



Biotech Daily

Thursday October 13, 2022

Daily news on ASX-listed biotechnology companies

- * **ASX, BIOTECH DOWN: NOVA EYE UP 27%; PRESCIENT DOWN 11%**
- * **CARTHERICS OPENS STEM CELL-CAR-T OFFICES, LABORATORY**
- * **TISSUE REPAIR: TR987 'SIGNIFICANT' EFFECT ON SKIN HEALING**
- * **ADALTA, GPCR PARTNER ON BETA BLOCKER I-BODIES FOR CANCER**
- * **INOVIQ, NICOYA WORK ON SUB-B2M SPR CANCER RISK TEST**
- * **IMMURON PAYS \$2.6m FOR 17.5% OF ARTERIA HEALTH**
- * **BOTANIX BTX1702 10% 'SAFE AND WELL-TOLERATED' FOR ROSACEA**
- * **ALTERITY STARTS PHASE II ATH434 FOR MSA TRIAL**
- * **INCANNEX COMPLETES PHASE I IHL-675A TRIAL DOSING**
- * **RADIOPHARM REQUESTS 'PIVALATE BRAIN CANCER TRIAL' HALT**
- * **PERENNIAL REDUCES TO 5.4% OF 4D MEDICAL**
- * **HEALTHCARE 2030, BERGEN, EUGENE TABLIS DOWN TO 13% NUHEARA**
- * **MERCHANT TAKES 8.7% OF HEXIMA**

MARKET REPORT

The Australian stock market slipped 0.07 percent on Thursday October 13, 2022, with the ASX200 down 4.9 points to 6,642.6 points. Thirteen Biotech Daily Top 40 companies were up, 17 fell, eight traded unchanged and two were untraded. All three Big Caps fell.

Nova Eye was the best on no news, up six cents or 27.3 percent to 28 cents, with 237,526 shares traded. Actinogen climbed 7.5 percent; Alcidion and Telix were up four percent or more; Dimerix and Imugene improved more than three percent; Immutep, Impedimed, Orthocell, Polynovo and Starpharma rose more than one percent; with Medical Developments and Nanosonics up by less than one percent.

Prescient led the falls, down two cents or 11.1 percent to 16 cents, with 4.3 million shares traded. Next Science lost 9.1 percent; Atomo, Clinuvel, Genetic Signatures and Volpara fell more than four percent; Neuren, Paradigm and Resonance were down more than three percent; Cochlear and Pro Medicus shed two percent or more; with Avita, CSL, Cyclopharm, Cynata, Emvision, Mesoblast, Opthea, Proteomics and Resmed down by one percent or more.

CARTHERICS PTY LTD

Cartherics formally opened its Notting Hill, Victoria offices and laboratory to develop stem cell chimeric antigen receptor (Car) T-cells for cancer.

Cartherics said it had spent \$4 million in the fit-out of tissue culture laboratories, clean rooms and bio-banking facilities in the 1,728 square metre (18,600 sq ft) research and manufacturing premises, adjacent to Monash University.

The building was formally opened by Victoria's Minister for Innovation, Medical Research and the Digital Economy Jaala Pulford, former Australia chief scientist and Monash University chancellor Dr Alan Finkel and Monash university executive Dr Doron Ben Meir. Cartherics founder and chief executive officer Prof Alan Trounson said the company intended to manufacture "stem cell products that will make living with cancer manageable".

Prof Trounson said the company was preparing for clinical trials with two autologous, or patient's own, cells treating T-cell lymphoma and ovarian cancer and said the company had partnered with the Peter MacCallum Cancer Centre, Mesoblast and Cell Therapies. "We are now focused on developing unique off-the-shelf products based on stem cells made from umbilical cord blood, the most primitive cells of the body, that we gene edit on this site to add what are known as chimeric antigen receptors (Cars) which specifically recognize cancer cells," Prof Trounson said.

"Then we knock out genes that cancers use to block our own immune cells from killing cancers," Prof Trounson said. "These engineered stem cells are then directed into immune killer cells and expanded ... to produce hundreds, perhaps thousands, of doses of Car-immune killer cells for therapy for ovarian or other cancers."

Prof Trounson said that the initial targets were adeno-carcinomas in particular ovarian and gastric cancers and the methodology had "never been tried before".

Ms Pulford said that laboratories like Cartherics were "making a difference to the lives of people in Victoria and around the world every day" and noted that one person was diagnosed with cancer every 15 minutes.

Ms Pulford praised the collaboration between industry, Monash University and Monash-based Hudson Institute of Medical Research.

Dr Finkel noted that the University of Melbourne and Monash University were ranked one and two, respectively, as Australia's best universities and cited an international comparison ranking them at 34 and 44, respectively.

Dr Finkel said there were not many cities that could claim two universities in the top 50.

Dr Finkel said that successful biotechnology companies need to have an excellent product, be quick, have generous supporters and a key ingredient was the founder and paid tribute to Prof Trounson as an excellent founder and chief executive officer.

Cartherics said the premises had incubators for cell growth and expansion, flow cytometry, polymerase chain reaction diagnostics, cell manufacturing, counting and sorting equipment, dedicated rooms for low temperature storage, 156m² (1,679 sq ft) of cleanroom laboratories and a bio-banking facility.

The company said it planned to sub-lease part of the space to other companies to develop their technologies.

Prof Trounson said the opening of the company's first research and development facility in Victoria was "an important step for our company as we grow closer to achieving our goal of developing immunotherapy solutions for the treatment of cancers".

"This wouldn't be possible without the support of our partners and the Commonwealth and Victorian Governments, which have always believed in our mission of creating cutting-edge innovation to improve patients' lives," Prof Trounson said.

Cartherics is a private company.

TISSUE REPAIR

Tissue Repair says a 42-person phase II trial of TR987 demonstrated “statistically significant” effects on wrinkling and elastosis.

Last year, in its initial public offer to raise \$22 million at a \$1.15 a share, Tissue Repair said that the active ingredient of its topical treatment for wound repair TR987 was Glucoprime, invented by former Novogen and Noxopharm chief executive officer Prof Graham Kelly (BD: Nov 24, 2021).

The company said at that time that TR-987 “behaves like a decoy cell and simulates a yeast infection resulting in the stimulation of the body’s own wound repair pathways.”

Tissue repair said that TR-987 provided “a platform for the opportunity to develop a range of products that have the potential to treat a broad range of conditions across the wound care market”.

Tissue Repair said that in 2020, it completed a phase IIb chronic wound trial achieving “a positive signal of efficacy” that warranted progression to phase III clinical trials.

Today, the company said that the trial data would be published in the Journal of Dermatologic Surgery from in December 2022.

Tissue Repair said the trial evaluated the efficacy of TR987 following laser skin resurfacing treatment and 85 percent of responders in the active group reported a 33 percent improvement in wrinkling, compared to 50 percent of those who responded in the placebo group.

The company said that the 35.0 percent difference was significant ($p = 0.041$).

The company said that for elastosis, 75 percent of trial group responders had a 33 percent or more improvement, compared to 35 percent of responders in the placebo group having a 33 percent or more improvement ($p = 0.011$).

Tissue Repair was up 1.5 cents or 5.45 percent to 29 cents.

ADALTA

Adalta says it and the Seoul, South Korea-based GPCR Therapeutics Inc will develop cancer treatments using beta blockers and Adalta’s i-bodies.

The company said under the agreement, it will supply a panel of its CXCR4 inhibiting i-bodies to GPCR Therapeutics, which will evaluate them in combination with a series of generic beta blocker molecules selected from its own platforms, which inhibit the G-protein coupled receptor B2AR.

Adalta previously said that i-bodies were named from the “intermediate” of four groups of immunoglobulin or immunoglobulin-like domains.

Adalta said the studies would explore whether targeting multiple G-protein coupled receptors, at the one time, could enhance the inhibitory effect on the target receptor CXCR4, which was “known to be over-expressed in more than 23 cancers”.

The company said that if the studies were successful, it would have first option to licence the technology for commercialization as a cancer treatment, subject to “pre-agreed up-front option exercise fees, development milestones, commercialization milestones and low to mid-single-digit royalties on sales, subject to development success”.

Adalta managing-director Dr Tim Oldham said the company hoped to show that its i-bodies, combined with other G-protein coupled receptor inhibitors could have enhanced therapeutic outcomes in cancer, in comparison with the typical approach of inhibiting individual G-protein coupled receptors.

Adalta was up 0.3 cents or six percent to 5.3 cents.

INOVIQ

Inoviq says the Ontario, Canada-based Nicoya will develop and evaluate a prototype Sub-B2M cancer risk test on its Alto surface plasmon resonance (SPR) platform.

Inoviq said that under the agreement, it would pay a “non-material” amount for Nicoya to provide services to transfer, develop and evaluate a Sub-B2M-based test conducted on its Alto high-throughput surface plasmon resonance (SPR) instrument.

The company said the project would aim to demonstrate effective discrimination between cancer and cancer-free blood samples by Sub-B2m on the Alto instrument.

Inoviq has previously said that Sub-B2M is an engineered protein that detects the pan-cancer biomarker Neu5Gc (BD: Sep 16, 2022).

The company said that on successful completion, the two companies intend to enter a commercial arrangement enabling Inoviq to commercialize the Sub-B2M-based SPR test on the Alto instrument for detection and monitoring of multiple cancers including breast ovarian and prostate.

Inoviq chief scientific officer Dr Greg Rice said the Nicoya Alto was “the world’s first digital, high-throughput, benchtop SPR system that has the potential to provide Inoviq with a competitive advantage in cancer diagnostics”.

“The Alto instrument has revolutionized SPR sample analysis using digital microfluidics and nanotechnology biosensors that are integrated into a disposable microwell plate, making it compatible for high throughput diagnostics,” Dr Rice said.

“We look forward to advancing our partnership with Nicoya to develop a highly sensitive Neu5Gc test for multi-cancer detection on the Alto instrument,” Dr Rice said.

Inoviq was up 1.5 cents or 2.6 percent to 60 cents.

IMMURON

Immuron says it has paid Arteria Health GBP1.48 million (\$2.6 million) to strengthen its Travelan distribution and distribute Arteria’s Juvia for irritable bowel syndrome.

Immuron said the \$2.6 million would acquire about 17.5 percent of Arteria, as well as one of the company’s board seats, and that the investment afforded Immuron pre-emptive rights to maintain its percentage holding in the company.

The company said its investment in the London-based Arteria would be allocated towards the commercialization and further research on the Juvia irritable bowel syndrome treatment and it would have the option to invest a further \$2.6 million in Arteria by July 31, 2023.

Immuron chief executive officer Steve Lydeamore said the company was “delighted to have agreed this strategic investment in Arteria Health, which has developed and distributes a ground-breaking gut health product for the treatment of irritable bowel syndrome, Juvia”.

“This investment allows Immuron to further strengthen its position in the broader [irritable bowel syndrome] market and allows us to capitalize on opportunities working alongside Arteria, both in the UK and Australia,” Mr Lydeamore said.

“Immuron will continue to focus on its strategy of expanding market verticals & product offering; growing its existing customer base; expanding its distribution network and sales and marketing of each product,” Mr Lydeamore said.

Arteria chief executive officer Neil Wickers said that his company welcomed Immuron as a strategic investor “and look forward to exploring mutual benefits in supporting our respective products in the UK, Australia and other markets”.

Immuron was up 0.7 cents or 8.6 percent to 8.8 cents.

BOTANIX PHARMACEUTICALS

Botanix says its 133-patient, phase Ib trial of BTX1702 synthetic cannabidiol for rosacea “showed statistically significant results” in reducing inflammatory lesions.

Botanix said the primary endpoints of safety and tolerability were met, and that only in the 20 percent BTX1702 gel did patients encounter any “localized and minor” adverse events.

Botanix said that on six exploratory endpoints, BTX1702 outperformed the vehicle, with the lower 10 percent dose outperforming the higher 20 percent dose.

Botanix executive chair Vince Ippolito said the company was “very pleased with the outcomes of this study and the statistically significant performance of the 10 percent BTX1702 synthetic [cannabidiol] dose against the Permetrex vehicle alone”.

“Going into this study, we wanted to push the dose of synthetic [cannabidiol] to test the safety and efficacy boundaries in this serious form of rosacea and this has been successfully achieved,” Mr Ippolito said.

“The outcomes show that the drug is safe at high doses, but also very effective at the lowest tested dose,” Mr Ippolito said.

Botanix was up 0.4 cents or 6.8 percent to 6.3 cents with 4.6 million shares traded.

ALTERITY THERAPEUTICS

Alterity says Melbourne’s St Vincent’s Hospital has approved its 60-patient, phase II trial of ATH434 for multiple system atrophy, with trial enrolment starting in Sydney.

Alterity said the study would explore the effect of ATH434 treatment on neuroimaging and protein biomarkers, such as excess brain iron and aggregating alpha-synuclein, which were contributors to the pathology of multiple system atrophy.

Last month, the company said the randomized, double-blind, placebo-controlled study in patients with early-stage multiple system atrophy would explore the efficacy of ATH434 on neuro-imaging and protein biomarkers as well as characterization of safety and pharmacokinetics of ATH434 (BD: Sep 20, 2022).

Alterity said that patients would receive one of two dose levels of ATH434 or placebo for 12 months and the use of wearable sensors would allow evaluation of motor parameters important in patients with multiple system atrophy.

Alterity was up 0.15 cents or 12 percent to 1.4 cents with 1.25 million shares traded.

INCANNEX HEALTHCARE

Incannex says it has completed dosing in its 36-participant phase I trial of IHL-675A as a multi-use anti-inflammatory and will begin phase II trials for inflammatory diseases.

Incannex said IHL-675A comprised cannabidiol and hydroxychloroquine and was “well tolerated, with no adverse events of concern reported to date”.

The company said it was arranging phase II trials of IHL-675A for rheumatoid arthritis and planned phase II trials for inflammatory bowel disease and lung inflammation.

Incannex said that in addition to the Australian trials, it was intending to open an investigational drug application with the US Food and Drug Administration, for the treatment of patients with arthritis.

The company said it expected the full study report to be available by April 2023.

Incannex was up one cent or 3.5 percent to 29.5 cents with 4.1 million shares traded.

[RADIOPHARM THERANOSTICS](#)

Radiopharm has requested a trading halt pending an announcement “in relation to the release of Pivalate phase II data in brain ‘mets’ trial”.

Trading will resume on October 17, 2022.

Radiopharm last traded at 16.5 cents.

[4D MEDICAL](#)

Perennial Value Management says it has reduced its holding in 4D Medical from 19,894,267 shares (6.76%) to 15,995,156 shares (5.43%).

The Sydney-based perennial said that between August 27, 2021, and October 12, 2022, it bought and sold shares, with the largest sale 6,610,750 shares for \$4,240,796, or 64.1 cents a share.

4D Medical fell 2.5 cents or 3.7 percent to 64.5 cents.

[NUHEARA](#)

Healthcare 2030, Bergen Global and Eugene Tablis say they have reduced their holding in Nuheara from 19,502,164 shares (14.22%) to 18,060,672 shares (13.16%).

The Boca Raton, Florida-based parties said that between July 25 and October 11, 2022, they bought 190,433 shares for \$42,090 or 22.1 cents a share and sold 1,631,925 shares for \$389,796 or 23.9 cents a share.

Nuheara was up one cent or 5.6 percent to 19 cents.

[HEXIMA](#)

Merchant Group Australia says it has increased its substantial holding in Hexima from 12,880,000 shares (7.71%) to 14,550,000 shares (8.71%).

The Perth-based Merchant said that between October 3 and October 12, 2022, it bought 1,670,000 shares in Hexima for \$26,718, or 1.6 cents a share.

In July, Hexima said it was winding-up after lead candidate HXP124 failed its nail fungus trial and the share price fell 85 percent to four cents (BD: Jun 24, Jul 11, 2022).

Hexima was unchanged at 2.1 cents.