pharmaceutical ingredient into Australia, which was being prepared to be batch manufactured into finished dosage forms.

The company said Cortexa manufacturing MDMA in Australia would ensure supply to for clinical and research demands and bulk psilocybin was in the process of being imported. Vitura said it expected the first psychiatrist to receive authorized prescriber approval in the "coming weeks", with the first patients to be treated with MDMA and psilocybin this year. Vitura fell half a cent or 1.4 percent to 34.5 cents.

NEXT SCIENCE

Next Science says it was not aware of a video about its Xperience for joint infection on the third-party site Vumedi until November 2, 2023.

In an ASX query dated November 3, 2023, the ASX said that Next Science had lodged a cleansing notice on Wednesday November 1 which implied there was no excluded information and on Friday November 3 published study findings on its Xperience On Friday, the company said a 423-patient study showed its Xperience for peri-prosthetic joint infection led to a zero percent infection rate within 90 days (BD: Nov 3, 2023). The ASX said that the November 3 announcement provided a link to a presentation titled 'Efficacy of a Novel Intraoperative Surgical Irrigant in Preventing Periprosthetic Joint

Infections in Primary Knee, Hip, and Shoulder Arthroplasties: A Retrospective Analysis' by Dr Robert Harris, dated 31 October 2023.

The ASX asked Next Science when it became aware of the Xperience data.

Next Science told the ASX it was "first informed that the video of the author reviewing his research was posted to a third party hosted site, Vumedi, on November 2, 2023".

The company said that the ASX "should also be aware that the date reference of October 31, 2023 in the Vumedi presentation is a reference to the date at a place in the US, which [it] believes may have been Alabama, where Dr Harris is situated, which, at the time, was 16 hours behind AEST" (sic).

Next Science said that "following confirmation of the research being posted to Vumedi, [it] released the announcement via ASX on November 3, 2023 less than 24 hours after [Next Science] first became aware of the information".

According to Commsec, on November 1, 2023, Next Science's share price closed up 3.5 cents, or 17.5 percent at 23.5 cents; on November 2 its price rose 4.3 percent to 24.5 cents and on November 3 it was up 6.5 cents or 26.5 percent to 31.0 cents.

The ASX asked Next Science whether it had "appropriate and timely access to material information to meet its continuous disclosure obligations"?

Next Science said it was in "continuous contact with physicians and scientists conducting research that is sponsored by [Next Science] or where [it] has donated product for the study ... and "monitors continued performance of its products in clinical usage".

The company said it did not have "control of independent journals or publication media and therefore when research was submitted for review".

Next Science was up six cents or 20 percent to 36 cents.

<u>INOVIQ</u>

Inoviq says it will present two posters of data on its Exo-Net diagnostic at the Australian and New Zealand Society for Extracellular Vesicles from November 7 to 10, 2023. Inoviq said the first poster, titled 'High-throughput isolation of extracellular vesicles and associated miRNAs', included data on the "first fully-automated high-throughput system for rapid and reproducible Exo-Net isolation of isolation of extracellular vesicles and downstream RNA extraction on the Promega Maxell and Thermo Fisher Scientific Kingfisher automated instruments".

Inoviq said the second poster, titled 'A novel engineered protein bead-based matrix for enrichment of tumor derived extracellular vesicles', outlined data from a study that showed "the effectiveness of Texo-Net in selectively capturing a subpopulation of extracellular vesicles enriched with tumor-specific biomarkers".

Inoviq chief executive officer Dr Leearne Hinch said the presentations delivered "new data to the scientific community supporting additional high-throughput and cancer applications for our rapid, efficiency and reproducible Exo-net technology".

"Exo-net enables the translation of exosome diagnostics from the bench-to-clinic and delivery by large pathology laboratories," Dr Hinch said.

Inoviq was up four cents or 6.7 percent to 4.5 cents.

RECCE PHARMACEUTICALS

Recce says its annual general meeting defeated its remuneration report with 21,772,862 votes (58.36%) against to 15,524,752 votes (41.64%) in favor.

Under the Corporations Amendment (Improving Accountability on Director and Executive Remuneration) Act 2011 any company sustaining a vote of 25 percent or more against the remuneration report in two successive annual meetings is required to vote on a board spill and if passed the directors must stand for re-election within 90 days.

Recce said that the resolution to re-elect director Justin Ward faced 31.02 percent opposition and the employee incentive plan was opposed by 27.27 percent of votes. Recce said all other resolutions, including the election of director Michele Dilizia, the approval of the placement capacity, ratification of prior issue of shares and approval of shortfall shares to chair Dr John Prendergast and director Dr Alan Dunton passed easily. According to Recce's most recent filing it had 203,451,861 shares on issue meaning that the votes against the remuneration report amounted to about 10.7 percent of the shares on issue, sufficient to requisition extraordinary general meetings. Recce was unchanged at 44 cents.

INCANNEX HEALTHCARE

Incannex says investors voted 99.55 percent in favor of the share scheme and 99.95 percent in favor of the option scheme to delist on the ASX and list on the Nasdaq. In July, Incannex said it intended to redomicile to the US and list its shares on the Nasdaq through the Delaware corporation Incannex Healthcare Inc (BD: Jul 10, 2023). Last month, the company said Incannex Healthcare Inc would acquire 100 percent of its shares and become the new parent entity of Incannex group, with all Incannex options to

be cancelled (BD: Oct 5, 2023).

Today, Incannex said it required Federal Court of Australia approval at a hearing scheduled for November 16, 2023, and subject to court approval, it would delist from the ASX on November 29 and list on the Nasdaq on the same day.

Incannex was up 0.2 cents or 2.9 percent to seven cents with 5.2 million shares traded.

<u>ACRUX</u>

Acrux says it has received \$2,868,795 from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

The company said the funds related to expenditure for the year to June 30, 2023. Acrux was unchanged at four cents.

PATRYS

Patrys says it has received \$2.7 million from the Australian Taxation Office under the Federal Research and Development Tax Incentive Program.

The company said the rebated related to expenditure for the year to June 30, 2023. Patrys was up 0.2 cents or 25 percent to one cent with 1.2 million shares traded.

INVEX THERAPEUTICS

Jason Peterson says he has increased his substantial shareholding in Invex from 4,792,883 shares (6.3774%) to 7,705,675 shares (10.2532%).

The Perth-based Mr Peterson said on "various" dates he bought 2,912,792 shares for \$551,782, or an average of 18.94 cents a share.

Invex was up half a cent or 2.2 percent to 23 cents.

ACTINOGEN MEDICAL

Actinogen says it has appointed William Souter as its chief financial officer, effective from February 5, 2024, with Jeff Carter resigning, effective from November 30, 2023.

Yesterday, Atomo said its chief financial officer Mr Souter would leave the company from December 13, 2023 (BD: Nov 7, 2023).

Today, Actinogen said Mr Souter had been chief financial officer of Atomo and previously Verton Technologies Australia, and had been a director of Montem Resources Ltd, PricewaterhouseCoopers and RFC Ambrian.

The company said Mr Souter held a Bachelor of Laws and a Bachelor of Commerce from the University of Adelaide.

Actinogen thanked outgoing part-time chief financial officer Jeff Carter for "his valuable service and contribution to the company".

Actinogen was up 0.3 cents or 16.7 percent to 2.1 cents with 3.9 million shares traded.

<u>HERAMED</u>

Heramed says managing-director David Groberman has resigned and will continue as an adviser, with chief financial officer Sivan Sadan heading business development.

Heramed said the chief financial officer role would be outsourced to financial services company Shimony Finance partner Ido Toronchik.

The company said that Mr Groberman would continue as product strategist "delivering advice and strategic input on the evolution of the technology".

Heramed said chair Dr Ron Weinberger would continue as executive chairman until a permanent managing director and chief executive officer was found, and that a search would "commence at the appropriate time".

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